Dataset name: e_exam_ex09_1b_0844d

Note: Spanish version of clinic exam data collection form is inlcluded in this protocol document.

FRAMINGHAM HEART STUDY

OFFSPRING EXAM 9
OMNI EXAM 4

CLINIC/OFFSITE PROTOCOL MANUAL

04/2011 – 03/2014

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   c. NAGI
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4) **Physical Activity Questionnaire**
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5) **Other**
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   b. Proxy Form

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2) SF12 Health Survey
3) Sleep Questionnaire
4) Willett Food Frequency Questionnaire

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3) Exit Interview
4) 24-Hour Urine Study

**Non-Invasive Vascular Testing has a separate manual of procedures.

Equipment For Offspring Exam 9 Procedures

1. A. Clinic: Detecto Scale (3)
Worcester Scale Co., Inc.
Higgins Industrial Park
228 Brooks Street
Worcester, MA 01606
(508) 853-2886
www.detectoscale.com
Room 100

B. Offsite: SECA Portable Scale Model #841
MSI: Measurement Specialties Inc.
Fairfield, NJ 07007

2. Weight to calibrate scale: 50 lbs.
Worcester Scale Co., Inc. (See above)

3. SECA Stadiometer
Halliday Medical
4-694-581
Walpole, MA 02081
(508) 668-8670

4. ECG Machines: Marquette MAC5000 (2), MAC 5500 (1)
Marquette Electronics
100 Marquette Drive
Jupiter, FL 33468-9100

Sales Rep: [redacted]

Field Engineer: [redacted]

5. Acquisition Module for Mac5000
Cam-14

6. Marquette Mac5000 – Offsite Visits

7. Portable standard mercury column sphygmomanometer:
   Baumanometer, 300 model; Catalogue #0661-0320
   W.A. Baum Co., Inc.
   620 Oak Street
   Copaigue, NY 11726-3292
   (631) 226-3940
   Fax (631) 226-3969
   http://www.wabaum.com
   Tech: [redacted]

8. Aneroid Sphygmomanometer – gauge type (offsite)
   P/N 5090 – 03 Tycos
   Samuel Perkins, Inc.
   Quincy, MA 02169

   Repairs and Calibration
   Welch Allyn
   Arden, NC 28704
   1-800-535-6663

9. Bauman latex free blood pressure cuffs in four sizes: regular adult, large adult, pediatric, thigh. (Ordered through Mainline Medical)

10. Litman stethoscope tubing and earpieces with bell: Classic II

11. Tailor's plastic tape measure (3)

12. Ultrasonic Flow Detector and 9.6 Megahertz Doppler Pen Probe
    Model # 811-B
    Powercord # 91-2305
    Gel Aquasonic # 748-0003-00
    Battery Charger # 984-0006-02
    Probe 9.6 frequency Pen Style Probe
    Parks Medical Electronics, Inc.
    6000 S. Eastern, Suite 10-D
    Las Vegas, NV 89119
    800-547-6427 opt.1

13. For Pulmonary Function Test (PFT), please see:
Manual of Operations: Pulmonary Function

[redacted]

Email: [redacted]

14. Spirometer: Collins CPL pf
Somerset Medical LLC
9 Loire Street
Somerset, MA 02726
[redacted]
Tech Support: [redacted]

15. Equipment for Collins CPL
a. DCII Disposable Filters and Mouthpieces (Ferraris) #K022454
b. Disposable Noseclips (Moore Medical) #021261
c. Nafion Tubing (Ferraris) #K381248
d. Blue Segented Tubing Spacers for Albuterol (Cardinal Health) #001426
e. Disposable Dessicator Columns (Ferraris) #K021501UK
f. Balloons Set of 4 #K700885
g. CO2 Absorbent Granules (Ferraris) #K022556
h. Microtach (Ferraris) #K003500

16. Gases
a. Oxygen Gas: Part # OX USP200, size 200 cylinder
b. Lung Diffusion Mix: .3% CH4, 21% O2, Bal N2
Part #z4n17852003060, SIZE 200 cylinder

Air Gas
199 Southwest Cutoff-Rte. 20
Worcester, MA 01604
1-866-718-0685
Sales 800-562-3815

17. Albuterol Inhalers
ProAir Inhalers Pharmaceutics # 71668

18. 3 Liter calibration syringe Model #021156

19. 60 Memory Stopwatch # 1025CC
Control Company
4455 Rex Road
Friendswood, TX 77546
281-482-1714

20. Heart Square, by Heartware Inc.
purchased from: Epicare
2000 W. First Street # 505
Winston-Salem, NC 27104
[redacted]

21. Pocket Talker II
Williams Sound Corp.
10300 Valley View Road
Eden Prairie, MN 55344
1-800-843-3544
(ordered through
101 Phones.com, GOGO Tech, Inc.
1410 Broadway FL20
New York, NY 10018

22. JAMAR dynamometer
Model #5030J1
Sales Address:
Lafayette Instrument Co.
P.O. Box 5729
Lafayette, IN 47903
1-800-428-7545

Calibration Address:
JLW Instruments, Inc
Sammons Preston
452 N. Sangamon
Chicago, IL 60622
1-800-323-5547
Fax (312) 733-0009
www.jlwinstruments.com

Equipment Calibration Time Table

Activity	Daily	Weekly	Monthly	Yearly
Detecto Scale				
Zero Reading	**X**			
50# Weight			**X**	
Professionally Calibrated				**X**
Manometer				
Zero Reading	**X**			
Check Inflation System			**X**	
Spirometer				
Leak Check	**X**			
Volume Calib. Check	**X**			
Linearity Check		**X**		
Control Test		**X**		
Stadiometer				
Check Level			**X**	
Tape Measure				
Against Stadiometer			**X**	
Dynamometer				
Professional Calibration				**X**

Annual/Monthly/Daily Equipment Calibration Protocol

1. **Scales: Annually/Monthly/Daily (during clinic)**

   Room 100- Detecto
   Room 101- Detecto
   Room 102- Seca 700

   Protocol:

   a. Once a month scales are to be calibrated.
   b. Place a 50 lb weight onto the scale.
   c. Set the scale at zero.
   d. If scale is balanced then calibration is done.
   e. If scale is unbalanced then turn knob slightly on the side of the zero bar.
   f. Mark the date in the calibration log book located in the clinic office.
   g. Furthermore, scales must be certified on a yearly basis. This information can be found in the Clinic Equipment Book located in the clinic office.

2. **Stadiometers: Monthly**

   Room 100- Seca Model # 216 1914009
   Room 101- Seca Model # 216 1914009
   Room 102- Seca Model # 216 1914009

   Protocol:

   a. Using the purple measuring tape located in the clinic office.
   b. Line up against the meter to determine correct marker points.
   c. Make sure to move up and down at different spots along the meter.
   d. If lines do not match up then a new stadiometer must be ordered.
   e. Mark date in calibration log book once a month.

3. **Manometers: Monthly/ Daily (during clinic)**

   Room 100- V88290
   Room 102- CE3201
   Room 101- T30928
   Room 107- T30927
   Room 109- T30906
   Spare- E95102 (located in clinic office rm.114)

Protocol:

a. Use the blood pressure calibrator located in the clinic office in the calibration equipment box.
b. Make sure to place manometer on a flat surface and at eye level.
c. Connect pieces making sure there is no leak and inflate.
d. Slowly release pressure stopping along the way at random places.
e. Make sure both meters read the exact same.
f. Repeat for all five then mark in the Calibration Log Book located in the clinic office.
g. If meter is off, the spare will be used while repairs are being made.
h. Calibrate once a month.

4. **Measuring Tape: Monthly**

Room 100
Room 102
(2) Offsite

Protocol:

a. Use Purple Measuring tape located in the clinic office.
b. Match up the two making sure they are exactly lined up.
c. Move around the whole tape at random spots.
d. If lines do not match then the tape has been stretched and a new one must be ordered.
e. Once a month mark in Calibration Log Book.

5. **Hand Grips: Annually/ Daily (during clinic)**

Room 100- 10322924
Room 102- 10100317
Offsite- 10593388

Protocol:

a. The hand grips must be certified on a yearly basis.
b. Use the Clinic Equipment Book for contact info.
c. Handgrip should be at zero and documented on the daily log sheet.
d. Offsite will be checked on a monthly basis and logged in the calibration book.

6. **AED: Monthly**

The AED is located in the clinic hall on stand outside of Room 109.

Protocol:

a. Once a month regular status (readiness) indicator checks are performed and recorded in Log Book.
b. Also check and make sure that the spare battery and pads have not exceeded their expiration date.

7. **Digital Timers: When certificate expires (around every two years)**

Clinic #1- 72318431
Clinic #2- 72318449
Clinic #3- 22087033
Offsite #1- 22086935
Offsite #2- 61768767

Protocol:

a. Digital timers are calibrated about every two years.
b. All information can be found in the Clinic Equipment Book.

8. **Digital Offsite Scales: Monthly**

(2) Offsite Digital Scales

Protocol:

a. Use a 50 lb weight.
b. Place scale on solid flat surface then place weight onto scale.
c. Weight must be 50 lbs exact.
d. Mark the date in Log Book once a month.

9. **Blood Pressure Gauge: Monthly**

(2) Offsite
(1) Used as a calibrator

Protocol:

a. All three gauges are Lifetime Certified, but they are still compared on a monthly basis for consistency.
b. Attach pressure gauges and inflate pressure.
c. Slowly release pressure making sure to stop at random spots for exact comparison.

Guidelines For Coding Accuracy

To insure maximum accuracy and legibility for persons performing data entry, please adhere to the following guidelines:

1. Use a red or any other pen which will stand out from the page (pencil or black ball-point pens are unacceptable).

2. Make sure all numerals are unmistakably clear.

3. If measurements are not taken, please enter **9**s in blanks if the coding option is available, and document the reason. If the coding option of 9 is not available, leave blank and write any comments on why the questions were not asked. Your comments are helpful at any point of the exam where data is not recorded in the standard manner.

4. If you make an error, please cross it out entirely, write the correct information *in the margin*, and **initial** *the change*. **Do not superimpose numerals one on top of the other**. **Do not use white out.**

5. Make sure both sides of the examination form are completed.

Informed Consent

A waiver of Informed Consent has been approved for the Offspring and Omni 1 Cohorts However, as there are new components in the current exam cycle, the waiver of Informed Consent will not be administered unless the participant is cognitively impaired and a LAR is not available. Participants will be re-examined in the FHS clinic. Health updates, research, and use of data and materials will continue by prior consents. A HIPAA Authorization form and the research proxy form will also be offered to the participants. New consent forms will emphasize descriptions of new research activities. Identified LARs may be asked to sign the informed consent in cases of cognitive impairment.

Cognitive capacity is assessed in interviews by trained admitting staff. If impairment is observed, the LAR is given the same information as the participant, and advised of the components of the exam that have been determined to be greater than minimal risk. A research proxy, a LAR appointed prior to the onset of cognitive impairment, may give consent for components of the exam that are greater than minimal risk. If a research proxy has not been appointed, the next of kin may sign as a LAR, but only for those research activities that are of no greater than minimal risk. If the participant does not have a LAR, only the exam components to which the participant has previously given informed consent will be administered.

Dissent of our participants or their LAR will always be honored regardless of cognitive capacity.

Informed consent is administered to each participant by a trained interviewer prior to the collection of any research study data. The "consent form" is a two-part document. The first part is a narrative description of the study goals, the content of the exam, the risks and benefits of participating, the study's confidentiality policy, each person's right to withdraw from the study, and compensation in the unlikely event that participation results in the need for medical care. The second part is the participant's authorization page, which the participant signs. The informed consent document complies with the National Heart, Lung, and Blood Institute guidelines and is approved by Boston University Medical Center's IRB.

I. Overview

Informed consent is the first data collection form administered during the FHS exam. Only updated versions of the informed consent form, approved by the BUMC IRB will be used. All study subjects will be provided with:

(1) a description of what data collection procedures will be followed and what is involved in each case;

(2) the benefits and risks of participating in a research study which includes genetic analysis;

(3) a description of what procedures are in place to protect their confidentiality;

(4) information on their right to withdraw from the study, to not participate in a procedure or to decline to answer a question(s) without penalty;

(5) an opportunity to document their preference for the use and disposition of their study data and genetic materials; and

(6) a record of and a mechanism for contacting the project director/principal investigator and the study coordinator.

II. Administration

The FHS staff person obtaining Informed Consent must provide ample time for the participant to read the consent and answer any questions the participant may have. Each interviewer should be trained to administer the consent form and to use the developed procedure for presenting the form to the participant. The Training Guide for Administrators follows below.

During the consent process the consenter must "…minimize the possibility of coercion or undue influence…" (46.116 Code of Federal Regulations). One does this by allowing the participant to make their decision to participate on their own, without time constraints during the consent process. Participants must be given "…sufficient opportunity to consider whether or not to participate…", and if the participant refuses the exam their wishes must be honored (46.116 Code of Federal Regulations).

Once the participant has agreed to participate in the current exam cycle, their consent must be documented. This is done by using "…a written consent form approved by the IRB and [the consent must be] signed and dated by the subject…" (50.27 Code of Federal Regulations). Note: Be sure to use the current version of the approved consent, if you have any question of what consent should be used please ask either Kathy Dee x411 or Moira Pryde x487.

Special attention is paid to the following details during the consent process.

Consent Check Boxes

The introduction of the check boxes gives participants options for participation and a clear understanding of each statement that requires a yes or no answer. Participant responses are documented for data collection and any negative responses are reported to the appropriate manager for follow up.

Photocopying Consents

A photocopy of the participants signed consent must be given to the participant. According to the Code of Federal Regulation 21CFR 50.27 *Documentation of Informed Consent* "(a)…informed consent shall be documented by the use of a written consent form approved by the IRB and signed and dated by the subject…at the time of the consent. A copy shall be given to the person signing the form."

For offsite visits, the signed consent will be copied and mailed to the participant after the visit.

Training Guide for Administrators of the FHS Informed Consent

Suggested language:

The Framingham Heart Study is required to give you detailed information about the exam so you can decide whether or not you want to participate. We call this process INFORMED consent.

Introduction to the Checkboxes

This section of the consent form asks for your permission for non-genetic and genetic studies. It allows you choices in your participation in FHS research studies and allows you choices in regards to having test results sent to your personal physician or other healthcare provider.

Checkbox 1 asks your permission for the examination today and all of the testing.

For Example: The questionnaires, the MD visit, lung functioning tests, blood samples and other non-invasive testing of your heart and blood vessels. This allows FHS researchers to study non-genetic factors contributing to heart and blood vessel diseases, as well as other diseases and health conditions.

Checkboxes 2-7 have to do with the blood samples we are obtaining today and participation in genetic studies. Your name is not linked to any of the genetic studies.

Checkboxes 2-4 allows you to choose to participate in the genetic studies of different health conditions.

Checkbox 2 allows you to agree to participate in genetic studies of factors contributing to heart and blood vessel disease, lung and blood vessel disease, stroke and memory loss.

These health conditions are the core research mission of the Framingham Study.

Checkbox 3 allows you to agree to participate in genetic studies of reproductive conditions and mental health conditions such as alcohol use and depressive symptoms.

Possible questions:

What do you mean by reproductive conditions?
The Heart Study has collected information about age periods started (menarche), age periods stopped (menopause), hysterectomy, removal of ovaries, and number of children (live births). There is great interest in these factors because hormones appear to play a role in many different diseases including cardiovascular disease. Understanding the genetic underpinnings of menopause for example may provide clues to cardiovascular disease, fertility, and even aging.

Why would researchers be interested in studying these conditions?
Menopause, alcohol use and depressive symptoms have all been linked to cardiovascular disease as well as other health conditions.

Checkbox 4 allows you to agree to provide a blood sample from Induced Pluripotent Stem Cells from which a range of cell products such as RNA, proteins and metabolites can be obtained.

RNA is a messenger of DNA

White cells of blood may be processed to become stem cells and altered so they function like cells from other organs such as liver cells, fat cells, heart cells and nerve cells

Checkbox 5 allows you to provide permission to the FHS to allow researchers from private companies to have access to you DNA and genetic data.

Researchers from private companies may be interested in studying Framingham data to develop diagnostic tests or new medications that may benefit many people.

Checkbox 6 allow the Framingham Heart Study to release findings from your examination today such as blood pressure readings, blood work results and results of your lung function tests to your physician or other healthcare provider.

Checkbox 7 allow the Framingham Heart Study to notify you in the future if researchers identify a genetic condition that may have potentially important health consequences and beneficial treatments exist for the condition.

You would only be notified if the risk for the disease is significant, the disease has important health implications and there are proven therapeutic or preventative interventions available. None of the current research meets these criteria however; it is possible in the future that genetic information with important health consequences might be discovered.

GUIDE OF EXCLUSIONS OF OFFSPRING EXAM 9 COMPONENTS BY CONSENT LEVEL

(INTERNAL FHS DOCUMENT – APRIL 27, 2011 – [redacted])

A 1. When Exam 9 Consent Form is completed by Participant at exam

Full exam is offered and Research Proxy form is offered. (Participant may decline any component)

A 2. When Exam 9 Consent Form is completed by a previously appointed Research Proxy

Full exam is offered. (Participant or Proxy may decline any component)

B 1. When a Participant has been previously assessed as having diminished capacity prior to Exam 9, and there is no previously appointed Research Proxy, the Consent may be completed by Next-of-Kin.

All components of the exam except those of greater than minimal risk are offered.

The albuterol challenge is not offered. (Participant or Next of Kin may decline any component)

B 2. . When a Participant is assessed as having diminished capacity during Exam 9, and there is no previously appointed Research Proxy, the Consent Form may be completed by Next-of-Kin.

All components of the exam except those of greater than minimal risk are offered.

The albuterol challenge is not offered. (Participant or Next of Kin may decline any component)

C. If a Participant is assessed as having diminished capacity either before or during Exam 9 and there is no Research Proxy or Spouse or Next-of-Kin available to give consent, consent may be waived.

Only components from previous exam cycles and of minimal risk may be offered.

Actical, Albuterol challenge, Buccal cells, IPSC, 24-hour urine collections are not offered. (Participant may decline any component). Tonometry and Gene Expression are offered if the participant attended Exam 8.

Assessment of capacity may be made in several ways before or during the exam.

If capacity is in doubt, Exam Component Plan C is to be used.

The selection of exam plan is to be documented by admitting staff.

The Dementia Study staff and records may be consulted.

HIPPA:
Research Subject's Authorization for Release of Health Information for Research Purposes

The HIPPA Privacy Rule, in effect April 14, 2003, protects the privacy of subject's health information which is used in human research. For researchers to gain access to health information that is stored at any HIPPA "covered entity" investigators must provide the covered entity with written assurances covering how the health information will be used and protected.

The Framingham Heart Study is not a "covered entity"; however hospitals, nursing homes, and physician offices from which the FHS collect medical records are covered by HIPPA rules. Therefore, in order for the FHS to retrieve medical records participants must sign the HIPPA medical release form. If the participant chooses not to sign the form they will be able to participate in the exam but the FHS will not be able to obtain any outside medical records.

The following explanation of the form is to be given during the intake process:

We want to use your private health information in this research study. This will include both information we collect about you as part of this study as well as health information about you that is stored in your medical records. The law requires us to get your authorization (permission) before we can use your information or share it with others for research purposes. You can choose to sign or not sign this authorization. If you choose not to sign this authorization, you will still be able to take part in the research study.

The participant must also be given adequate time to read the release form. If they agree to sign the form, they must also be given a copy of it with their signature. For offsite exams, a photocopy will be mailed with the Informed Consent to the participant.

Participants need only sign the HIPAA Authorization form to allow FHS to view their medical records one time.

If a participant is cognitively impaired and is unable to consent for himself/herself then the HIPAA Authorization Form may only be signed by a Legally Authorized Representative (LAR).

The Framingham Heart Study

Research Proxy Form

One of the most important goals of the Framingham Heart Study (FHS) is to keep track of any major changes in your health through the end of the study. This information is important for answering scientific questions about heart disease and other health conditions. You are the best source of information regarding your health, but there may come a time when you are no longer able to provide details of your health. We are asking you to name a person who can answer questions about your health and give consent for FHS research if you cannot. This person will be considered your "proxy" for the Framingham Heart Study.

What is a proxy?
A proxy is someone who can "stand in" for you and tell us about your health when you cannot because of a physical or mental illness.

Why is a proxy needed?
For many years you have been providing important information about your health to FHS. This information should be updated, even if you are unable to provide it.

What does a proxy do?
We will ask your proxy to give consent for your research participation and answer questions about your health, just like the questions you have been asked at each exam cycle on your medical history update.

Whom should I name as my proxy?
You should select someone who knows you well enough to provide health information about you. For example, your proxy can be your power of attorney, your legal health care proxy, or your legal next-of-kin (including your spouse, son, daughter, brother, sister, etc.).

Am I allowed to change my proxy?
Yes, you may change your proxy at any time by calling FHS, (508 935-3417 or 1-800-536-4143) or by indicating your wishes at your FHS examination.

Will you give my proxy information about me?
No, all of your information is strictly confidential and will not be provided to your proxy.

What would you like me to do now?
Using the attached form please indicate whom you have chosen to be your proxy. Please indicate his/her name, contact information, relationship to you, and then sign the form.

You will be given a copy of this form for your own records and one to give to your proxy. This material should be kept by your proxy so he/she understands your wishes as a participant in the Framingham Heart Study.

If you have any questions, call [redacted], Offspring Participant Coordinator, at ([redacted])

Thank you for your continued dedication to the Framingham Heart Study!

Framingham Heart Study Research Proxy

FHS ID: ___ - _____ Participant Name:_____
First MI Last

I, living at _____ appoint the following person(s) to make decisions about my participation in the Framingham Heart Study ("Research Proxy"):

Research Proxy:	Alternate: If Research Proxy cannot serve or continue to serve, I name this person (Optional):
Name: _____	Name:_____
Relationship to Participant: _____	Relationship to Participant_____
Address: _____	Address:_____
_____	_____
_____	_____
(City) (State) (ZIP)	(City) (State) (ZIP)
Telephone:_____ _____	Telephone:_____ _____
(Home) (Work)	(Home) (Work)
_____	_____
(Other)	(Other)

Effective Date and Termination

This durable power of attorney shall take effect when signed by me and shall not be affected by lapse in time or by my subsequent disability or incapacity which makes me unable to make decisions about participation in research.

Powers of Research Proxy

My Research Proxy shall have the authority to make all research participation decisions for me, including decisions about whether or not to enroll me or continue my participation in a research study [both minimal and greater than minimal risk research procedures as determined by the federal regulations and in consultation with the IRB]. My Research Proxy is to have the same authority to make research participation decisions as I would have. S/he has the authority to provide medical information and to consent for testing and examinations,. S/he further has the power to authorize the provision of records related to payment, treatment or services to me or on my behalf from any hospital, physician, or medical source to the Framingham Heart Study.

I, the undersigned Principal, by signing my name to this declare that I understand its contents and that I sign it willingly.

_____Principal Date:_____

[*Complete the following if the Principal is physically incapable of signing*:]

I hereby sign the name of the Principal at the Principal's direction and in the presence of the Principal and two witnesses.

Name of Signer: _____
Date: _____
Address of Signer: _____
_____

Witness Signature/Date Witness Signature/Date

_____ _____

RESEARCH CONSENT FORM

Offspring Examination 9

H-22762– THE FRAMINGHAM HEART STUDY N01-HC-25195 1910G

Background

You are participating in the continuation of the Framingham Heart Study (FHS), Offspring Cohort. This ninth examination of the FHS Offspring will be similar to previous visits in many ways. There are also some new study activities. Exam components, both old and new, are described below.

Purpose

The purpose of this research is 1) to better understand the development of heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, cancer, and other major diseases and health conditions; and 2) to examine DNA and its relationship to the risks of developing these diseases and other health conditions.

THIS EXAMINATION IS FOR RESEARCH AND DOES NOT TAKE THE PLACE OF A ROUTINE MEDICAL CHECK UP BY YOUR PHYSICIAN

Taking part in this study is voluntary. You have the right to refuse to take part in this study. If you choose to take part, you have the right to stop at any time.

What Happens In This Research Study

You will be one of approximately 5124 subjects to be asked to participate in this study.

All or part of the research in this study will take place at the following location(s): Boston University Medical Center.

Your research examination will take place at the FHS at 73 Mt. Wayte Avenue in Framingham, MA, or may take place in your home or other residence.

New Study Activities:

1) With your permission, white cells (from the blood collected as a regular part of the FHS exam) will be processed so that they function like cells from other organs such as liver cells, fat cells heart cells or nerve cells. The resulting cells are called Induced Pluripotent Stem cells. These cells may be studied in laboratories to learn more about causes of health and disease in such organs. FHS investigators will not alter white cells to behave as reproductive cells.

2) We will ask if we may obtain a sample of cells from the inside of your cheek by gently scraping the inside surface with a single-use plastic utensil. The cells will be used to examine how changes in DNA called DNA methylation are related to lung function and lung diseases and other diseases,

3) You will be asked to wear a physical activity monitor on a belt for a week and to return it to FHS. It measures how active you are throughout the day.

4) You will be asked after your visit to use a kit to collect urine samples for 24 hours and send it by mail to a laboratory. The kit will be mailed to you for a day convenient to you shortly after this exam visit.

RESEARCH CONSENT FORM

Offspring Examination 9

H-22762– THE FRAMINGHAM HEART STUDY N01-HC-25195 1910G

Ongoing Exam components for which you have previously given informed consent: In addition to the new procedures described above, the following procedures will be done at this visit:

1) Medical History Interview.

2) Physical Examination including ECG

3) Collection of blood (up to 117.5 cc or four ounces) and urine specimens to test for many risk factors for the diseases and health conditions under investigation.

4) Genetic Studies: You will be asked if a sample of the blood you donate may be used for additional genetic studies.

5) Vascular Function Testing: Arterial Tonometry is a measure of arterial stiffness. Along with a very limited view of the aorta (the large artery carrying blood flow from the base of the heart), a waveform is obtained by gently placing a flat sensor over arteries on the arm (brachial and radial), the groin (femoral) and the neck (carotid).

6) Pulmonary function testing is performed by breathing into a tube connected to a machine that measures exhaled air volume and flow. Some individuals may be asked to repeat the testing after using an inhaler to improve airflow.

7) Questionnaires about memory, mood and physical function; diet and exercise

8) Blood pressures in your arms and ankles

(In the event that you may have a stroke, you would be examined during your hospitalization (if applicable) and at 3, 6, 12 and 24 months. The examination would include a neurological-evaluation and an assessment of your ability to perform daily activities.)

9) Medical Records: You will be asked to sign a form to allow FHS to obtain copies of hospital and Medicare (CMS) and medical records. The release form is valid to obtain these records unless canceled by you. You will be asked for your social security number for the purpose of locating you in the future. You may choose to decline this request. You will also be asked if investigators and their research collaborators at other institutions, in this case Duke University, may link your Social Security Number to CMS data to obtain Medicare information. Social Security Numbers to will not be released to outside institutions.

10) Results of some FHS research measurements will be sent to you and/or to your physician within six weeks of your FHS visit. However, some other measurements could be made months or years later as part of special research projects. You may receive results of some measurements long after your FHS visit.

RESEARCH CONSENT FORM

Offspring Examination 9

H-22762– THE FRAMINGHAM HEART STUDY N01-HC-25195 1910G

11) Follow Up: You may be contacted later by mail or by phone to obtain additional health information or to be invited to participate in further FHS health-related studies. You may be invited to return for another examination in the future.

Risks and Discomforts

Risk or injury, as a result of participation, is not expected. In the unlikely event that during the examination you require medical care, first aid will be available.

The Blood Draw: Minimal bruising, pain, bleeding, or in rare circumstances, an infection may occur.

The Lung Function test involves a low level of risk. You may feel lightheaded or you may faint and risk injury from falling. Participants asked to inhale the medication called albuterol, used during lung function testing, may notice an increase in heart rate (pulse) or symptoms of jitteriness or shakiness (tremors). Pregnant women, as determined by self report or by a positive pregnancy test, will be excluded from the second part of the pulmonary function test, which includes the albuterol challenge.

Other discomforts include headaches, feeling hungry due to fasting, fatigue and chill during the visit. The exam is time consuming and repetitive. The 24 hour urine collection is inconvenient.

Safeguards are in place to protect the security of your study information. FHS ID numbers are used on most data files instead of names. Firewalls and password protection are in place on the computer systems. Staff is trained in safe computer practices. However there is still a minimal risk of a breach in confidentiality.

There is potential risk in genetic testing for uncovering and conveying unwanted information regarding parentage or specific risk of disease. Also, sometimes, knowledge of DNA test results can provoke anxiety and influence decisions regarding marriage and family planning:

Both Massachusetts state laws and a new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally make it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. These laws generally will protect you in the following ways:

1. *Health insurance companies and group health plans may not request your genetic information that we get from this research.*

2. *Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.*

3. *Employers with 6 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.*

All health insurance companies and group health plans must follow the GINA law by May 21, 2010. All employers with 15 or more employees must follow the GINA law as of November 21, 2009. Massachusetts law currently applies to all employers of 6 or more employees.
Be aware that neither Massachusetts law nor the new Federal law protects you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Thus, life insurance, disability insurance and long-term care insurance companies may legally ask whether you have had genetic testing and deny coverage for refusal to answer this question.

There may be unknown risks/discomforts involved. Study staff will update you in a timely way on any new information that may affect your health, welfare, or decision to stay in this study

Potential Benefits

You will receive no direct benefit from your participation in this study. However, your participation may help the investigators better understand the causes and prevention of cardiovascular disease and other medical conditions, including the potential of genetic factors..

Alternatives

Your alternative is to not participate in the study.

Subject Costs and Payments

You will not be charged or paid for any part of the examination. If the examination finds medical problems that require tests or treatments, information will be provided to you and to the physician or clinic that you have named to receive your test results. If your physician decides that follow up tests or treatments are necessary, then you (or a third party such as health insurance or Medicare) will be responsible for the cost. No special arrangement will be made by the Framingham Heart Study for compensation or payment solely because of your participation in this study. This does not waive any of your legal rights. Costs that you may incur on the day of your participation include, but are not limited to, loss of work, and transportation (gas, tolls, etc.). You will not receive payment for your participation.

Patenting Discoveries

Research from this study may, one day, result in new tests to diagnose or predict diseases. It may also lead to the development of new medicines to prevent or cure diseases. As is true of all federally-funded research, researchers and their employers are permitted by Federal law to patent discoveries from

which they may gain financially. It was the judgment of the U.S. Congress that permitting such patents would greatly increase the likelihood that a public health benefit would be realized from federally funded research.

CONFIDENTIALITY

Information obtained about you will be treated as confidential. A code number will be assigned to your data and specimens. The codes will only be provided to qualified investigators but your name and other personally identifying information will not be provided. Your samples will be kept until they are not of scientific value. You will not be routinely informed of results of research performed upon your genetic samples, although with your permission you may be informed of some findings about genetics, cardiovascular disease or other health conditions generated from DNA analyses, directly to you or through publication in newsletters.

When study results are published, your name and other identifying information will not be revealed. Information from this study and from your medical record may be reviewed and photocopied by state and federal regulatory agencies, such as the Office of Human Research Protection, as applicable, and the Institutional Review Board of Boston University Medical Center.

To help us further protect your privacy, the investigators have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer or employer learns of your participation, and obtains your consent to receive research information, then FHS is not allowed to use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy. Finally, you should understand that the Certificate of Confidentiality does not prevent the investigators from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

RESEARCH CONSENT FORM

Offspring Examination 9

H-22762– THE FRAMINGHAM HEART STUDY N01-HC-25195 1910G

Please check the appropriate box above each of the following statements:

1) |___| YES |___| NO (Office Code 0)

I agree to participate in the FHS clinic examination, the collections of blood, cheek cells and urine, and studies of the factors contributing to heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, cancer, and other major diseases and health conditions.

2|___| YES |___|NO (Office Code 3)

I agree to allow my data, cheek cells, blood and urine samples to be used in future genetic studies of factors contributing to heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, cancer, and other diseases and health conditions.

3) |___| YES |___| NO (Office Code 12)

I agree to allow my data, cheek cells, blood and urine and DNA samples to be used in future genetic studies of reproductive conditions, and mental health conditions such as alcohol use and depressive symptoms.

4 |___| YES |___|NO (Office Code 13)

I agree to provide a blood sample from which Induced Pluripotent Stem Cells can be made and from which a range of cell products such as RNA, proteins and metabolites can be obtained. This means that white cells from my blood may be processed to become stem cells and then altered so that they function like cells from other organs such as liver cells, fat cells, heart cells or nerve cells.

5 |___| YES |___| NO (Office Code 4)

I agree to allow researchers from commercial companies to have access to my blood and urine samples, DNA, other genetic material, and data in the future which may be used to develop new lab tests or treatments that could benefit many people. (You or your heirs will not benefit financially from this, nor will your DNA be sold to anyone.)

6) |___| YES |___| NO (Office Code 30)

I agree to allow the FHS to release the findings of non-genetic tests and examinations to my physician, clinic, or hospital.

7) |___| YES |___| NO (Office Code 31)

If a genetic condition is identified that may have important health and treatment implications for me, I agree to allow the FHS to notify me, and then with my permission to notify my physician.

RESEARCH CONSENT FORM

Offspring Examination 9

H-22762– THE FRAMINGHAM HEART STUDY N01-HC-25195 1910G

Subject's Rights

By consenting to participate in this study you do not waive any of your legal rights. Giving consent means that you have heard or read the information about this study and that you agree to participate. You will be given a copy of this form to keep.

If at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled.

You may obtain further information about your rights as a research subject by calling the Office of the Institutional Review Board of Boston University Medical Center at [redacted].

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury while participating in this research, contact [redacted].

Compensation for Research Related Injury

If you think that you have been injured by being in this study, please let the investigator know right away. If your part in this study takes place at Boston Medical Center, you can get treatment for the injury at Boston Medical Center. If your part of the study is not at Boston Medical Center, ask the investigator where treatment for injury would be available locally. Boston University Medical Center and the sponsor do not offer a program to provide compensation for the cost of care for research related injury or other expenses such as lost wages, disability, pain, or discomfort. You will be sent a bill for the medical care you receive for research injury if your medical insurance does not pay for your medical care. You are not giving up any of your legal rights by signing this form.

Right to Refuse or Withdraw

Taking part in this study is voluntary. You have the right to refuse to take part in this study. If you decide to be in the study and then change your mind, you can withdraw from the research. Your participation is completely up to you. Your decision will not affect you being able to get health care at this institution or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get.

If you choose to take part, you have the right to stop at any time. If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them as soon as possible.

The investigator may decide to discontinue your participation without your permission because he/she may decide that staying in the study will be bad for you, or the sponsor may stop the study.

RESEARCH CONSENT FORM

Offspring Examination 9

H-22762– THE FRAMINGHAM HEART STUDY N01-HC-25195 1910G

Protection of Subject Health Information

You have certain rights related to your health information. These include the right to know who will get your health information and why they will get it. If you choose to be in this research study, we will get information about you as explained below.

HEALTH INFORMATION ABOUT YOU THAT MIGHT BE USED OR GIVEN OUT DURING THIS RESEARCH:

Information from your hospital or office health records at BUMC/BMC or elsewhere. This information is reasonably related to the conduct and oversight of the research study. If health information is needed from your doctors or hospitals outside of BUMC/BMC, you will be asked to give permission for these records to be sent to the researcher.

New health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.

WHY HEALTH INFORMATION ABOUT YOU MIGHT BE USED OR GIVEN OUT TO OTHERS

The reasons we might use or share your health information are:

- To do the research described here

- To make sure we do the research according to certain standard set by ethics, law, and quality groups

PEOPLE AND GROUPS THAT MAY USE OR GIVE OUT YOUR HEALTH INFORMATION

1. PEOPLE OR GROUPS WITHIN BUMC/BMC

- Researchers involved in this research study

- The BUMC Institutional Review Board that oversees this research

2. PEOPLE OR GROUPS OUTSIDE BUMC/BMC

- People or groups that we hire to do certain work for us, such as data storage companies, or laboratories.

- Federal and state agencies if they are required by law or involved in research oversight. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, the Massachusetts Department of Public Health.

- Organizations that make sure hospital standards are met

- The sponsor(s) of the research study, and people or groups it hires to help them do the research

- Other researchers that are part of this research study

- A group that oversees the research information and safety of this study

Other:

Some people or groups who get your health information might not have to follow the same privacy rules that we follow. We share your health information only when we must. We ask anyone who gets it from us to protect your privacy. However, once the information leaves BUMC, we cannot promise that it will be kept private.

In most cases any health data that is being given out to others is identified by a unique study number and not with your name. So, although in some cases it is possible to link your name to the study data, this is not usually done.

TIME PERIOD FOR USING OR GIVING OUT YOUR HEALTH INFORMATION

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

YOUR PRIVACY RIGHTS

You have the right not to sign this form that allows us to use and give out your health information for research. If you don't sign this form, you can't be in the research. This is because we need to use the health information to do the research.

You have the right to withdraw your permission to use or share your health information in this research study. If you want to withdraw your permission, you must write a letter to the researchers in charge of this research study.

If you withdraw your permission, you will not be able to take back information that has already been used or shared with others. This includes information used or shared to do the research study or to be sure the research is safe and of high quality.

If you withdraw your permission, you cannot continue to be in the study.

You have the right to see and get a copy of your health information that is used or shared for research. However, you may only get this after the research is finished. To ask for this information, please contact the person in charge of this research study.

IF RESEARCH RESULTS ARE PUBLISHED OR USED TO TEACH OTHERS

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information will not be used for these purposes without your specific permission.

RESEARCH CONSENT FORM

Offspring Examination 9

H-22762– THE FRAMINGHAM HEART STUDY N01-HC-25195 1910G

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

Participant's Signature	**Printed Name**	**Date**
Legally Authorized Representative (LAR)'s Signature	**Printed Name**	**Date**
Person Obtaining Consent Signature	**Printed Name**	**Date**
Witness' Signature	**Printed Name**	**Date**

RESEARCH SUBJECT'S AUTHORIZATION

FOR RELEASE OF HEALTH INFORMATION FOR RESEARCH PURPOSES

Name of Research Study: Framingham Heart Study

IRB Number: H-24583

Subject's Name: _____ Birth Date: _____

We want to use your private health information in this research study. This will include both information we collect about you as part of this study as well as health information about you that is stored in your medical record. The law requires us to get your authorization (permission) before we can use your information or share it with others for research purposes. You can choose to sign or not to sign this authorization. However, if you choose not to sign this authorization, you will still be able to take part in the research study. Whatever decision you make about this research study will not affect your access to medical care.

Section A:

I authorize the use or sharing of my health information as described below:
Who will be asked to give us your health information:

Who will be able to use your health information for research:

- *The researchers and research staff conducting this study at the Framingham Heart Study*

We may also be asked or required by law to share your health information with the following people if they request it. Once we give it to them, your information is no longer protected under the federal Privacy Rule. However, its use and further disclosures remain limited as stated in your Informed Consent Form as part of BUMC Institutional Review Board oversight.

- *Boston University Medical Center Institutional Review Board*
- *Other governmental agencies that oversee research*

Section B: Description of information:

(1) If you choose to be in this study, the research team needs to collect information about you and your health. This will include information collected during the study as well as information from your existing medical records

(2) **from _____ through_____**

Your health information will be used and shared with others for the following study-related purpose(s):

Data Analysis of Results

(2) Specific description of information we will collect:

- ***Face sheet,***
- ***Discharge Summary***
  ER Report
  Admission Notes
  Progress Notes,
  Operative Report
- ***Pathology Report,***
- ***Chest X-Rays***
- ***EKGS***
- ***CT Scan(Head /Heart)***
- ***MRI/MRA (Head/Neck)***
- ***Lab Reports- Cardiac Enzymes***
  Consults (Cardiology & Neurology)
  Cardiac Catheterization
  Exercise Tolerance Test
  Nursing Home notes
  Notes Near Time of Death

Other (for example: Echocardiogram, Arteriography, Venous Ultrasound, V/Q Scan, PA gram, etc)

Section C: General

Expiration:

This authorization expires at .the end of the study

Right To Revoke:

You may revoke (take back) this authorization at any time. To do this, you must ask us the Framingham Heart Study for the names of the Privacy Officers at the

institutions where we got your health information. You must then notify those Privacy Officers in writing that you want to take back your Authorization. If you do, we will still be permitted to use and share the information that we obtained before you revoked your authorization but we will only use and share your information the way the Informed Consent Form says.

1. **If you revoke this authorization, we may still need to share your health information if you have a bad effect (adverse event) during the research.**

Your Access to the Information:

You have the right to see your medical records, but you will not be allowed to review your Framingham Heart Study research record until after the study is completed.

……..

I have read this information, and I will receive a signed copy of this form.

_____ _____

Signature of research subject or personal representative **Date**

Printed name of personal representative: _____

Relationship to research subject: _____

Please describe the personal representative's authority to act on behalf of the subject:

_____

RESEARCH CONSENT FORM

Omni 1 Examination 4

H-24583 Evaluation of Omni Generation 1 of the Framingham Heart Study

Background

You are participating in the continuation of the Framingham Heart Study (FHS), Omni Group 1 Cohort. This fourth examination of the FHS Omni 1 Cohort will be similar to previous visits in many ways. There are also some new study activities. Exam components, both old and new, are described below.

Purpose

The purpose of this research is 1) to better understand the development of heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, cancer, and other major diseases and health conditions; and 2) to examine DNA and its relationship to the risks of developing these diseases and other health conditions.

THIS EXAMINATION IS FOR RESEARCH AND DOES NOT TAKE THE PLACE OF A ROUTINE MEDICAL CHECK UP BY YOUR PHYSICIAN

Taking part in this study is voluntary. You have the right to refuse to take part in this study. If you choose to take part, you have the right to stop at any time.

What Happens In This Research Study

You will be one of approximately 520 subjects to be asked to participate in this study.

All or part of the research in this study will take place at the following location(s): Boston University Medical Center.

Your research examination will take place at the FHS at 73 Mt. Wayte Avenue in Framingham, MA, or may take place in your home or other residence.

New Study Activities:

1) With your permission, white cells (from the blood collected as a regular part of the FHS exam) will be processed so that they function like cells from other organs such as liver cells, fat cells heart cells or nerve cells. The resulting cells are called Induced Pluripotent Stem cells. These cells may be studied in laboratories to learn more about causes of health and disease in such organs. FHS investigators will not alter white cells to behave as reproductive cells.

2) We will ask if we may obtain a sample of cells from the inside of your cheek by gently scraping the inside surface with a single-use plastic utensil. The cells will be used to examine how changes in DNA called DNA methylation are related to lung function and lung diseases and other diseases,

3) You will be asked to wear a physical activity monitor on a belt for a week and to return it to FHS. It measures how active you are throughout the day

4) You will be asked after your visit to use a kit to collect urine samples for 24 hours and send it by mail to a laboratory. The kit will be mailed to you for a day convenient to you shortly after this exam visit.

RESEARCH CONSENT FORM

Omni 1 Examination 4

H-24583 Evaluation of Omni Generation 1 of the Framingham Heart Study

Ongoing Exam components for which you have previously given informed consent: In addition to the new procedures described above, the following procedures will be done at this visit:

1) Medical History Interview.

2) Physical Examination including ECG

3) Collection of blood (up to 117.5 cc or four ounces) and urine specimens to test for many risk factors for the diseases and health conditions under investigation.

4) Genetic Studies: You will be asked if a sample of the blood you donate may be used for additional genetic studies.

5) Vascular Function Testing: (a) Arterial Tonometry is a measure of arterial stiffness. A waveform is obtained by gently placing a flat sensor over arteries on the arm (brachial and radial), the groin (femoral) and the neck (carotid). (b) An Echocardiogram, which is ultrasound pictures of the heart.

6) Pulmonary function testing is performed by breathing into a tube connected to a machine that measures exhaled air volume and flow. Some individuals may be asked to repeat the testing after using an inhaler to improve airflow.

7) Questionnaires about memory, mood and physical function; diet and exercise

8) Blood pressures in your arms and ankles

9) Medical Records: You will be asked to sign a form to allow FHS to obtain copies of hospital and Medicare (CMS) and medical records. The release form is valid to obtain these records unless canceled by you. You will be asked for your social security number for the purpose of locating you in the future. You may choose to decline this request. You will also be asked if investigators and their research collaborators at other institutions, in this case Duke University, may link your Social Security Number to CMS data to obtain Medicare information. Social Security Numbers will not be released to outside institutions.

10) Results of some FHS research measurements will be sent to you and/or to your physician within six weeks of your FHS visit. However, some other measurements could be made months or years later as part of special research projects. You may receive results of some measurements long after your FHS visit.

11) Follow Up: You may be contacted later by mail or by phone to obtain additional health information or to be invited to participate in further FHS health-related studies. You may be invited to return for another examination in the future.

RESEARCH CONSENT FORM

Omni 1 Examination 4

H-24583 Evaluation of Omni Generation 1 of the Framingham Heart Study

Risks and Discomforts

Risk or injury, as a result of participation, is not expected. In the unlikely event that during the examination you require medical care, first aid will be available.

The Blood Draw: Minimal bruising, pain, bleeding, or in rare circumstances, an infection may occur.

The Lung Function test involves a low level of risk. You may feel lightheaded or you may faint and risk injury from falling. Participants asked to inhale the medication called albuterol, used during lung function testing, may notice an increase in heart rate (pulse) or symptoms of jitteriness or shakiness (tremors).

Other discomforts include headaches, feeling hungry, fatigue and chill during the visit.

Safeguards are in place to protect the security of your study information. FHS ID numbers are used on most data files instead of names. Firewalls and password protection are in place on the computer systems. Staff is trained in safe computer practices. However there is still a minimal risk of a breach in confidentiality.

There may be unknown risks/discomforts involved. Study staff will update you in a timely way on any new information that may affect your health, welfare, or decision to stay in this study

Potential Benefits

You will receive no direct benefit from your participation in this study. However, your participation may help the investigators better understand the causes and prevention of cardiovascular disease and other medical conditions, including the potential of genetic factors..

Alternatives

Your alternative is to not participate in the study.

Subject Costs and Payments

You will not be charged or paid for any part of the examination. If the examination finds medical problems that require tests or treatments, information will be provided to you and to the physician or clinic that you have named to receive your test results.. If your physician decides that follow up tests or treatments are necessary, then you (or a third party such as health insurance or Medicare) will be responsible for the cost. No special arrangement will be made by the Framingham Heart Study for compensation or payment solely because of your participation in this study. This does not waive any of your legal rights. Costs that you may incur the day of your participation include, but are not limited to, loss of work, and transportation (gas, tolls, etc.). You will not receive payment for your participation.

RESEARCH CONSENT FORM

Omni 1 Examination 4

H-24583 Evaluation of Omni Generation 1 of the Framingham Heart Study

Patenting Discoveries

Research from this study may, one day, result in new tests to diagnose or predict diseases. It may also lead to the development of new medicines to prevent or cure diseases. As is true of all federally-funded research, researchers and their employers are permitted by Federal law to patent discoveries from which they may gain financially. It was the judgment of the U.S. Congress that permitting such patents would greatly increase the likelihood that a public health benefit would be realized from federally funded research.

CONFIDENTIALITY

Information obtained about you will be treated as confidential. A code number will be assigned to your data and specimens. The codes will only be provided to qualified investigators but your name and other personal identifying information will not be provided. Your samples will be kept until they are not of scientific value. You will not be routinely informed of results of research performed upon your genetic samples, although with your permission you may be informed of some findings about genetics, cardiovascular disease or other health conditions generated from DNA analyses, directly to you or through publication in newsletters.

When study results are published, your name and other identifying information will not be revealed. Information from this study and from your medical record may be reviewed and photocopied by state and federal regulatory agencies, such as the Office of Human Research Protection, as applicable, and the Institutional Review Board of Boston University Medical Center.

To help us further protect your privacy, the investigators have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer or employer learns of your participation, and obtains your consent to receive research information, then FHS is not allowed to use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy. Finally, you should understand that the Certificate of Confidentiality does not prevent the investigators from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

RESEARCH CONSENT FORM

Omni 1 Examination 4

H-24583 Evaluation of Omni Generation 1 of the Framingham Heart Study

Please check the appropriate box above each of the following statements:

1) |___| YES |___| NO (Office Code 0)

I agree to participate in the FHS clinic examination, the collections of blood, cheek cells and urine, and studies of the factors contributing to heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, cancer, and other major diseases and health conditions.

2|___| YES |___|NO (Office Code 3)

I agree to allow my data, cheek cells, blood and urine samples to be used in future genetic studies of factors contributing to heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, cancer, and other diseases and health conditions.

3) |___| YES |___| NO (Office Code 12)

I agree to allow my data, cheek cells, blood and urine and DNA samples to be used in future genetic studies of reproductive conditions, and mental health conditions such as alcohol use and depressive symptoms.

4 |___| YES |___|NO (Office Code 13)

I agree to provide a blood sample from which Induced Pluripotent Stem Cells can be made and from which a range of cell products such as RNA, proteins and metabolites can be obtained. This means that white cells from my blood may be processed to become stem cells and then altered so that they function like cells from other organs such as liver cells, fat cells, heart cells or nerve cells.

5 |___| YES |___| NO (Office Code 4)

I agree to allow researchers from commercial companies to have access to my blood and urine samples, DNA, other genetic material, and data in the future which may be used to develop new lab tests or treatments that could benefit many people. (You or your heirs will not benefit financially from this, nor will your DNA be sold to anyone.)

6) |___| YES |___| NO (Office Code 30)

I agree to allow the FHS to release the findings of non-genetic tests and examinations to my physician, clinic, or hospital.

7) |___| YES |___| NO (Office Code 31)

If a genetic condition is identified that may have important health and treatment implications for me, I agree to allow the FHS to notify me, and then with my permission to notify my physician.

RESEARCH CONSENT FORM

Omni 1 Examination 4

H-24583 Evaluation of Omni Generation 1 of the Framingham Heart Study

Subject's Rights

By consenting to participate in this study you do not waive any of your legal rights. Giving consent means that you have heard or read the information about this study and that you agree to participate. You will be given a copy of this form to keep.

If at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled.

You may obtain further information about your rights as a research subject by calling the Office of the Institutional Review Board of Boston University Medical Center at [redacted]. If this study is being done outside the United States you can ask the investigator for contact information for the local Ethics Board.

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury while participating in this research, contact [redacted].

Compensation for Research Related Injury

If you think that you have been injured by being in this study, please let the investigator know right away. If your part in this study takes place at Boston Medical Center, you can get treatment for the injury at Boston Medical Center. If your part of the study is not at Boston Medical Center, ask the investigator where treatment for injury would be available locally. Boston University Medical Center and the sponsor do not offer a program to provide compensation for the cost of care for research related injury or other expenses such as lost wages, disability, pain, or discomfort. You will be sent a bill for the medical care you receive for research injury if your medical insurance does not pay for your medical care. You are not giving up any of your legal rights by signing this form.

Right to Refuse or Withdraw

Taking part in this study is voluntary. You have the right to refuse to take part in this study. If you decide to be in the study and then change your mind, you can withdraw from the research. Your participation is completely up to you. Your decision will not affect your being able to get health care at this institution or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get.

If you choose to take part, you have the right to stop at any time. If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them as soon as possible.

The investigator may decide to discontinue your participation without your permission because he/she may decide that staying in the study will be bad for you, or the sponsor may stop the study.

RESEARCH CONSENT FORM

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Protection of Subject Health Information

You have certain rights related to your health information. These include the right to know who will get your health information and why they will get it. If you choose to be in this research study, we will get information about you as explained below.

HEALTH INFORMATION ABOUT YOU THAT MIGHT BE USED OR GIVEN OUT DURING THIS RESEARCH:

Information from your hospital or office health records at BUMC/BMC or elsewhere. This information is reasonably related to the conduct and oversight of the research study. If health information is needed from your doctors or hospitals outside of BUMC/BMC, you will be asked to give permission for these records to be sent to the researcher.

New health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.

WHY HEALTH INFORMATION ABOUT YOU MIGHT BE USED OR GIVEN OUT TO OTHERS

The reasons we might use or share your health information are:

- To do the research described here

- To make sure we do the research according to certain standard set by ethics, law, and quality groups

PEOPLE AND GROUPS THAT MAY USE OR GIVE OUT YOUR HEALTH INFORMATION

1. PEOPLE OR GROUPS WITHIN BUMC/BMC

- Researchers involved in this research study

- The BUMC Institutional Review Board that oversees this research

2. PEOPLE OR GROUPS OUTSIDE BUMC/BMC

- People or groups that we hire to do certain work for us, such as data storage companies, or laboratories.

- Federal and state agencies if they are required by law or involved in research oversight. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, the Massachusetts Department of Public Health.

- Organizations that make sure hospital standards are met

- The sponsor(s) of the research study, and people or groups it hires to help them do the research

- Other researchers that are part of this research study

- A group that oversees the research information and safety of this study

Other: Some people or groups who get your health information might not have to follow the same privacy rules that we follow. We share your health information only when we must. We ask anyone who gets it from us to protect your privacy. However, once the information leaves BUMC, we cannot promise that it will be kept private.

RESEARCH CONSENT FORM

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In most cases any health data that is being given out to others is identified by a unique study number and not with your name. So, although in some cases it is possible to link your name to the study data, this is not usually done.

TIME PERIOD FOR USING OR GIVING OUT YOUR HEALTH INFORMATION

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

YOUR PRIVACY RIGHTS

You have the right not to sign this form that allows us to use and give out your health information for research. If you don't sign this form, you can't be in the research. This is because we need to use the health information to do the research.

You have the right to withdraw your permission to use or share your health information in this research study. If you want to withdraw your permission, you must write a letter to the researchers in charge of this research study.

If you withdraw your permission, you will not be able to take back information that has already been used or shared with others. This includes information used or shared to do the research study or to be sure the research is safe and of high quality.

If you withdraw your permission, you cannot continue to be in the study.

You have the right to see and get a copy of your health information that is used or shared for research. However, you may only get this after the research is finished. To ask for this information, please contact the person in charge of this research study.

IF RESEARCH RESULTS ARE PUBLISHED OR USED TO TEACH OTHERS

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information will not be used for these purposes without your specific permission.

RESEARCH CONSENT FORM

Omni 1 Examination 4

H-24583 Evaluation of Omni Generation 1 of the Framingham Heart Study

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

_____	_____	_____
Participant's Signature	**Printed Name**	**Date**
_____	_____	_____
Legally Authorized Representative (LAR)'s Signature	**Printed Name**	**Date**
_____	_____	_____
Person Obtaining Consent Signature	**Printed Name**	**Date**

RESEARCH CONSENT FORM

Blood Draw Consent for Cell Line Creation

H-24583 Evaluation of Omni Generation 1 of the Framingham Heart Study

Background

A cell line is a frozen sample of specially processed white cells from your blood that allows the Framingham Heart Study to grow more white cells and get more DNA from them in future as needed for research projects.

Purpose

A cell line will be created from a blood sample you provide in order to study the cause and prevention of cardiovascular disease and other health conditions, including the possibility of how genetic factors influence health status.

What Happens In This Research Study

You will be one of approximately 520 subjects to be asked to participate in this study.

All or part of the research in this study will take place at the following location(s): Boston University Medical Center.

Your research blood draw will take place at the Framingham Heart Study located at 73 Mount Wayte Avenue in Framingham, MA, or the place where you reside. A laboratory technician will draw a sample of your blood (16 cc or about 1 tablespoon) for the preparation of DNA (genetic material) and for the creation of a living sample of white blood cells (cell line).

Risks and Discomforts

Minimal bruising, pain, or bleeding may occur as a result of the blood draw. A latex allergy can occur from the gloves worn by the technician. If you have a known latex allergy, inform the technician and he/she will use another form of protection.

There may be unknown risks/discomforts involved. Study staff will update you in a timely way on any new information that may affect your health, welfare, or decision to stay in this study

Potential Benefits

You will receive no direct benefit from your participation in this study. However, your participation may help the investigators better understand the cause and prevention of cardiovascular disease and other health conditions, including the possibility of how genetic factors influence health status.

Alternatives

Your alternative is to not participate in the study.

RESEARCH CONSENT FORM

Blood Draw Consent for Cell Line Creation

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Subject Costs and Payments

You will not be charged for the examination. If the examination finds any medical problems requiring medical diagnosis or treatment, you will be so advised and that information will be provided to the physician or clinic that you choose.

In the event that your physician decides that follow up clinical tests or treatments are necessary, payment must be provided by you or your third party payer, if applicable (for example, health insurance or Medicare). No special arrangements will be made by the Framingham Heart Study for compensation or for payment of treatment solely because of your participation in this study. This does not waive any of your legal rights.

Costs that you might incur the day of your participation include, but are not limited to, transportation costs (gas, tolls, etc). You will not receive payment for your participation. However, if necessary, we will provide transportation to the clinic and your return home at no cost.

Confidentiality

Information obtained during this study will be treated as strictly confidential. A code number will be assigned to you and to your personally identifying information. Cell lines will be stored at a central site. Files linking names to samples will be kept locked and accessible only to the Framingham Heart Study (FHS) data managers. The coded samples will be stored securely and kept until no longer of scientific value. The risk in providing this sample is minimal.

Data and DNA will be distributed to the FHS researchers and other qualified researchers interested in the genetics of heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, joint disease, bone loss, deafness, cancer, and other major diseases and health conditions. The researchers will be given the DNA without any personally identifying information. Information gained from research on your DNA may be used for the development of diagnostic procedures or new treatments for major diseases. Your DNA will not be sold to any person, institution, or company for financial gain or commercial profit. However, neither you nor your heirs will gain financially from discoveries made using the information and/or specimens that you provide.

When study results are published, your name and any other identifying information will not be revealed. You will be informed through periodic publications from the FHS of some findings about genetics, cardiovascular disease or other health conditions generated from the DNA analyses.

To help us further protect your privacy, the investigators have obtained a Confidentiality Certificate from

the Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes. You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. Note however, that if an insurer or employer learns about your participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy. Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

You may choose to withdraw your blood samples and your samples would be destroyed after the request is received. If you choose to withdraw your samples, you should call the Framingham Heart Study at [redacted] and ask for the lab manager.

The FHS is a medical research project sponsored by the National Institutes of Health. It is authorized under 42USC 285b-3. The system of records which applies to the FHS is documented in the Federal Register: September 26, 2002 (Vol. 67, No. 1879) pages 60776-60780.

Please check the appropriate box below:

1) |___| YES |___| NO (Office Code 1)

I agree to allow a cell line to be made from my blood to provide a renewable supply of DNA. (A cell line is a frozen sample of specially processed white cells from your blood that allows us to grow more white cells and obtain more DNA from them as needed for future research projects).

Subject's Rights

By consenting to participate in this study you do not waive any of your legal rights. Giving consent means that you have heard or read the information about this study and that you agree to participate. You will be given a copy of this form to keep.

If at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled.

You may obtain further information about your rights as a research subject by calling the Office of the

RESEARCH CONSENT FORM

Blood Draw Consent for Cell Line Creation

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Institutional Review Board of Boston University Medical Center at [redacted].

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury while participating in this research, contact [redacted].

Compensation for Research Related Injury

If you think that you have been injured by being in this study, please let the investigator know right away. If your part in this study takes place at Boston Medical Center, you can get treatment for the injury at Boston Medical Center. If your part in the study is not at Boston Medical Center, ask the investigator where treatment for injury would be available locally. You and your insurance company will be billed for this treatment. Some research sponsors may offer a program to cover some of the treatment costs which are not covered by your insurance. You should ask the research team if such a program is available.

Right to Refuse or Withdraw

Taking part in this study is voluntary. You have the right to refuse to take part in this study. If you decide to be in the study and then change your mind, you can withdraw from the research. Your participation is completely up to you. Your decision will not affect your being able to get health care at this institution or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get.

If you choose to take part, you have the right to stop at any time. If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them as soon as possible.

The investigator may decide to discontinue your participation without your permission because he/she may decide that staying in the study will be bad for you, or the sponsor may stop the study.

BUMC/BMC Institutional Review Board
IRB NUMBER: H-24583
IRB APPROVAL DATE: 01/19/2012
IRB EXPIRATION DATE: 01/18/2013

RESEARCH CONSENT FORM

Blood Draw Consent for Cell Line Creation

H-24583 Evaluation of Omni Generation 1 of the Framingham Heart Study

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

Subject Signature	**Printed Name**	**Date**
Legally Authorized Representative (LAR)	**Printed Name**	**Date**
Signature of Person Obtaining Consent	**Printed Name**	**Date**

RESEARCH SUBJECT'S AUTHORIZATION

FOR RELEASE OF HEALTH INFORMATION FOR RESEARCH PURPOSES

Name of Research Study: Framingham Heart Study

IRB Number: H-24583

Subject's Name: _____ Birth Date: _____

We want to use your private health information in this research study. This will include both information we collect about you as part of this study as well as health information about you that is stored in your medical record. The law requires us to get your authorization (permission) before we can use your information or share it with others for research purposes. You can choose to sign or not to sign this authorization. However, if you choose not to sign this authorization, you will still be able to take part in the research study. Whatever decision you make about this research study will not affect your access to medical care.

Section A:

I authorize the use or sharing of my health information as described below:
Who will be asked to give us your health information:

Who will be able to use your health information for research:

- *The researchers and research staff conducting this study at the Framingham Heart Study*

We may also be asked or required by law to share your health information with the following people if they request it. Once we give it to them, your information is no longer protected under the federal Privacy Rule. However, its use and further disclosures remain limited as stated in your Informed Consent Form as part of BUMC Institutional Review Board oversight.

- *Boston University Medical Center Institutional Review Board*
- *Other governmental agencies that oversee research*

Section B: Description of information:

(1) If you choose to be in this study, the research team needs to collect information about you and your health. This will include information collected during the study as well as information from your existing medical records

(2) **from _____ through_____**

Your health information will be used and shared with others for the following study-related purpose(s):

Data Analysis of Results

(2) Specific description of information we will collect:

- ***Face sheet,***
- ***Discharge Summary***
  ER Report
  Admission Notes
  Progress Notes,
  Operative Report
- ***Pathology Report,***
- ***Chest X-Rays***
- ***EKGS***
- ***CT Scan(Head /Heart)***
- ***MRI/MRA (Head/Neck)***
- ***Lab Reports- Cardiac Enzymes***
  Consults (Cardiology & Neurology)
  Cardiac Catheterization
  Exercise Tolerance Test
  Nursing Home notes
  Notes Near Time of Death

Other (for example: Echocardiogram, Arteriography, Venous Ultrasound, V/Q Scan, PA gram, etc)

Section C: General

Expiration:

This authorization expires at .the end of the study

Right To Revoke:

You may revoke (take back) this authorization at any time. To do this, you must ask us the Framingham Heart Study for the names of the Privacy Officers at the

institutions where we got your health information. You must then notify those Privacy Officers in writing that you want to take back your Authorization. If you do, we will still be permitted to use and share the information that we obtained before you revoked your authorization but we will only use and share your information the way the Informed Consent Form says.

1. **If you revoke this authorization, we may still need to share your health information if you have a bad effect (adverse event) during the research.**

Your Access to the Information:

You have the right to see your medical records, but you will not be allowed to review your Framingham Heart Study research record until after the study is completed.

……..

I have read this information, and I will receive a signed copy of this form.

_____ _____

Signature of research subject or personal representative **Date**

Printed name of personal representative: _____

Relationship to research subject: _____

Please describe the personal representative's authority to act on behalf of the subject:

_____

FORMA DE CONSENTIMIENTO PARA INVESTIGACION

OMNI Generación I Examen 4

H-24583 –EVALUACION DE OMNI GENERACION 1 DEL ESTUDIO DEL CORAZON DE FRAMINGHAM

Antecedentes

Usted está participando en la continuación del estudio para Omni 1 del Estudio del Corazón de Framingham. Este es el cuarto examen y en muchos sentidos será similar a los exámenes previos, pero hay algunas pruebas que son nuevas. Los componentes de este Examen, tanto los anteriores como los nuevos, se describen abajo.

Propósito

El propósito de este estudio es 1) entender mejor el desarrollo de enfermedades del corazón y las arterias, enfermedades del pulmón y la sangre, accidentes cerebro-vasculares, pérdida de memoria, cáncer y otras enfermedades y condiciones de la salud; y 2) examinar el ADN y su relación con los riesgos a desarrollar estas enfermedades y otras condiciones de la salud.

ESTE EXAMEN ES SOLO PARA INVESTIGACION MEDICA Y NO TOMA EL LUGAR DE UN CHEQUEO GENERAL HECHO POR SU DOCTOR.

Su participación es voluntaria. Tiene el derecho de rehusar o no tomar parte en este estudio. Si decide participar, tiene el derecho de dejar su participación en el futuro en cualquier momento.

Qué sucede en este Estudio de Investigación

Usted será una de aproximadamente 520 personas a quienes se les pedirá participar en este estudio. Toda o parte de la investigación tendrá lugar en la siguiente localidad (es): Centro Médico de la Universidad de Boston. Su examen se llevará a cabo en las facilidades del Estudio del Corazón de Framingham, localizado en 73 Mount Wayte Avenue, en Framingham, Massachusetts o en otras facilidades o residencias.

Nuevas pruebas:

1) Con su permiso, se van a procesar células blancas (tomadas de las muestras de sangre durante su examen aquí) para que imiten el funcionamiento de las células de otros órganos de su cuerpo; como células del hígado, células grasas del corazón y células de los nervios. A estas células que han sido procesadas se les conoce como Células Pluripotenciales Inducidas. Estas células pueden ser estudiadas en laboratorios para aprender más sobre las causas de enfermedades de esos órganos así como las causas de su buena salud. Los investigadores del Estudio del Corazón de Framingham jamás alterarán células para que imiten a las células reproductivas.
2) Le preguntaremos si podemos obtener células de la parte interna de su mejilla, raspando suavemente con un cepillo de plástico. Las células se usarán para examinar cómo algunos cambios en el ADN (llamados metilación del ADN) se pudieran relacionar con la función pulmonar y otras enfermedades.
3) Se le preguntará si desea usar un pequeño monitor para medir la actividad física. Se usa con un cinturón suave durante una semana y después se le pide que lo envíe por correo al Estudio del Corazón de Framingham. Mide su actividad diaria.
4) Se le preguntará si desea participar en un estudio de colección de orina durante 24 horas, usando un equipo especial de plástico que se le enviará por correo cuando a usted le convenga después de participar aquí.

FORMA DE CONSENTIMIENTO PARA INVESTIGACION

OMNI Generación I Examen 4

H-24583 –EVALUACION DE OMNI GENERACION 1 DEL ESTUDIO DEL CORAZON DE FRAMINGHAM

Otros componentes del estudio por los que ya nos ha dado consentimiento en el pasado. Además de las nuevas pruebas descritas arriba, se harán las siguientes pruebas que ya ha hecho:

1) Historial Médico.
2) Examen físico, incluyendo electrocardiograma o ECG
3) Colección de sangre (hasta 117.5 cc o cuatro onzas) y muestra de orina para hacer pruebas sobre factores de riesgo de las enfermedades y condiciones de salud que están siendo investigadas.
4) Estudios Genéticos: Se le preguntará si se puede usar una parte de su muestra de sangre para más estudios genéticos.
5) Prueba de la Función Vascular: a) Tonometría Arterial, mide la rigidez de las arterias. Se obtiene una onda colocando un sensor plano sobre las arterias en el brazo (braquial y radial), la ingle (femoral) y el cuello (carótida). b) Ecocardiograma; dos imágenes del corazón por ultrasonido.
6) Prueba de la función pulmonar; se hace respirando de un tubo conectado a una máquina que mide el volumen y flujo del aire exhalado. A algunos participantes se les pedirá que repitan la prueba usando un inhalador para mejorar el flujo del aire.
7) Cuestionarios sobre su memoria, estados de ánimo y función física, así como dieta y ejercicio.
8) Presión arterial en brazos y tobillos.
9) Registros médicos: Se le pedirá que firme una forma para dar permiso al Estudio del Corazón de Framingham a que obtenga copias de registros de hospital, Medicare (CMS) y otros registros médicos. Este permiso es válido para obtener registros médicos a menos que usted lo cancele. Se le pedirá su número de seguro social con el propósito de localizarlo en el futuro. Puede rehusar esta solicitud nuestra. También se le preguntará si investigadores, así como sus colaboradores de investigación en otros institutos, en este caso la Universidad de Duke, pueden relacionar su número de seguro social a la base de datos de CMS para obtener información de Medicare. Los números de seguro social no serán dados a ninguna otra institución.
10) Algunos de los resultados serán enviados a usted y/o a su doctor dentro de seis semanas después de su examen. Sin embargo, hay otras pruebas que pueden requerir meses, incluso años antes de que se pueda enviar algún resultado, porque son parte de proyectos especiales de investigación.
11) Seguimiento: Posiblemente se le contacte en el futuro, ya sea por correo o por teléfono, para obtener más información de su salud o para que se le invite a participar en otros estudios de salud del Estudio del Corazón de Framingham, y para volver a venir a otro examen en el futuro.

Riesgos y Molestias

No esperamos que sucedan riesgos o daños inesperados como resultado de su participación, pero en el extremo caso de que durante su examen usted requiriera atención médica, contamos con primeros auxilios.

Muestra de Sangre: Son posibles un pequeño moretón, dolor, sangrado o en raras ocasiones, infección.

La Prueba de la Función Pulmonar involucra un nivel muy bajo de riesgo. Usted podría sentirse mareado o desmayarse y arriesgarse a sufrir una lesión si se cayera. Los participantes a quienes se les haya pedido que inhalen albuterol durante la prueba pulmonar, podrían experimentar un incremento en los latidos del corazón (pulso) o síntomas de agitación o temblores.

Otras molestias generales incluyen dolores de cabeza, sentir hambre, cansancio y frío durante su visita.

Se toman todas las medidas para proteger la seguridad de su información en el estudio. En lugar de nombres, se usan números de identificación en la gran mayoría de las bases de datos. Se utilizan protecciones con bloqueos y claves en los sistemas computacionales. Sin embargo, aun así hay un mínimo riesgo de que se quebrante la confidencialidad.

Quizá existan riesgos y molestias desconocidos por el momento. Los empleados del estudio le actualizarán oportunamente sobre cualquier información nueva que pudiera afectar su salud, su bienestar y su decisión de seguir en el estudio.

Posibles Beneficios

Usted no recibirá ningún beneficio directo de su participación en este estudio. Sin embargo, su participación puede ayudar a los investigadores a comprender mejor las causas y prevención de enfermedades cardiovasculares y otras condiciones médicas, incluyendo el potencial de factores genéticos.

Alternativas

Tiene la alternativa de no participar en el estudio.

Costos y pagos

A usted no se le pagará ni se le cobrará por ninguna parte del examen. Si en su examen se descubre algún problema médico que requiera un diagnóstico o tratamiento, se le dará aviso y esta información también se le dará al doctor o a la clínica que usted nos indique. Si su doctor decide que usted debe someterse a más exámenes clínicos o más tratamientos, usted o una tercera persona (por ejemplo su seguro médico o Medicare) serán responsables del costo. No se harán arreglos especiales por compensaciones o pagos de tratamientos por el solo hecho de haber participado en este estudio. Con este párrafo usted no renuncia a sus derechos legales. Los gastos que puede incurrir el día de su participación incluyen, pero no se limitan a, pérdida de horas de trabajo y transportación (gasolina, peaje, etc.). A usted no se le pagará por participar en el estudio.

Descubrimientos Patentables

Puede ser que algún día las investigaciones de este estudio den como resultado nuevos procedimientos para diagnosticar o predecir enfermedades. También puede llevarnos al desarrollo de nuevas medicinas para curar o prevenir enfermedades. Como sucede con toda investigación patrocinada federalmente, los investigadores y sus empleados tienen el permiso por ley, de patentar descubrimientos por los que podrían ser pagados. El Congreso de los Estados Unidos opina que el permitir tales patentes, podría incrementar la posibilidad de que un beneficio de salud pública se lleve a cabo a través del patrocinio federal para la investigación.

FORMA DE CONSENTIMIENTO PARA INVESTIGACION

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Confidencialidad

La información obtenida de usted será tratada como confidencial. Se le asignará un código a usted y a la información que obtengamos de usted. Los códigos solo se darán a investigadores calificados, pero su nombre y otros datos personales no serán proveídos. El riesgo en proveer muestras es mínimo. Las muestras serán guardadas hasta que ya no sirvan para la investigación científica. Usted no será informado de forma rutinaria sobre los resultados de las investigaciones hechas con su material genético, sin embargo, con su permiso, podrá ser informado de algunos hallazgos sobre genética, enfermedades cardiovasculares y otras condiciones de salud generadas por los análisis de su ADN, ya sea directamente o a través de las publicaciones en los boletines.

Cuando los resultados basados en su información sean publicados, su nombre y cualquier otra información que lo pudiera identificar, no serán revelados. Es posible que la información de este estudio, así como de sus registros médicos, sean revisados y fotocopiados por agencias de reglamento estatal o federal, como son: el Comité de Protección de Sujetos Humanos y el Comité de Revisión Institucional del Centro Médico de la Universidad de Boston.

Para ayudarnos a proteger aún más su privacidad, los investigadores han obtenido un Certificado de Confidencialidad del Departamento de Salud y Servicios Humanos (DHHS, por sus siglas en Ingles). Con este certificado, los investigadores no pueden ser forzados (por ejemplo por alguna corte) a divulgar información de la investigación que lo pudiera identificar en ningún procedimiento federal, estatal, local civil, criminal, administrativo, legislativo u otros. Sin embargo, será necesaria la divulgación si fuera requerida para hacer una auditoría por parte del DHHS o con propósitos de evaluación del programa. Un Certificado de Confidencialidad no le previene a usted ni a su familia de suministrar voluntariamente su propia información, ni la de su participación en este estudio. Tome nota que si por ejemplo, un asegurador o empleador sabe que usted es participante de este Estudio, y obtiene su consentimiento para obtener más información, en ese caso el investigador no podrá usar el Certificado de Confidencialidad para no divulgar su información. Esto significa que usted y su familia también deben proteger su propia privacidad. Finalmente, por favor comprenda que el investigador no está prevenido de tomar las medidas necesarias (incluyendo reportar a autoridades) para prevenir daños severos a usted mismo y a otros.

Por favor cheque las casillas correspondientes para indicar si está o no está de acuerdo con lo siguiente:

1) l__l SI l__l NO (Código de Oficina 0)
Estoy de acuerdo en participar en el examen clínico del Estudio del Corazón de Framingham, colección de sangre, células del cachete y orina, y en estudios de factores que contribuyen a enfermedades del corazón, las arterias, los pulmones y la sangre, accidentes cerebro-vasculares, pérdida de memoria, cáncer y otras enfermedades graves y condiciones de salud.

2) l__l SI l__l NO (Código de Oficina 3)
Estoy de acuerdo en permitir que mi información de datos, células del interior de mi cachete y muestras de sangre y orina se usen en futuros estudios genéticos de factores que contribuyen a enfermedades del corazón, las arterias, los pulmones y la sangre, accidentes cerebro-vasculares, pérdida de memoria,

cáncer y otras enfermedades y condiciones de salud.

3) l__l SI l__l NO (Código de Oficina 12)

Estoy de acuerdo en permitir que mi información de datos, células del interior de mi cachete, muestras de sangre, orina y ADN se usen en futuros estudios genéticos concernientes a la reproducción y salud mental como alcoholismo y síntomas de depresión.

4) l__l SI l__l NO (Código de Oficina 13)

Estoy de acuerdo en proveer una muestra de sangre para que se formen células pluripotenciales inducidas y con ellas hacer otros tipos de células, como ARN, proteínas y metabolitos. Esto significa que las células blancas de mi sangre se pueden procesar para obtener células madre y luego ser alteradas para que funcionen como células de otros órganos del cuerpo, como: hígado, células grasas, células del corazón y de los nervios.

5) l__l SI l__l NO (Código de Oficina 4)

Estoy de acuerdo en conceder a investigadores de compañías privadas el acceso a mis muestras de orina, sangre, ADN, otra información genética e información de datos en el futuro, que podrían ser utilizados en pruebas de laboratorio o tratamientos que podrían beneficiar a mucha gente. (Nota: Usted o sus familiares no se beneficiarán económicamente por esto, tampoco su ADN será vendido a nadie).

6) l__l SI l__l NO (Código de Oficina 30)

Estoy de acuerdo en dar permiso al Estudio del Corazón de Framingham para que informe los resultados de mis exámenes no-genéticos y exámenes a mi doctor, clínica u hospital.

7) l__l SI l__l NO (Código de Oficina 31)
Si se identifica alguna condición genética que tuviera importantes implicaciones para mí sobre mi salud y tratamientos, estoy de acuerdo en permitir que el Estudio del Corazón de Framingham me lo notifique y con mi permiso, a mi doctor.

Derechos del participante

Al darnos su consentimiento para participar en este estudio, usted no cancela ninguno de sus derechos legales. Dar consentimiento significa que usted ha escuchado o leído la información sobre este estudio y que está de acuerdo en participar. Se le dará una copia de esta forma.

Si en cualquier momento decidiera no seguir participando en este estudio, no sufrirá ningún tipo de penalidad ni perderá ningún beneficio al que tuviera derecho.

Puede obtener más información sobre sus derechos como sujeto en el estudio llamando al Comité de Revisión Institucional del Centro Médico de la Universidad de Boston al [redacted]. Si el estudio es hecho fuera de Estados Unidos, puede preguntarle al investigador por el Comité de Ética.

El investigador o algún miembro del equipo de investigadores tratará de responder a todas sus preguntas.

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Si tiene preguntas o dudas o si necesita reportar una herida que haya ocurrido mientras participó en el estudio, por favor contacte al [redacted] (en inglés).

Compensación por daños relacionados con la Investigación

Si piensa que ha sido herido por participar en este estudio, por favor déjeselo saber al investigador inmediatamente. Si su participación es en el Centro Médico de Boston, puede obtener tratamiento por la herida en el Centro Médico de Boston. Si su participación NO es en el Centro Médico de Boston, pregúntele a su investigador dónde puede obtener tratamiento localmente para su herida. El Centro Médico de la Universidad de Boston y su benefactor, no ofrecen programas para proveer compensación por el costo de cuidados médicos en caso de heridas ocurridas durante el estudio, ni otros gastos como pérdida de dinero por no trabajar, incapacidad, dolor o molestias. Se le enviará la cuenta por el tratamiento recibido si su seguro médico no paga por sus cuidados médicos. Usted no cancela sus derechos legales por firmar esta forma.

Sus Derechos a Rehusar o Descontinuar

Su participación en este estudio es voluntaria. Tiene el derecho de rehusar tomar parte en este estudio. Si decide participar y luego cambia de opinión, puede salirse del estudio. Su participación es completamente voluntaria. Su decisión no afectará el poder obtener cuidado médico en el Centro Médico de Boston, ni los pagos por su cuidado médico. No afectará su enrolamiento a ningún plan de salud o beneficios que pueda obtener. Si decide participar, tiene el derecho a descontinuar en cualquier momento. Si durante el estudio hubiera descubrimientos que pudieran afectar su buena voluntad de participar, se lo harán saber lo más pronto posible.
Es posible que el investigador decida descontinuar su participación sin su permiso porque pudiera decidir que continuar en el estudio sería malo para usted, o porque el patrocinador interrumpa el estudio.

Información de Salud para Protección de Sujetos

Usted tiene ciertos derechos relacionados con su información de salud. Estos incluyen el derecho a saber quién obtendrá su información de salud y para qué se utilizará. Si decide tomar parte de este estudio de investigación, obtendremos información sobre usted según se indica a continuación.

INFORMACION DE SALUD DE USTED QUE PUEDE SER USADA O DADA A OTROS DURANTE ESTE ESTUDIO:

- Información de su hospital o registros médicos de BUMC/BMC (Centro Médico de la Universidad de Boston) o de otra parte. Esta información es razonablemente relacionada al propósito del estudio de investigación. Si se necesitara información de sus doctores u hospitales fuera de BUMC/BMC, se le pedirá que nos dé permiso para que estos registros sean enviados al investigador del estudio.

- Nueva información que se obtenga de pruebas, procedimientos, visitas, entrevistas o formas completadas como parte de este estudio.

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RAZONES POR LAS QUE ES POSIBLE QUE DEMOS SU INFORMACION DE SALUD A OTROS

Las razones por las que es posible que usemos o compartamos su información de salud son:

- Para hacer el estudio descrito aquí.
- Para asegurarnos de llevar a cabo el estudio de acuerdo con ciertos estándares de ética, la ley y grupos de control.

GENTE Y GRUPOS QUE PUDIERAN USAR O DAR SU INFORMACION DE SALUD

1. GENTE O GRUPOS DENTRO DE BUMC/BMC

- Investigadores involucrados en el estudio
- La Mesa Institucional de Revisión del Centro Médico de la Universidad de Boston que supervisa este estudio.

2. GENTE O GRUPOS FUERA DE BUMC/BMC

- Gente o grupos que empleamos para hacer ciertos trabajos, como compañías de almacenamiento de información de datos o laboratorios.
- Agencias federales y estatales si lo requiere la ley o si están involucradas con la supervisión del estudio. Estas agencias pueden incluir el Departamento de Salud y Servicios Humanos de Estados Unidos, La Administración de Alimentos y Drogas, Los Institutos Nacionales de Salud, y el Departamento de Salud de Massachusetts.
- Organizaciones que aseguran que los estándares de los hospitales se mantengan.
- El o los Benefactores del estudio, y gente o grupos que emplean para ayudarles a realizar la investigación.
- Otros investigadores que forman parte de este estudio.
- Un grupo que supervisa la información de la investigación y la seguridad de este estudio.

Otros:

Puede que alguna gente o grupos que obtengan su información de salud no sigan las mismas reglas de privacidad que seguimos. Compartimos su información de saludo sólo cuando es

indispensable. Pedimos a quienes la obtengan que protejan su privacidad como participante. Sin embargo, una vez la información sale de BUMC (Centro Médico de la Universidad de Boston), no podemos prometer que la información se mantenga privada. En la mayoría de los casos, cualquier información que es dada a otros, se identifica con un número único de estudio, y no con su nombre. Así que, aunque pudiera ser posible relacionar el número con su información, esto usualmente no sucede.

PERIODO DE TIEMPO PARA USAR O DAR SU INFORMACION DE SALUD

Dado que los estudios de investigación son un proceso continuo, no podemos darle una fecha exacta sobre cuándo su información de salud será destruida o se dejará de usar o compartir.

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SUS DERECHOS A LA PRIVACIDAD

- Usted tiene el derecho a no firmar esta forma que nos permite usar y compartir su información de salud para investigación. Si no firma esta forma, no puede participar en el estudio, ya que necesitamos usar su información de salud para poderla estudiar.
- Tiene el derecho de detener su permiso para usar o compartir su información de salud en este estudio de investigación. Si así lo desea, debe escribir una carta a los investigadores encargados de este estudio de investigación. Si deja de darnos permiso, no podrá tomar de vuelta la información que ya ha sido usada o compartida con otros. Esto incluye información usada o compartida con propósitos de investigación o para garantizar la seguridad y calidad del estudio. Si retira su permiso, no puede continuar en el estudio.
- Tiene el derecho de ver y obtener una copia de la información de salud que es usada o compartida para uso de investigación. Sin embargo, solo puede obtener esto cuando la investigación haya terminado. Para pedir esta información, por favor contacte a la persona encargada de este estudio de investigación.

EN CASO DE QUE LOS RESULTADOS DEL ESTUDIO SEAN USADOS PARA SER PUBLICADOS O PARA LA ENSEÑANZA

Los resultados del estudio podrían ser publicados en alguna revista o libro médicos, o usados para enseñar a otros. Sin embargo, su nombre u otra información que lo pudiera identificar, no será usada sin su permiso específico.

Firmar esta forma de consentimiento indica que usted ha leído esta forma (o se la han leído), que sus preguntas han sido contestadas a su satisfacción y que usted voluntariamente accede a participar en este estudio de investigación. Usted recibirá una copia firmada de esta forma de consentimiento.

Firma del Participante	Nombre con Letra de Molde	Fecha
Representante legal autorizado (LAR) firma y nombre con Letra de Molde		Fecha
Firma de la Persona que Obtiene el Consentimiento y Nombre		Fecha

The Framingham Heart Study

Seguimiento médico a través de un Representante

(Research Proxy Form)

Una de las metas más importantes del Estudio del Corazón de Framingham (FHS por sus siglas en inglés) es mantenerse informado de cualquier cambio en su salud hasta que el estudio finalice. Esta información es importante para obtener respuestas a preguntas científicas acerca de enfermedades del corazón y otras condiciones de la salud. Usted es la mejor fuente de información respecto a su salud, pero quizá pudiera llegar un momento en el que usted no pueda proveer detalles sobre su salud. Por eso le pedimos que nos dé el nombre de alguna persona que pudiera contestar preguntas sobre su salud, en caso de que usted no pueda. A esta persona se le considerará su "Representante" o "Proxy" para el Estudio del Corazón de Framingham.

¿Qué es un representante?
Un representante es una persona que puede "estar en su lugar", para darnos información sobre su salud si usted no pudiera debido a una enfermedad grave o una enfermedad mental.

¿Por qué se necesita un representante?
Por muchos años, usted ha estado dando información importante sobre su salud para el Estudio del Corazón de Framingham. Esta información se perdería si por razones médicas usted no pudiera seguir dándola.

¿Qué hace un representante?
Preguntaremos acerca de su salud a su representante, de la misma forma que le hemos preguntado a usted cuando viene a un examen o cuando hace una actualización de su historial médico.

¿A quién debería nombrar como mi representante?
A alguien que le conozca lo suficientemente bien como para que pudiera proveer información médica de usted. Por ejemplo, su representante podría su abogado o representante legal, su representante o proxy para cuestiones médicas o un miembro de su familia próxima (como su esposo(a), hijo(a), hermano(a), etc.).

¿Puedo cambiar de representante?
Sí. Puede cambiar de representante en cualquier momento llamándonos al Estudio del Corazón de Framingham ([redacted]) o en persona cuando venga para un examen.

¿Le darán a mi representante información sobre mí?
No, toda la información que tenemos sobre usted es estrictamente confidencial y no será dada a su representante.

¿Qué debo hacer ahora?
Por favor indíquenos en la forma adjunta a quién ha escogido como su representante. Escriba el nombre de su representante, información para contactarlo, qué relación tiene con usted y luego firme la forma.

Se le darán dos copias de esta forma; una para usted y otra para que se la dé a su representante. Su representante deberá tener una copia para que conozca sus deseos como participante del Estudio del Corazón de Framingham.

Si tiene cualquier pregunta, por favor comuníquese con [redacted], Coordinadora de Omni al [redacted].

Gracias por su contínua dedicación al Estudio del Corazón de Framingham!

Framingham Heart Study Research Proxy

Representante de Investigación Médica para el Estudio del Corazón de Framingham

FHS ID: ___ - _____ Nombre del Participante:_____
Nombre Apellido

Yo, con domicilio en _____ escojo a la siguiente / las siguientes personas para que hagan decisiones sobre mi participación en el Estudio del Corazón de Framingham (Research Proxy):

Representante: Nombre:_____ Relación con participante:_____ Domicilio:_____ _____ _____ (Ciudad) (Estado) (Código postal) Telephone:_____ _____ (Home) (Work) (Otro) _____	Alterno: Si el representante principal no puede o no puede continuar dando mi permiso, nombro a esta persona (opcional): Nombre:_____ Relación con participante:_____ Domicilio:_____ _____ _____ (Ciudad) (Estado) (Código postal) Telephone:_____ _____ (Home) (Work) (Otro) _____

Fechas de Comienzo y Terminación

Este poder legal de larga duración tendrá efecto cuando esté firmado por mí y no se verá afectado por el transcurso del tiempo ni por mi inhabilidad, en caso de que ocurriera, haciéndome incapaz de tomar decisiones sobre mi participación en el estudio de investigación.

Poder del Representante (Proxy) de Investigación

El representante que yo elija tendrá autoridad para tomar todas las decisiones sobre mi participación en el estudio, incluyendo decisiones sobre enrrolarme o continuar participando en un estudio de investigación (tanto procedimientos con mínimo riesgo o con más que mínimo riesgo serán determinados por las regulaciones federales y en consulta con la Mesa de Revisión Institucional (IRB). Mi representante tendrá la misma autoridad que yo de tomar decisiones sobre mi participación en estudios de investigación. El o ella tienen la autoridad de proveer información médica y dar consentimiento para otras pruebas y examines en el studio. El o ella también tiene el poder de autorizar la provision de registros relacionados con pagos, tratamientos o servicios hechos a mí o por mí de cualquier hospital, doctor, o cualquier facilidad médica para el Estudio del Corazón de Framingham.

Yo, el suscrito Principal, al firmar mi nombre en esta forma, declaro que entiendo sus contenidos y que firmo bajo mi propia voluntad.

_____Principal Fecha:_____

(Lo siguiente se llena si el Principal está físicamente incapacitado para firmar):

Yo, aquí mismo firmo el nombre del Principal segó los deseos y dirección del Principal y en presencia del Principal y doe testigos más.

Nombre de quien firma: _____
Fecha: _____
Dirección de quien firma: _____
_____

Testigo Firma / Fecha _____ Testigo Firma / Fecha _____

FORMA DE CONSENTIMIENTO PARA INVESTIGACION
Consentimiento para crear una línea de células de su muestra de sangre
H-24583- EVALUACION DE OMNI GENERACION 1 DEL ESTUDIO DEL CORAZON DE FRAMINGHAM

Antecedentes

Una línea de células es una muestra congelada de células blancas de su sangre, que han sido especialmente procesadas para que el Estudio del Corazón de Framingham pueda reproducir más células blancas y así obtener más ADN, según se vaya necesitando para futuros estudios.

Propósito

Una línea de células será creada de una muestra de sangre que usted nos dé, para estudiar las causas de enfermedades del corazón y otras condiciones de salud, cómo prevenirlas y la posibilidad de estudiar la influencia de los factores genéticos para la salud.

Qué Sucede en este Estudio de Investigación

Usted será una de las aproximadamente 520 personas a quienes se les pedirá que participen en este estudio.
Todo o parte del estudio se realizará en El Centro Médico de la Universidad de Boston (Boston University Medical Center o BUMC por sus siglas en Inglés).
La muestra de su sangre será tomada en el Estudio del Corazón de Framingham, localizado en 73 Mt. Wayte Ave. en Framingham, MA, o en su lugar de residencia. Un técnico tomará una muestra de su sangre (16 cc o alrededor de 1 cucharada) para la preparación de ADN (material genético) y para la creación de una muestra de células blancas vivas (línea de células).

Riesgos y molestias

Los riesgos de dar la muestra de sangre incluyen un pequeño moretón, dolor o sangrado. También puede ocurrir una alergia al látex de los guantes usados por los técnicos. Si sabe que es alérgico al latex, por favor dígaselo al técnico para que use otro tipo de protección.

Pudiera haber riesgos y molestias hasta ahora desconocidos. Los empleados del estudio le actualizarán sobre cualquier información nueva que pudiera afectar su salud, su bienestar y su decisión de seguir participando en el estudio.

Posibles Beneficios

Usted no recibirá ningún beneficio directo de su participación en este estudio. Sin embargo, su participación puede ayudar a los investigadores a comprender mejor las causas y prevención de enfermedades cardiovasculares y otras condiciones de la salud, incluyendo la posibilidad de saber cómo los factores genéticos influencian el estado de salud.

FORMA DE CONSENTIMIENTO PARA INVESTIGACION
Consentimiento para crear una línea de células de su muestra de sangre
H-24583- EVALUACION DE OMNI GENERACION 1 DEL ESTUDIO DEL CORAZON DE FRAMINGHAM

Alternativas

Tiene la alternativa de no participar en el estudio.

Costos y pagos

No se le cobrará por este examen. Si en su examen se descubriera algún problema médico que requiera más diagnóstico o tratamiento, se le avisará a usted y a su doctor o a la clínica que usted nos indique.
En caso de que su doctor decida que usted debe someterse a más exámenes clínicos o más tratamientos, estos deberán ser pagados ya sea por usted o por una tercera persona (por ejemplo su seguro médico o Medicare). No se harán arreglos especiales por compensaciones o pagos de tratamientos por el solo hecho de haber participado en este estudio. Con este párrafo usted no renuncia a ninguno de sus derechos legales.

Los gastos que puede incurrir el día de su participación incluyen (pero no se limitan) a costos de transportación (gasolina, peaje, etc.). A usted no se le pagará por participar en el estudio. Sin embargo, si fuera necesario, le proveeremos con transportación a la clínica y de vuelta a su hogar sin costo para usted.

Confidencialidad

La información obtenida durante el estudio será tratada con estricta confidencialidad. Se le asignará un código a usted y a cualquier información personal que pudiera identificarle. Las líneas de células serán guardadas en un lugar central. Los documentos que vinculen los nombres con las muestras serán guardados bajo llave y serán accesibles solo a los administradores de bancos de datos del Estudio del Corazón de Framingham. Las muestras con códigos serán guardadas hasta que ya no tengan valor científico. El riesgo en proveer esta muestra es mínimo.

La información de datos y el ADN será distribuido a los investigadores del Estudio del Corazón de Framingham y a investigadores calificados interesados en la genética de enfermedades del corazón y las venas, enfermedades del pulmón y la sangre, accidentes cerebro-vasculares, pérdida de memoria, enfermedades de las articulaciones, pérdida de densidad ósea, sordera, cáncer, y otras enfermedades graves y condiciones de salud. A los investigadores se les dará el ADN sin ningún dato que pudiera identificar a los donadores. La información obtenida de su ADN puede ser utilizada para el desarrollo de procedimientos para diagnosticar o para nuevos tratamientos de enfermedades graves. Su ADN no será vendido a ninguna persona, institución o compañía por ganancia financiera ni por beneficio comercial. Sin embargo, ni usted ni sus familiares ganarán provecho financiero de los descubrimientos hechos usando la información o especímenes que usted nos dé.

FORMA DE CONSENTIMIENTO PARA INVESTIGACION
Consentimiento para crear una línea de células de su muestra de sangre
H-24583- EVALUACION DE OMNI GENERACION 1 DEL ESTUDIO DEL CORAZON DE FRAMINGHAM

Cuando los resultados sean publicados, su nombre y cualquier otra información que lo pudiera identificar, no serán revelados. Se le mantendrá informado a través de publicaciones periódicas del Estudio del Corazón de Framingham sobre descubrimientos de genética, enfermedades cardiovasculares y otras condiciones de salud que hayan sido generadas de los análisis del ADN.

Para ayudarnos a proteger su privacidad, los investigadores calificados han obtenido un Certificado de Confidencialidad del Departamento de Salud y Derechos Humanos (DHHS). Con este certificado, los investigadores no pueden ser forzados (por ejemplo por la corte) a divulgar ninguna información que le pueda identificar en ningún procedimiento federal, estatal, local civil, criminal, administrativo, legislativo o ningún otro procedimiento. Sin embargo, el suministro de información será necesario si fuera requerido para una auditoría o evaluación del programa por parte del Departamento de Salud y Derechos Humanos. Por favor comprenda que un Certificado de Confidencialidad no lo previene a usted ni a su familia de voluntariamente suministrar información de usted mismo, ni de su participación en este estudio. Por ejemplo, si un asegurador o empleador sabe que usted es participante de este Estudio, y obtiene el consentimiento de usted mismo para obtener más información, en ese caso el investigador no podrá usar su Certificado de Confidencialidad para no divulgar su información. Esto significa que usted y su familia también deben actuar para proteger su propia privacidad. Finalmente, por favor comprenda que el investigador no está prevenido de tomar las medidas necesarias (incluyendo reportar a autoridades) para prevenir daños severos a usted mismo y a otros.

Tiene la opción de retirar su muestra de sangre en el futuro, en cuyo caso la muestra será destruida. Si elije retirar sus muestras, deberá comunicarse con la encargada del laboratorio del Estudio del Corazón de Framingham al [redacted].

El Estudio del Corazón de Framingham es un proyecto de investigación médica patrocinado por los Institutos Nacionales de la Salud. Autorizado bajo 42USC285b-3. El sistema de registros aplicado al Estudio del Corazón de Framingham, está documentado en el Registro Federal: Septiembre 26, 2002 (Vol. 67, No. 1879) páginas 60776-60780.

Por favor cheque en la casilla apropiada abajo:

1. |___| SI |___| NO (Office Code 1)

Estoy de acuerdo en permitir la formación de una línea de células hecha con mi sangre para proveer un suministro renovable de ADN. (Una línea de células es una muestra de células blancas de su sangre, congeladas y procesadas, para poder reproducir más células blancas y así obtener más ADN para futuros estudios).

FORMA DE CONSENTIMIENTO PARA INVESTIGACION
Consentimiento para crear una línea de células de su muestra de sangre
H-24583- EVALUACION DE OMNI GENERACION 1 DEL ESTUDIO DEL CORAZON DE FRAMINGHAM

Derechos del Participante

Al darnos su consentimiento para participar en este estudio, usted no renuncia a ninguno de sus derechos legales. Dar consentimiento significa que usted ha escuchado o leído la información sobre este estudio y que está de acuerdo en participar. Se le dará una copia de esta forma.

Si en cualquier momento decidiera no seguir participando en este estudio, no sufrirá ningún tipo de penalidad ni perderá ningún beneficio al que tuviera derecho. Puede obtener más información sobre sus derechos como sujeto en el estudio llamando a la Oficina de Revisión Institucional del Comité de Protección de Derechos Humanos del Centro Médico de la Universidad de Boston al [redacted]

El investigador o algún miembro del equipo de investigadores tratará de responder a todas sus preguntas. Si en cualquier momento tiene preguntas o dudas, o si necesita reportar alguna herida ocurrida durante su participación en esta investigación, por favor comuníquese con el [redacted].

Compensación por daños relacionados con la Investigación

Si piensa que ha sido herido por participar en este estudio, por favor déjeselo saber al investigador inmediatamente. Si su participación es en el Centro Médico de Boston, puede obtener tratamiento por la herida en el Centro Médico de Boston. Si su participación NO es en el Centro Médico de Boston, pregúntele a su investigador dónde puede obtener tratamiento localmente para la herida. Usted y su seguro médico recibirán la cuenta por el tratamiento recibido. Algunos patrocinadores de investigación ofrecen un programa para cubrir parte de los costos del tratamiento que no son cubiertos por su seguro médico. Debería preguntarle al equipo de investigación si tal programa está disponible.

Sus Derechos a Rehusar o Descontinuar

Su participación en este estudio es voluntaria. Tiene el derecho de rehusar tomar parte en el estudio. Si decide participar y después cambia de opinión, puede salirse del estudio. Su participación es totalmente opcional. Su decisión no afectará el cuidado médico que pueda recibir en esta institución ni el pago de su cuidado médico. No afectará su inscripción a seguros médicos o beneficios que pudiera obtener.

Si decide tomar parte, tiene el derecho a descontinuar su participación en cualquier momento. Si hubiera nuevos descubrimientos durante la investigación que pudieran afectar su voluntad de participar, se lo harán saber lo más pronto posible.

Es posible que el investigador decida descontinuar su participación sin su permiso, porque pudiera decidir que continuar en el estudio será malo para usted o porque nuestro patrocinador interrumpa el estudio.

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Consentimiento para crear una línea de células de su muestra de sangre
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Firmar esta forma de consentimiento indica que usted ha leído esta forma (o se la han leído), que sus preguntas han sido contestadas a su satisfacción y que usted voluntariamente accede a participar en este estudio de investigación. Usted recibirá una copia de esta forma de consentimiento firmada.

_____	_____	_____
Firma del Participante	Nombre con Letra de Molde	Fecha
_____	_____	_____
Firma del Representante Legal Autorizado (LAR)	Nombre con Letra de Molde	Fecha
_____	_____	_____
Firma de la Persona que Obtiene el Consentimiento	Nombre con Letra de Molde	Fecha

RESEARCH SUBJECT'S AUTHORIZATION

FOR RELEASE OF HEALTH INFORMATION FOR RESEARCH PURPOSES

Name of Research Study: Framingham Heart Study

IRB Number: H-24583

Nombre: _____ Fecha de nacimiento: _____

Deseamos usar la información privada sobre su salud en este estudio de investigación. Esto incluirá la información que colectemos de usted como participante del estudio, así como información sobre su salud guardada en sus records médicos. La ley requiere que obtengamos su autorización (su permiso) antes de que podamos usar esta información o la compartamos con propósitos de investigación médica. Usted tiene la elección de firmar o no firmar esta autorización. Si no desea firmar la autorización, de cualquier forma podrá seguir participando en el estudio de investigación. Su acceso a cuidados médicos no se verá afectado por la decisión que tome respecto a este estudio de investigación.

Sección A:

Autorizo el uso de mi información médica o compartirla como se describe abajo:
A quién se le pedirá que nos dé información sobre su salud:

Quién podrá usar su información médica para investigación:

- *Investigadores y personal de investigación del Estudio del Corazón de Framingham.*

Es posible que nos pidan, o que por ley tengamos que compartir su información de salud con las siguientes organizaciones, si lo requirieran. Una vez les demos la información, esta ya no estará protegida por la Ley Federal de Privacidad. Sin embargo, su uso y futuras divulgaciones permanecerán limitadas según usted lo haya indicado en la Forma de Consentimiento Informado, como parte de la supervisión del Comité de Revisión Institucional del Centro Médico de la Universidad de Boston.

- *Comité de Revisión Institucional del Centro Médico de la Universidad de Boston.*
- *Otras agencias gubernamentales que supervisan estudios de investigación.*

Sección B: Descripción de la información:

(1) Si decide participar en este estudio, el equipo de investigadores necesita colectar información sobre usted y su salud. Esto incluirá información colectada durante el estudio, así como información de sus récords médicos

(2) Desde _____ hasta _____

Su información de salud será usada y compartida con otros por el siguiente propósito relacionado con el estudio:
Análisis de información de datos de los resultados

(3) Descripción específica de la información que colectaremos:

- *Primera hoja*
- *Resumen de despacho*
- *Reporte de Emergencias*
- *Notas de Admisión*
- *Notas sobre su progreso*
- *Reporte operativo*
- *Reporte patológico*
- *Rayos x del pecho*
- *Electrocardiogramas*
- *Tomografía computarizada CT Scan (cabeza/corazón)*
- *MRI/MRA Imagen de Resonancia Magnética (cabeza/cuello)*
- *Reportes de laboratorios – enzimas cardiacas*
- *Consultas médica s(Cardiología y Neurología)*
- *Cateterismo cardiaco*
- *Prueba de Tolerancia de Ejercicio*
- *Notas de la casa de cuidados para ancianos*
- *Notas del tiempo cercano a la muerte*
- *Otros: (Por ejemplo: Ecocardiograma, Arteriografía, ultrasonido de las venas, V/Q scan, PA gram. ,etc.)*

Sección C: General

(1) Expiración:
Esta aurotización expira al finalizar el estudio.

(2) Derecho a Revocar:

Usted tiene derecho a revocar (retractar) esta autorización en cualquier momento. Para hacer esto debe pedir al personal del Estudio del Corazón de Framingham los nombres de los Oficiales encargados de proteger su privacidad en las instituciones de donde obtuvimos su información médica. Deberá notificarles por escrito su deseo de revocar esta autorización. Si lo hace, tenemos permiso de seguir usando la información que obtuvimos antes de su revocación, pero únicamente de la manera en que lo estatuta la Forma de Consentimiento Informado.

1. Si revoca esta autorización, puede ser que aún necesitemos compartir su información de salud si usted tuviera algún mal efecto (evento adverso) durante el estudio.

(3) Su Acceso a la Información:

Usted tiene derecho a ver sus registros médicos, pero no podrá revisar sus records de investigación del Estudio del Corazón de Framingham hasta que el Estudio haya terminado.

……..

He leído esta información y recibiré una copia firmada de esta forma.

_____ _____

Firma del sujeto de la investigación o representante personal Fecha

Nombre del representante personal: _____

Relación con el sujeto de investigación: _____

Por favor describa la autoridad del representante personal para actuar en lugar del sujeto:

_____

RESEARCH CONSENT FORM

Offspring Examination 9

THE FRAMINGHAM HEART STUDY N01-HC-25195 1910G

Background

You are participating in the continuation of the Framingham Heart Study (FHS), Offspring Cohort. This ninth examination of the FHS Offspring will be similar to previous visits in many ways. There are also some new study activities. Exam components, both old and new, are described below.

Purpose

The purpose of this research is 1) to better understand the development of heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, cancer, and other major diseases and health conditions; and 2) to examine DNA and its relationship to the risks of developing these diseases and other health conditions.

THIS EXAMINATION IS FOR RESEARCH AND DOES NOT TAKE THE PLACE OF A ROUTINE MEDICAL CHECK UP BY YOUR PHYSICIAN

Taking part in this study is voluntary. You have the right to refuse to take part in this study. If you choose to take part, you have the right to stop at any time.

What Happens In This Research Study

You will be one of approximately 5124 subjects to be asked to participate in this study.

All or part of the research in this study will take place at the following location(s): Boston University Medical Center.

Your research examination will take place at the FHS at 73 Mt. Wayte Avenue in Framingham, MA, or may take place in your home or other residence.

New Study Activities:

1) With your permission, white cells (from the blood collected as a regular part of the FHS exam) will be processed so that they function like cells from other organs such as liver cells, fat cells heart cells or nerve cells. The resulting cells are called Induced Pluripotent Stem cells. These cells may be studied in laboratories to learn more about causes of health and disease in such organs. FHS investigators will not alter white cells to behave as reproductive cells.

2) We will ask if we may obtain a sample of cells from the inside of your cheek by gently scraping the inside surface with a single-use plastic utensil. The cells will be used to examine how changes in DNA called DNA methylation are related to lung function and lung diseases and other diseases,

3) You will be asked to wear a physical activity monitor on a belt for a week and to return it to FHS. It measures how active you are throughout the day.

4) You will be asked after your visit to use a kit to collect urine samples for 24 hours and send it by mail to a laboratory. The kit will be mailed to you for a day convenient to you shortly after this exam visit.

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Ongoing Exam components for which you have previously given informed consent: In addition to the new procedures described above, the following procedures will be done at this visit:

1) Medical History Interview.

2) Physical Examination including ECG

3) Collection of blood (up to 117.5 cc or four ounces) and urine specimens to test for many risk factors for the diseases and health conditions under investigation.

4) Genetic Studies: You will be asked if a sample of the blood you donate may be used for additional genetic studies.

5) Vascular Function Testing: Arterial Tonometry is a measure of arterial stiffness. Along with a very limited view of the aorta (the large artery carrying blood flow from the base of the heart), a waveform is obtained by gently placing a flat sensor over arteries on the arm (brachial and radial), the groin (femoral) and the neck (carotid).

6) Pulmonary function testing is performed by breathing into a tube connected to a machine that measures exhaled air volume and flow. Some individuals may be asked to repeat the testing after using an inhaler to improve airflow.

7) Questionnaires about memory, mood and physical function; diet and exercise

8) Blood pressures in your arms and ankles

(In the event that you may have a stroke, you would be examined during your hospitalization (if applicable) and at 3, 6, 12 and 24 months. The examination would include a neurological-evaluation and an assessment of your ability to perform daily activities.)

9) Medical Records: You will be asked to sign a form to allow FHS to obtain copies of hospital and Medicare (CMS) and medical records. The release form is valid to obtain these records unless canceled by you. You will be asked for your social security number for the purpose of locating you in the future. You may choose to decline this request. You will also be asked if investigators and their research collaborators at other institutions, in this case Duke University, may link your Social Security Number to CMS data to obtain Medicare information. Social Security Numbers to will not be released to outside institutions.

10) Results of some FHS research measurements will be sent to you and/or to your physician within six weeks of your FHS visit. However, some other measurements could be made months or years later as part of special research projects. You may receive results of some measurements long after your FHS visit.

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11) Follow Up: You may be contacted later by mail or by phone to obtain additional health information or to be invited to participate in further FHS health-related studies. You may be invited to return for another examination in the future.

Risks and Discomforts

Risk or injury, as a result of participation, is not expected. In the unlikely event that during the examination you require medical care, first aid will be available.

The Blood Draw: Minimal bruising, pain, bleeding, or in rare circumstances, an infection may occur.

The Cheek Swab: There may be minor irritation of brief duration and/or some may experience a minor sensation of gagging.

The Lung Function test involves a low level of risk. You may feel lightheaded or you may faint and risk injury from falling. Participants asked to inhale the medication called albuterol, used during lung function testing, may notice an increase in heart rate (pulse) or symptoms of jitteriness or shakiness (tremors). Pregnant women, as determined by self-report or by a positive pregnancy test, will be excluded from the second part of the pulmonary function test, which includes the albuterol challenge.

Other discomforts include headaches, feeling hungry due to fasting, fatigue and chill during the visit. The exam is time consuming and repetitive. The 24 hour urine collection is inconvenient.

Safeguards are in place to protect the security of your study information. FHS ID numbers are used on most data files instead of names. Firewalls and password protection are in place on the computer systems. Staff is trained in safe computer practices. However there is still a minimal risk of a breach in confidentiality.

There is potential risk in genetic testing for uncovering and conveying unwanted information regarding parentage or specific risk of disease. Also, sometimes, knowledge of DNA test results can provoke anxiety and influence decisions regarding marriage and family planning:

Both Massachusetts state laws and a new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally make it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. These laws generally will protect you in the following ways:

1. *Health insurance companies and group health plans may not request your genetic information that we get from this research.*

2. *Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.*

3. *Employers with 6 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.*

All health insurance companies and group health plans must follow the GINA law by May 21, 2010. All employers with 15 or more employees must follow the GINA law as of November 21, 2009. Massachusetts law currently applies to all employers of 6 or more employees.

Be aware that neither Massachusetts law nor the new Federal law protects you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Thus, life insurance, disability insurance and long-term care insurance companies may legally ask whether you have had genetic testing and deny coverage for refusal to answer this question.

There may be unknown risks/discomforts involved. Study staff will update you in a timely way on any new information that may affect your health, welfare, or decision to stay in this study

Potential Benefits

You will receive no direct benefit from your participation in this study. However, your participation may help the investigators better understand the causes and prevention of cardiovascular disease and other medical conditions, including the potential of genetic factors.

Alternatives

Your alternative is to not participate in the study.

Subject Costs and Payments

You will not be charged or paid for any part of the examination. If the examination finds medical problems that require tests or treatments, information will be provided to you and to the physician or clinic that you have named to receive your test results. If your physician decides that follow up tests or treatments are necessary, then you (or a third party such as health insurance or Medicare) will be responsible for the cost. No special arrangement will be made by the Framingham Heart Study for compensation or payment solely because of your participation in this study. This does not waive any of your legal rights. Costs that you may incur on the day of your participation include, but are not limited to, loss of work, and transportation (gas, tolls, etc.). You will not receive payment for your participation.

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Patenting Discoveries

Research from this study may, one day, result in new tests to diagnose or predict diseases. It may also lead to the development of new medicines to prevent or cure diseases. As is true of all federally-funded research, researchers and their employers are permitted by Federal law to patent discoveries from which they may gain financially. It was the judgment of the U.S. Congress that permitting such patents would greatly increase the likelihood that a public health benefit would be realized from federally funded research.

CONFIDENTIALITY

Information obtained about you will be treated as confidential. A code number will be assigned to your data and specimens. The codes will only be provided to qualified investigators but your name and other personally identifying information will not be provided. Your samples will be kept until they are not of scientific value. You will not be routinely informed of results of research performed upon your genetic samples, although with your permission you may be informed of some findings about genetics, cardiovascular disease or other health conditions generated from DNA analyses, directly to you or through publication in newsletters.

When study results are published, your name and other identifying information will not be revealed. Information from this study and from your medical record may be reviewed and photocopied by state and federal regulatory agencies, such as the Office of Human Research Protection, as applicable, and the Institutional Review Board of Boston University Medical Center.

To help us further protect your privacy, the investigators have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer or employer learns of your participation, and obtains your consent to receive research information, then FHS is not allowed to use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy. Finally, you should understand that the Certificate of Confidentiality does not prevent the investigators from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

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Please check the appropriate box above each of the following statements:

1) |___| YES |___| NO (Office Code 0)

I agree to participate in the FHS clinic examination, the collections of blood, cheek cells and urine, and studies of the factors contributing to heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, cancer, and other major diseases and health conditions.

2|___| YES |___|NO (Office Code 3)

I agree to allow my data, cheek cells, blood and urine samples to be used in future genetic studies of factors contributing to heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, cancer, and other diseases and health conditions.

3) |___| YES |___| NO (Office Code 12)

I agree to allow my data, cheek cells, blood and urine and DNA samples to be used in future genetic studies of reproductive conditions, and mental health conditions such as alcohol use and depressive symptoms.

4 |___| YES |___|NO (Office Code 13)

I agree to provide a blood sample from which Induced Pluripotent Stem Cells can be made and from which a range of cell products such as RNA, proteins and metabolites can be obtained. This means that white cells from my blood may be processed to become stem cells and then altered so that they function like cells from other organs such as liver cells, fat cells, heart cells or nerve cells.

5 |___| YES |___| NO (Office Code 4)

I agree to allow researchers from commercial companies to have access to my blood and urine samples, DNA, other genetic material, and data in the future which may be used to develop new lab tests or treatments that could benefit many people. (You or your heirs will not benefit financially from this, nor will your DNA be sold to anyone.)

6) |___| YES |___| NO (Office Code 30)

I agree to allow the FHS to release the findings of non-genetic tests and examinations to my physician, clinic, or hospital.

7) |___| YES |___| NO (Office Code 31)

If a genetic condition is identified that may have important health and treatment implications for me, I agree to allow the FHS to notify me, and then with my permission to notify my physician.

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Subject's Rights

By consenting to participate in this study you do not waive any of your legal rights. Giving consent means that you have heard or read the information about this study and that you agree to participate. You will be given a copy of this form to keep.

If at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled.

You may obtain further information about your rights as a research subject by calling the Office of the Institutional Review Board of Boston University Medical Center at [redacted]

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury while participating in this research, contact [redacted].

Compensation for Research Related Injury

If you think that you have been injured by being in this study, please let the investigator know right away. If your part in this study takes place at Boston Medical Center, you can get treatment for the injury at Boston Medical Center. If your part of the study is not at Boston Medical Center, ask the investigator where treatment for injury would be available locally. Boston University Medical Center and the sponsor do not offer a program to provide compensation for the cost of care for research related injury or other expenses such as lost wages, disability, pain, or discomfort. You will be sent a bill for the medical care you receive for research injury if your medical insurance does not pay for your medical care. You are not giving up any of your legal rights by signing this form.

Right to Refuse or Withdraw

Taking part in this study is voluntary. You have the right to refuse to take part in this study. If you decide to be in the study and then change your mind, you can withdraw from the research. Your participation is completely up to you. Your decision will not affect you being able to get health care at this institution or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get.

If you choose to take part, you have the right to stop at any time. If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them as soon as possible.

The investigator may decide to discontinue your participation without your permission because he/she may decide that staying in the study will be bad for you, or the sponsor may stop the study.

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Protection of Subject Health Information

You have certain rights related to your health information. These include the right to know who will get your health information and why they will get it. If you choose to be in this research study, we will get information about you as explained below.

HEALTH INFORMATION ABOUT YOU THAT MIGHT BE USED OR GIVEN OUT DURING THIS RESEARCH:

Information from your hospital or office health records at BUMC/BMC or elsewhere. This information is reasonably related to the conduct and oversight of the research study. If health information is needed from your doctors or hospitals outside of BUMC/BMC, you will be asked to give permission for these records to be sent to the researcher.

New health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.

WHY HEALTH INFORMATION ABOUT YOU MIGHT BE USED OR GIVEN OUT TO OTHERS

The reasons we might use or share your health information are:

- To do the research described here
- To make sure we do the research according to certain standard set by ethics, law, and quality groups

PEOPLE AND GROUPS THAT MAY USE OR GIVE OUT YOUR HEALTH INFORMATION

1. PEOPLE OR GROUPS WITHIN BUMC/BMC

- Researchers involved in this research study
- The BUMC Institutional Review Board that oversees this research

2. PEOPLE OR GROUPS OUTSIDE BUMC/BMC

- People or groups that we hire to do certain work for us, such as data storage companies, or laboratories.
- Federal and state agencies if they are required by law or involved in research oversight. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, the Massachusetts Department of Public Health.
- Organizations that make sure hospital standards are met
- The sponsor(s) of the research study, and people or groups it hires to help them do the research
- Other researchers that are part of this research study
- A group that oversees the research information and safety of this study

Other:

Some people or groups who get your health information might not have to follow the same privacy rules that we follow. We share your health information only when we must. We ask anyone who gets it from us to protect your privacy. However, once the information leaves BUMC, we cannot promise that it will be kept private.

In most cases any health data that is being given out to others is identified by a unique study number and not with your name. So, although in some cases it is possible to link your name to the study data, this is not usually done.

TIME PERIOD FOR USING OR GIVING OUT YOUR HEALTH INFORMATION

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

YOUR PRIVACY RIGHTS

You have the right not to sign this form that allows us to use and give out your health information for research. If you don't sign this form, you can't be in the research. This is because we need to use the health information to do the research.

You have the right to withdraw your permission to use or share your health information in this research study. If you want to withdraw your permission, you must write a letter to the researchers in charge of this research study.

If you withdraw your permission, you will not be able to take back information that has already been used or shared with others. This includes information used or shared to do the research study or to be sure the research is safe and of high quality.

If you withdraw your permission, you cannot continue to be in the study.

You have the right to see and get a copy of your health information that is used or shared for research. However, you may only get this after the research is finished. To ask for this information, please contact the person in charge of this research study.

IF RESEARCH RESULTS ARE PUBLISHED OR USED TO TEACH OTHERS

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information will not be used for these purposes without your specific permission.

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Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

Participant's Signature	**Printed Name**	**Date**
Legally Authorized Representative (LAR)'s Signature	**Printed Name**	**Date**
Person Obtaining Consent Signature	**Printed Name**	**Date**

RESEARCH CONSENT FORM

Omni 1 Exam 4

THE FRAMINGHAM HEART STUDY N01-HC-25195 1910G

Background

You are participating in the continuation of the Framingham Heart Study (FHS), Omni 1 Cohort. This ninth examination of the FHS Omni 1 will be similar to previous visits in many ways. There are also some new study activities. Exam components, both old and new, are described below.

Purpose

The purpose of this research is 1) to better understand the development of heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, cancer, and other major diseases and health conditions; and 2) to examine DNA and its relationship to the risks of developing these diseases and other health conditions.

THIS EXAMINATION IS FOR RESEARCH AND DOES NOT TAKE THE PLACE OF A ROUTINE MEDICAL CHECK UP BY YOUR PHYSICIAN

Taking part in this study is voluntary. You have the right to refuse to take part in this study. If you choose to take part, you have the right to stop at any time.

What Happens In This Research Study

You will be one of approximately 520 subjects to be asked to participate in this study.

All or part of the research in this study will take place at the following location(s): Boston University Medical Center.

Your research examination will take place at the FHS at 73 Mt. Wayte Avenue in Framingham, MA, or may take place in your home or other residence.

New Study Activities:

1) With your permission, white cells (from the blood collected as a regular part of the FHS exam) will be processed so that they function like cells from other organs such as liver cells, fat cells heart cells or nerve cells. The resulting cells are called Induced Pluripotent Stem cells. These cells may be studied in laboratories to learn more about causes of health and disease in such organs. FHS investigators will not alter white cells to behave as reproductive cells.

2) We will ask if we may obtain a sample of cells from the inside of your cheek by gently scraping the inside surface with a single-use plastic utensil. The cells will be used to examine how changes in DNA called DNA methylation are related to lung function and lung diseases and other diseases,

3) You will be asked to wear a physical activity monitor on a belt for a week and to return it to FHS. It measures how active you are throughout the day.

4) You will be asked after your visit to use a kit to collect urine samples for 24 hours and send it by mail to a laboratory. The kit will be mailed to you for a day convenient to you shortly after this exam visit.

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Ongoing Exam components for which you have previously given informed consent: In addition to the new procedures described above, the following procedures will be done at this visit:

1) Medical History Interview.

2) Physical Examination including ECG

3) Collection of blood (up to 117.5 cc or four ounces) and urine specimens to test for many risk factors for the diseases and health conditions under investigation.

4) Genetic Studies: You will be asked if a sample of the blood you donate may be used for additional genetic studies.

5) Vascular Function Testing: Arterial Tonometry is a measure of arterial stiffness. Along with a very limited view of the aorta (the large artery carrying blood flow from the base of the heart), a waveform is obtained by gently placing a flat sensor over arteries on the arm (brachial and radial), the groin (femoral) and the neck (carotid).

6) Pulmonary function testing is performed by breathing into a tube connected to a machine that measures exhaled air volume and flow. Some individuals may be asked to repeat the testing after using an inhaler to improve airflow.

7) Questionnaires about memory, mood and physical function; diet and exercise

8) Blood pressures in your arms and ankles

(In the event that you may have a stroke, you would be examined during your hospitalization (if applicable) and at 3, 6, 12 and 24 months. The examination would include a neurological-evaluation and an assessment of your ability to perform daily activities.)

9) Medical Records: You will be asked to sign a form to allow FHS to obtain copies of hospital and Medicare (CMS) and medical records. The release form is valid to obtain these records unless canceled by you. You will be asked for your social security number for the purpose of locating you in the future. You may choose to decline this request. You will also be asked if investigators and their research collaborators at other institutions, in this case Duke University, may link your Social Security Number to CMS data to obtain Medicare information. Social Security Numbers to will not be released to outside institutions.

10) Results of some FHS research measurements will be sent to you and/or to your physician within six weeks of your FHS visit. However, some other measurements could be made months or years later as part of special research projects. You may receive results of some measurements long after your FHS visit.

11) Follow Up: You may be contacted later by mail or by phone to obtain additional health information

or to be invited to participate in further FHS health-related studies. You may be invited to return for another examination in the future.

Risks and Discomforts

Risk or injury, as a result of participation, is not expected. In the unlikely event that during the examination you require medical care, first aid will be available.

The Blood Draw: Minimal bruising, pain, bleeding, or in rare circumstances, an infection may occur.

The Cheek Swab: There may be minor irritation of brief duration and/or some may experience a minor sensation of gagging.

The Lung Function test involves a low level of risk. You may feel lightheaded or you may faint and risk injury from falling. Participants asked to inhale the medication called albuterol, used during lung function testing, may notice an increase in heart rate (pulse) or symptoms of jitteriness or shakiness (tremors). Pregnant women, as determined by self-report or by a positive pregnancy test, will be excluded from the second part of the pulmonary function test, which includes the albuterol challenge.

Other discomforts include headaches, feeling hungry due to fasting, fatigue and chill during the visit. The exam is time consuming and repetitive. The 24 hour urine collection is inconvenient.

Safeguards are in place to protect the security of your study information. FHS ID numbers are used on most data files instead of names. Firewalls and password protection are in place on the computer systems. Staff is trained in safe computer practices. However there is still a minimal risk of a breach in confidentiality.

There is potential risk in genetic testing for uncovering and conveying unwanted information regarding parentage or specific risk of disease. Also, sometimes, knowledge of DNA test results can provoke anxiety and influence decisions regarding marriage and family planning:

Both Massachusetts state laws and a new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally make it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. These laws generally will protect you in the following ways:

1. *Health insurance companies and group health plans may not request your genetic information that we get from this research.*

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2. *Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.*

3. *Employers with 6 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.*

All health insurance companies and group health plans must follow the GINA law by May 21, 2010. All employers with 15 or more employees must follow the GINA law as of November 21, 2009. Massachusetts law currently applies to all employers of 6 or more employees.

Be aware that neither Massachusetts law nor the new Federal law protects you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Thus, life insurance, disability insurance and long-term care insurance companies may legally ask whether you have had genetic testing and deny coverage for refusal to answer this question.

There may be unknown risks/discomforts involved. Study staff will update you in a timely way on any new information that may affect your health, welfare, or decision to stay in this study

Potential Benefits

You will receive no direct benefit from your participation in this study. However, your participation may help the investigators better understand the causes and prevention of cardiovascular disease and other medical conditions, including the potential of genetic factors.

Alternatives

Your alternative is to not participate in the study.

Subject Costs and Payments

You will not be charged or paid for any part of the examination. If the examination finds medical problems that require tests or treatments, information will be provided to you and to the physician or clinic that you have named to receive your test results. If your physician decides that follow up tests or treatments are necessary, then you (or a third party such as health insurance or Medicare) will be responsible for the cost. No special arrangement will be made by the Framingham Heart Study for compensation or payment solely because of your participation in this study. This does not waive any of your legal rights. Costs that you may incur on the day of your participation include, but are not limited to, loss of work, and transportation (gas, tolls, etc.). You will not receive payment for your participation.

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Patenting Discoveries

Research from this study may, one day, result in new tests to diagnose or predict diseases. It may also lead to the development of new medicines to prevent or cure diseases. As is true of all federally-funded research, researchers and their employers are permitted by Federal law to patent discoveries from which they may gain financially. It was the judgment of the U.S. Congress that permitting such patents would greatly increase the likelihood that a public health benefit would be realized from federally funded research.

CONFIDENTIALITY

Information obtained about you will be treated as confidential. A code number will be assigned to your data and specimens. The codes will only be provided to qualified investigators but your name and other personally identifying information will not be provided. Your samples will be kept until they are not of scientific value. You will not be routinely informed of results of research performed upon your genetic samples, although with your permission you may be informed of some findings about genetics, cardiovascular disease or other health conditions generated from DNA analyses, directly to you or through publication in newsletters.

When study results are published, your name and other identifying information will not be revealed. Information from this study and from your medical record may be reviewed and photocopied by state and federal regulatory agencies, such as the Office of Human Research Protection, as applicable, and the Institutional Review Board of Boston University Medical Center.

To help us further protect your privacy, the investigators have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer or employer learns of your participation, and obtains your consent to receive research information, then FHS is not allowed to use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy. Finally, you should understand that the Certificate of Confidentiality does not prevent the investigators from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

Please check the appropriate box above each of the following statements:

1) |___| YES |___| NO (Office Code 0)

BUMC/BMC Institutional Review Board
IRB NUMBER: H-32132
IRB APPROVAL DATE: 01/16/2013
IRB EXPIRATION DATE: 01/15/2014

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I agree to participate in the FHS clinic examination, the collections of blood, cheek cells and urine, and studies of the factors contributing to heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, cancer, and other major diseases and health conditions.

2|___| YES |___|NO (Office Code 3)

I agree to allow my data, cheek cells, blood and urine samples to be used in future genetic studies of factors contributing to heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, cancer, and other diseases and health conditions.

3) |___| YES |___| NO (Office Code 12)

I agree to allow my data, cheek cells, blood and urine and DNA samples to be used in future genetic studies of reproductive conditions, and mental health conditions such as alcohol use and depressive symptoms.

4 |___| YES |___|NO (Office Code 13)

I agree to provide a blood sample from which Induced Pluripotent Stem Cells can be made and from which a range of cell products such as RNA, proteins and metabolites can be obtained. This means that white cells from my blood may be processed to become stem cells and then altered so that they function like cells from other organs such as liver cells, fat cells, heart cells or nerve cells.

5 |___| YES |___| NO (Office Code 4)

I agree to allow researchers from commercial companies to have access to my blood and urine samples, DNA, other genetic material, and data in the future which may be used to develop new lab tests or treatments that could benefit many people. (You or your heirs will not benefit financially from this, nor will your DNA be sold to anyone.)

6) |___| YES |___| NO (Office Code 30)

I agree to allow the FHS to release the findings of non-genetic tests and examinations to my physician, clinic, or hospital.

7) |___| YES |___| NO (Office Code 31)

If a genetic condition is identified that may have important health and treatment implications for me, I agree to allow the FHS to notify me, and then with my permission to notify my physician.

Subject's Rights

By consenting to participate in this study you do not waive any of your legal rights. Giving consent

means that you have heard or read the information about this study and that you agree to participate. You will be given a copy of this form to keep.

If at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled.

You may obtain further information about your rights as a research subject by calling the Office of the Institutional Review Board of Boston University Medical Center at [redacted].

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury while participating in this research, contact [redacted]

Compensation for Research Related Injury

If you think that you have been injured by being in this study, please let the investigator know right away. If your part in this study takes place at Boston Medical Center, you can get treatment for the injury at Boston Medical Center. If your part of the study is not at Boston Medical Center, ask the investigator where treatment for injury would be available locally. Boston University Medical Center and the sponsor do not offer a program to provide compensation for the cost of care for research related injury or other expenses such as lost wages, disability, pain, or discomfort. You will be sent a bill for the medical care you receive for research injury if your medical insurance does not pay for your medical care. You are not giving up any of your legal rights by signing this form.

Right to Refuse or Withdraw

Taking part in this study is voluntary. You have the right to refuse to take part in this study. If you decide to be in the study and then change your mind, you can withdraw from the research. Your participation is completely up to you. Your decision will not affect you being able to get health care at this institution or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get.

If you choose to take part, you have the right to stop at any time. If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them as soon as possible.

The investigator may decide to discontinue your participation without your permission because he/she may decide that staying in the study will be bad for you, or the sponsor may stop the study.

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Protection of Subject Health Information

You have certain rights related to your health information. These include the right to know who will get your health information and why they will get it. If you choose to be in this research study, we will get information about you as explained below.

HEALTH INFORMATION ABOUT YOU THAT MIGHT BE USED OR GIVEN OUT DURING THIS RESEARCH:

Information from your hospital or office health records at BUMC/BMC or elsewhere. This information is reasonably related to the conduct and oversight of the research study. If health information is needed from your doctors or hospitals outside of BUMC/BMC, you will be asked to give permission for these records to be sent to the researcher.

New health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.

WHY HEALTH INFORMATION ABOUT YOU MIGHT BE USED OR GIVEN OUT TO OTHERS

The reasons we might use or share your health information are:

- To do the research described here

- To make sure we do the research according to certain standard set by ethics, law, and quality groups

PEOPLE AND GROUPS THAT MAY USE OR GIVE OUT YOUR HEALTH INFORMATION

1. PEOPLE OR GROUPS WITHIN BUMC/BMC

- Researchers involved in this research study

- The BUMC Institutional Review Board that oversees this research

2. PEOPLE OR GROUPS OUTSIDE BUMC/BMC

- People or groups that we hire to do certain work for us, such as data storage companies, or laboratories.

- Federal and state agencies if they are required by law or involved in research oversight. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, the Massachusetts Department of Public Health.

- Organizations that make sure hospital standards are met

- The sponsor(s) of the research study, and people or groups it hires to help them do the research

- Other researchers that are part of this research study

- A group that oversees the research information and safety of this study

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Other:

Some people or groups who get your health information might not have to follow the same privacy rules that we follow. We share your health information only when we must. We ask anyone who gets it from us to protect your privacy. However, once the information leaves BUMC, we cannot promise that it will be kept private.

In most cases any health data that is being given out to others is identified by a unique study number and not with your name. So, although in some cases it is possible to link your name to the study data, this is not usually done.

TIME PERIOD FOR USING OR GIVING OUT YOUR HEALTH INFORMATION

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

YOUR PRIVACY RIGHTS

You have the right not to sign this form that allows us to use and give out your health information for research. If you don't sign this form, you can't be in the research. This is because we need to use the health information to do the research.

You have the right to withdraw your permission to use or share your health information in this research study. If you want to withdraw your permission, you must write a letter to the researchers in charge of this research study.

If you withdraw your permission, you will not be able to take back information that has already been used or shared with others. This includes information used or shared to do the research study or to be sure the research is safe and of high quality.

If you withdraw your permission, you cannot continue to be in the study.

You have the right to see and get a copy of your health information that is used or shared for research. However, you may only get this after the research is finished. To ask for this information, please contact the person in charge of this research study.

IF RESEARCH RESULTS ARE PUBLISHED OR USED TO TEACH OTHERS

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information will not be used for these purposes without your specific permission.

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Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

_____	_____	_____
Participant's Signature	**Printed Name**	**Date**
_____	_____	_____
Legally Authorized Representative (LAR)'s Signature	**Printed Name**	**Date**
_____	_____	_____
Person Obtaining Consent Signature	**Printed Name**	**Date**

FORMA DE CONSENTIMIENTO PARA INVESTIGACION

Omni 1 Examen 4

ESTUDIO DEL CORAZON DE FRAMINGHAM N01-HC-25195 1910G

Antecedentes

Usted está participando en la continuación del estudio para Omni 1 del Estudio del Corazón de Framingham. Este es el cuarto examen y en muchos sentidos será similar a los exámenes previos, pero hay algunas pruebas que son nuevas. Los componentes de este Examen, tanto los anteriores como los nuevos, se describen abajo.

Propósito

El propósito de este estudio es 1) entender mejor el desarrollo de enfermedades del corazón y las arterias, enfermedades del pulmón y la sangre, accidentes cerebro-vasculares, pérdida de memoria, cáncer y otras enfermedades y condiciones de la salud; y 2) examinar el ADN y su relación con los riesgos a desarrollar estas enfermedades y otras condiciones de la salud.

ESTE EXAMEN ES SOLO PARA INVESTIGACION MEDICA Y NO TOMA EL LUGAR DE UN CHEQUEO GENERAL HECHO POR SU DOCTOR.

Su participación es voluntaria. Tiene el derecho de rehusar o no tomar parte en este estudio. Si decide participar, tiene el derecho de dejar su participación en el futuro en cualquier momento.

Qué sucede en este Estudio de Investigación

Usted será una de aproximadamente 520 personas a quienes se les pedirá participar en este estudio. Toda o parte de la investigación tendrá lugar en la siguiente localidad (es): Centro Médico de la Universidad de Boston. Su examen se llevará a cabo en las facilidades del Estudio del Corazón de Framingham, localizado en 73 Mount Wayte Avenue, en Framingham, Massachusetts o en otras facilidades o residencias.

Nuevas pruebas:

1) Con su permiso, se van a procesar células blancas (tomadas de las muestras de sangre durante su examen aquí) para que imiten el funcionamiento de las células de otros órganos de su cuerpo; como células del hígado, células grasas del corazón y células de los nervios. A estas células que han sido procesadas se les conoce como Células Pluripotenciales Inducidas. Estas células pueden ser estudiadas en laboratorios para aprender más sobre las causas de enfermedades de esos órganos así como las causas de su buena salud. Los investigadores del Estudio del Corazón de Framingham jamás alterarán células para que imiten células reproductivas.
2) Le preguntaremos si podemos obtener células de la parte interna de su mejilla, raspando suavemente con un cepillo de plástico. Las células se usarán para examinar cómo algunos cambios en el ADN (llamados metilación del ADN) se pudieran relacionar con la función pulmonar y otras enfermedades.
3) Se le preguntará si desea usar un pequeño monitor para medir la actividad física. Se usa con un cinturón suave durante una semana y después se le pide que lo envíe por correo al Estudio del Corazón de Framingham. Mide su actividad diaria.

4) Se le preguntará si desea participar en un estudio de colección de orina durante 24 horas, usando un equipo especial de plástico que se le enviará por correo cuando a usted le convenga después de participar aquí.

Otros componentes del estudio por los que ya nos ha dado consentimiento en el pasado. Además de las nuevas pruebas descritas arriba, se harán las siguientes pruebas que ya ha hecho:

1) Historial Médico.
2) Examen físico, incluyendo electrocardiograma o ECG
3) Colección de sangre (hasta 117.5 cc o cuatro onzas) y muestra de orina para hacer pruebas sobre factores de riesgo de las enfermedades y condiciones de salud que están siendo investigadas.
4) Estudios Genéticos: Se le preguntará si se puede usar una parte de su muestra de sangre para más estudios genéticos.
5) Prueba de la Función Vascular: a) Tonometría Arterial, mide la rigidez de las arterias. Junto con una vista limitada de la aorta (la arteria mayor que lleva el flujo de sangre desde la base del corazón), se obtiene una onda colocando un sensor plano sobre las arterias en el brazo (braquial y radial), la ingle (femoral) y el cuello (carótida).
6) Prueba de la función pulmonar; se hace respirando de un tubo conectado a una máquina que mide el volumen y flujo del aire exhalado. A algunos participantes se les pedirá que repitan la prueba usando un inhalador para mejorar el flujo del aire.
7) Cuestionarios sobre su memoria, estados de ánimo y función física, así como dieta y ejercicio.
8) Presión arterial en brazos y tobillos.

   En caso de que llegue a sufrir un derrame cerebral, se le examinará durante su hospitalización (si es pertinente) y a los 3, 6, 12 y 24 meses. El examen incluirá una evaluación neurológica y una evaluación de su habilidad para realizar las actividades.
9) Registros médicos: Se le pedirá que firme una forma para dar permiso al Estudio del Corazón de Framingham a que obtenga copias de registros de hospital, Medicare (CMS) y otros registros médicos. Este permiso es válido para obtener registros médicos a menos que usted lo cancele. Se le pedirá su número de seguro social con el propósito de localizarlo en el futuro. Puede rehusar esta solicitud nuestra. También se le preguntará si investigadores, así como sus colaboradores de investigación en otros institutos, en este caso la Universidad de Duke, pueden relacionar su número de seguro social a la base de datos de CMS para obtener información de Medicare. Los números de seguro social no serán dados a ninguna otra institución.
10) Algunos de los resultados serán enviados a usted y/o a su doctor dentro de seis semanas después de su examen. Sin embargo, hay otras pruebas que pueden requerir meses, incluso años antes de que se pueda enviar algún resultado, porque son parte de proyectos especiales de investigación.

11) Seguimiento: Posiblemente se le contacte en el futuro, ya sea por correo o por teléfono, para obtener más información de su salud o para que se le invite a participar en otros estudios de salud del Estudio del Corazón de Framingham, y para volver a venir a otro examen en el futuro.

Riesgos y Molestias

No esperamos que sucedan riesgos o daños inesperados como resultado de su participación, pero en el extremo caso de que durante su examen usted requiriera atención médica, contamos con primeros auxilios.

Muestra de Sangre: Son posibles un pequeño moretón, dolor, sangrado o en raras ocasiones, infección.

Recolección de células del interior de la mejilla: algunas personas podrían experimentar una sensación de vomito y/o una irritación menor por un corto periodo de tiempo.

La Prueba de la Función Pulmonar involucra un nivel muy bajo de riesgo. Usted podría sentirse mareado o desmayarse y arriesgarse a sufrir una lesión si se cayera. Los participantes a quienes se les haya pedido que inhalen albuterol durante la prueba pulmonar, podrían experimentar un incremento en los latidos del corazón (pulso) o síntomas de agitación o temblores. Las mujeres que estén embarazadas, ya sea determinado por ellas mismas o por una prueba de embarazo, serán excluidas de la segunda parte de la función pulmonar, la cual incluye inhalar albuterol.

Otras molestias incluyen dolores de cabeza, sentirse hambriento por estar ayunando, cansancio y tener frío durante la visita. El examen toma tiempo y es repetitivo. La colección de orina de 24 horas puede ser inconveniente.

Se toman todas las medidas para proteger la seguridad de su información en el estudio. En lugar de nombres, se usan números de identificación en la gran mayoría de las bases de datos. Se utilizan protecciones con bloqueos y claves en los sistemas computacionales. Sin embargo, aun así hay un mínimo riesgo de que se quebrante la confidencialidad.

En las pruebas genéticas existe el riesgo potencial de descubrir y transmitir información indeseada respecto a tener ciertas enfermedades o el riesgo a desarrollarlas. En algunas ocasiones, el saber los resultados de pruebas de ADN puede provocar ansiedad y puede influenciar decisiones respecto a matrimonio y planeación familiar.

Tanto leyes estatales de Massachusetts como una nueva ley Federal llamada El Acta para la No-Discriminación de Información Genética (GINA, por sus siglas en inglés) generalmente hacen ilegal que compañías de seguros, grupos de planes de salud y la mayoría de los empleos discriminen a cualquier persona por su información genética. Estas leyes lo protegerán de la siguiente forma:

1. *Compañías de seguro medico y grupos de planes de salud, no pueden pedir la información genética que obtenemos en este estudio.*

2. *Compañías de seguro medico y grupos de planes de salud no pueden usar su información genética para hacer decisiones respecto a su elegibilidad o primas.*

3. *Empleos con 6 o mas empleados no podrán usar la información genética obtenida de este estudio para hacer decisiones en cuanto a emplearlo, promoverlo o despedirlo, o al reglamentar estatutos en cuanto a su empleo.*

Todas las compañías de seguro medico y grupos de planes de salud deberán seguir la ley de GINA para el 21 de mayo de 2010. Empleos con 15 o más empleados deberán seguir la ley de GINA para el 21 de noviembre de 2009. La ley de Massachusetts la aplica a empleos de 6 o más empleados.

Esté en aviso que ni la ley de Massachusetts ni la nueva ley Federal lo protegen contra discriminación genética de compañías que venden seguros de vida, seguros de incapacidad o seguros de cuidados médicos a largo plazo. Por lo tanto, seguros de vida, seguros de incapacidad y seguros de cuidados médicos a largo plazo tienen el derecho a preguntarle si ha tenido pruebas genéticas y si se rehúsa contestar esta pregunta, pueden negarle la cobertura.

Quizá existan riesgos y molestias desconocidos por el momento. Los empleados del estudio le actualizarán oportunamente sobre cualquier información nueva que pudiera afectar su salud, su bienestar y su decisión de seguir en el estudio.

Posibles Beneficios

Usted no recibirá ningún beneficio directo de su participación en este estudio. Sin embargo, su participación puede ayudar a los investigadores a comprender mejor las causas y prevención de enfermedades cardiovasculares y otras condiciones médicas, incluyendo el potencial de factores genéticos.

Alternativas

Tiene la alternativa de no participar en el estudio.

Costos y pagos

A usted no se le pagará ni se le cobrará por ninguna parte del examen. Si en su examen se descubre algún problema médico que requiera un diagnóstico o tratamiento, se le dará aviso y esta información también se le dará al doctor o a la clínica que usted nos indique. Si su doctor decide que usted debe someterse a más exámenes clínicos o más tratamientos, usted o una tercera persona (por ejemplo su seguro médico o Medicare) serán responsables del costo. No se harán arreglos especiales por compensaciones o pagos de tratamientos por el solo hecho de haber participado en este estudio. Con este párrafo usted no renuncia a sus derechos legales. Los gastos que puede incurrir el día de su participación incluyen, pero no se limitan a, pérdida de horas de trabajo y transportación (gasolina, peaje, etc.). A usted no se le pagará por participar en el estudio.

Descubrimientos Patentables

Puede ser que algún día las investigaciones de este estudio den como resultado nuevos procedimientos para diagnosticar o curar enfermedades. También puede llevarnos al desarrollo de nuevas medicinas para curar o prevenir enfermedades. Como sucede con toda investigación patrocinada federalmente, los investigadores y sus empleados tienen el permiso por ley, de patentar descubrimientos por los que podrían ser pagados. El Congreso de los Estados Unidos opina que el permitir tales patentes, podría incrementar la posibilidad de que un beneficio de salud pública se lleve a cabo a través del patrocinio federal para la investigación.

FORMA DE CONSENTIMIENTO PARA INVESTIGACION
Omni 1 Examen 4
ESTUDIO DEL CORAZON DE FRAMINGHAM N01-HC-25195 1910G

Confidencialidad

La información obtenida de usted será tratada como confidencial. Se le asignará un código a usted y a la información que obtengamos de usted. Los códigos solo se darán a investigadores calificados, pero su nombre y otros datos personales no serán proveídos. El riesgo en proveer muestras es mínimo. Las muestras serán guardadas hasta que ya no sirvan para la investigación científica. Usted no será informado de forma rutinaria sobre los resultados de las investigaciones hechas con su material genético, sin embargo, con su permiso, podrá ser informado de algunos hallazgos sobre genética, enfermedades cardiovasculares y otras condiciones de salud generadas por los análisis de su ADN, ya sea directamente o a través de las publicaciones en los boletines.

Cuando los resultados basados en su información sean publicados, su nombre y cualquier otra información que lo pudiera identificar, no serán revelados. Es posible que la información de este estudio, así como de sus registros médicos, sean revisados y fotocopiados por agencias de reglamento estatal o federal, como son: el Comité de Protección de Sujetos Humanos y el Comité de Revisión Institucional del Centro Médico de la Universidad de Boston.

Para ayudarnos a proteger aún más su privacidad, los investigadores han obtenido un Certificado de Confidencialidad del Departamento de Salud y Servicios Humanos (DHHS, por sus siglas en ingles). Con este certificado, los investigadores no pueden ser forzados (por ejemplo por alguna corte) a divulgar información de la investigación que lo pudiera identificar en ningún procedimiento federal, estatal, local civil, criminal, administrativo, legislativo u otros. Sin embargo, será necesaria la divulgación si fuera requerida para hacer una auditoría por parte del DHHS o con propósitos de evaluación del programa. Un Certificado de Confidencialidad no le previene a usted ni a su familia de suministrar voluntariamente su propia información, ni la de su participación en este estudio. Tome nota que si por ejemplo, un asegurador o empleador sabe que usted es participante de este Estudio, y obtiene su consentimiento para obtener más información, en ese caso el investigador no podrá usar el Certificado de Confidencialidad para no divulgar su información. Esto significa que usted y su familia también deben proteger su propia privacidad. Finalmente, por favor comprenda que el investigador no está prevenido de tomar las medidas necesarias (incluyendo reportar a autoridades) para prevenir daños severos a usted mismo y a otros.

Por favor cheque las casillas correspondientes para indicar si está o no está de acuerdo con lo siguiente:
1) l__l SI l__l NO (Código de Oficina 0)
Estoy de acuerdo en participar en el examen clínico del Estudio del Corazón de Framingham, colección de sangre, células del cachete y orina, y en estudios de factores que contribuyen a enfermedades del corazón, las arterias, los pulmones y la sangre, accidentes cerebro-vasculares, pérdida de memoria, cáncer y otras enfermedades graves y condiciones de salud.

2) l__l SI l__l NO (Código de Oficina 3)
Estoy de acuerdo en permitir que mi información de datos, células del interior de mi cachete y muestras de

sangre y orina se usen en futuros estudios genéticos de factores que contribuyen a enfermedades del corazón, las arterias, los pulmones y la sangre, accidentes cerebro-vasculares, pérdida de memoria, cáncer y otras enfermedades y condiciones de salud.

3) l__l SI l__l NO (Código de Oficina 12)
Estoy de acuerdo en permitir que mi información de datos, células del interior de mi cachete, muestras de sangre, orina y ADN se usen en futuros estudios genéticos concernientes a la reproducción y salud mental como alcoholismo y síntomas de depresión.

4) l__l SI l__l NO (Código de Oficina 13)
Estoy de acuerdo en proveer una muestra de sangre para que se formen células pluripotenciales inducidas y con ellas hacer otros tipos de células, como ARN, proteínas y metabolitos. Esto significa que las células blancas de mi sangre se pueden procesar para obtener células madre y luego ser alteradas para que funcionen como células de otros órganos del cuerpo, como: hígado, células grasas, células del corazón y de los nervios.

5) l__l SI l__l NO (Código de Oficina 4)
Estoy de acuerdo en conceder a investigadores de compañías privadas el acceso a mis muestras de orina, sangre, ADN, otra información genética e información de datos en el futuro, que podrían ser utilizados en pruebas de laboratorio o tratamientos que podrían beneficiar a mucha gente. (Nota: ni usted ni sus familiares se beneficiarán económicamente por esto, tampoco su ADN será vendido a nadie).

6) l__l SI l__l NO (Código de Oficina 30)
Estoy de acuerdo en dar permiso al Estudio del Corazón de Framingham para que informe los resultados de mis exámenes no-genéticos y exámenes a mi doctor, clínica u hospital.

7) l__l SI l__l NO (Código de Oficina 31)
Si se identifica alguna condición genética que tuviera importantes implicaciones para mí sobre mi salud y tratamientos, estoy de acuerdo en permitir que el Estudio del Corazón de Framingham me lo notifique y con mi permiso, a mi doctor.

Derechos del participante

Al darnos su consentimiento para participar en este estudio, usted no cancela ninguno de sus derechos legales. Dar consentimiento significa que usted ha escuchado o leído la información sobre este estudio y que está de acuerdo en participar. Se le dará una copia de esta forma.

Si en cualquier momento decidiera no seguir participando en este estudio, no sufrirá ningún tipo de penalidad ni perderá ningún beneficio al que tuviera derecho.

Puede obtener más información sobre sus derechos como sujeto en el estudio llamando al Comité de Revisión Institucional del Centro Médico de la Universidad de Boston al [redacted].

El investigador o algún miembro del equipo de investigadores tratará de responder a todas sus preguntas.

Si tiene preguntas o dudas o si necesita reportar una herida que haya ocurrido mientras participó en el estudio, por favor contacte al [redacted] (en inglés).

Compensación por daños relacionados con la Investigación

Si piensa que ha sido herido por participar en este estudio, por favor déjeselo saber al investigador inmediatamente. Si su participación es en el Centro Médico de Boston, puede obtener tratamiento por la herida en el Centro Médico de Boston. Si su participación NO es en el Centro Médico de Boston, pregúntele a su investigador dónde puede obtener tratamiento localmente por su herida. El Centro Médico de la Universidad de Boston y su benefactor, no ofrecen programas para proveer compensación por el costo de cuidados médicos en caso de heridas ocurridas durante el estudio, ni otros gastos como pérdida de dinero por no trabajar, incapacidad, dolor o molestias. Se le enviará la cuenta por el tratamiento recibido si su seguro médico no paga por sus cuidados médicos. Usted no cancela sus derechos legales por firmar esta forma.

Sus Derechos a Rehusar o Descontinuar

Su participación en este estudio es voluntaria. Tiene el derecho de rehusar tomar parte en este estudio. Si decide participar y luego cambia de opinión, puede salirse del estudio. Su participación es completamente voluntaria. Su decisión no afectará el poder obtener cuidado médico en el Centro Médico de Boston, ni los pagos por su cuidado médico. No afectará su enrolamiento a ningún plan de salud o beneficios que pueda obtener. Si decide participar, tiene el derecho a descontinuar en cualquier momento. Si durante el estudio hubiera descubrimientos que pudieran afectar su buena voluntad de participar, se lo harán saber lo más pronto posible.
Es posible que el investigador decida descontinuar su participación sin su permiso porque pudiera decidir que continuar en el estudio sería malo para usted, o porque el patrocinador interrumpa el estudio.

Información de Salud para Protección de Sujetos

Usted tiene ciertos derechos relacionados con su información de salud. Estos incluyen el derecho a saber quién obtendrá su información de salud y para qué se utilizará. Si decide tomar parte en este estudio de investigación, obtendremos información sobre usted según se indica a continuación.

INFORMACION DE SALUD DE USTED QUE PUEDE SER USADA O DADA A OTROS DURANTE ESTE ESTUDIO:

- Información de su hospital o registros médicos de BUMC/BMC (Centro Médico de la Universidad de Boston) o de otra parte. Esta información es razonablemente relacionada al propósito del estudio de investigación. Si se necesitara información de sus doctores u hospitales fuera de BUMC/BMC, se le pedirá que nos dé permiso para que estos registros sean enviados al investigador del estudio.

- Nueva información que se obtenga de pruebas, procedimientos, visitas, entrevistas o formas completadas como parte de este estudio.

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RAZONES POR LAS QUE ES POSIBLE QUE DEMOS SU INFORMACION DE SALUD A OTROS

Las razones por las que es posible que usemos o compartamos su información de salud son:

- Para hacer el estudio descrito aquí.
- Para asegurarnos de llevar a cabo el estudio de acuerdo con ciertos estándares de ética, la ley y grupos de control.

GENTE Y GRUPOS QUE PUDIERAN USAR O DAR SU INFORMACION DE SALUD

1. GENTE O GRUPOS DENTRO DE BUMC/BMC

- Investigadores involucrados en el estudio
- La Mesa Institucional de Revisión del Centro Médico de la Universidad de Boston que supervisa este estudio.

2. GENTE O GRUPOS FUERA DE BUMC/BMC

- Gente o grupos que empleamos para hacer ciertos trabajos, como compañías de almacenamiento de información de datos o laboratorios.
- Agencias federales y estatales si lo requiere la ley o si están involucradas con la supervisión del estudio. Estas agencias pueden incluir el Departamento de Salud y Servicios Humanos de Estados Unidos, La Administración de Alimentos y Drogas, Los Institutos Nacionales de Salud, y el Departamento de Salud de Massachusetts.
- Organizaciones que aseguran que los estándares de los hospitales se mantengan.
- El o los Benefactores del estudio, y gente o grupos que emplean para ayudarles a realizar la investigación.
- Otros investigadores que forman parte de este estudio.
- Un grupo que supervisa la información de la investigación y la seguridad de este estudio.

Otros:

Puede que alguna gente o grupos que obtengan su información de salud no sigan las mismas reglas de privacidad que seguimos. Compartimos su información de saludo sólo cuando es indispensable. Pedimos a quienes la obtengan que protejan su privacidad como participante. Sin embargo, una vez la información sale de BUMC (Centro Médico de la Universidad de Boston), no podemos prometer que la información se mantenga privada. En la mayoría de los casos, cualquier información que es dada a otros, se identifica con un número único de estudio, y no con su nombre. Así que, aunque pudiera ser posible relacionar el número con su información, esto usualmente no sucede.

PERIODO DE TIEMPO PARA USAR O DAR SU INFORMACION DE SALUD

Dado que los estudios de investigación son un proceso continuo, no podemos darle una fecha exacta sobre cuándo su información de salud será destruida o se dejará de usar o compartir.

SUS DERECHOS A LA PRIVACIDAD

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- Usted tiene el derecho a no firmar esta forma que nos permite usar y compartir su información de salud para investigación. Si no firma esta forma, no puede participar en el estudio, ya que necesitamos usar su información de salud para poderla estudiar.
- Tiene el derecho de detener su permiso para usar o compartir su información de salud en este estudio de investigación. Si así lo desea, debe escribir una carta a los investigadores encargados de este estudio de investigación. Si deja de darnos permiso, no podrá tomar de vuelta la información que ya ha sido usada o compartida con otros. Esto incluye información usada o compartida con propósitos de investigación o para garantizar la seguridad y calidad del estudio. Si retira su permiso, no puede continuar en el estudio.
- Tiene el derecho de ver y obtener una copia de la información de salud que es usada o compartida para uso de investigación. Sin embargo, solo puede obtener esto cuando la investigación haya terminado. Para pedir esta información, por favor contacte a la persona encargada de este estudio de investigación.

EN CASO DE QUE LOS RESULTADOS DEL ESTUDIO SEAN USADOS PARA SER PUBLICADOS O PARA LA ENSEÑANZA

Los resultados del estudio podrían ser publicados en alguna revista o libro médicos, o usados para enseñar a otros. Sin embargo, su nombre u otra información que lo pudiera identificar, no será usada sin su permiso específico.

Firmar esta forma de consentimiento indica que usted ha leído esta forma (o se la han leído), que sus preguntas han sido contestadas a su satisfacción y que usted voluntariamente accede a participar en este estudio de investigación. Usted recibirá una copia firmada de esta forma de consentimiento.

Firma del Participante	Nombre con Letra de Molde	Fecha
Representante legal autorizado (LAR) firma y nombre con Letra de Molde		Fecha
Firma de la Persona que Obtiene el Consentimiento y Nombre		Fecha

RESEARCH CONSENT FORM

Blood Draw Consent for Cell Line Creation

THE FRAMINGHAM HEART STUDY N01-HC-25195 1910G

Background

A cell line is a frozen sample of specially processed white cells from your blood that allows the Framingham Heart Study to grow more white cells and get more DNA from them in future as needed for research projects.

Purpose

A cell line will be created from a blood sample you provide in order to study the cause and prevention of cardiovascular disease and other health conditions, including the possibility of how genetic factors influence health status.

What Happens In This Research Study

You will be one of approximately 1080 subjects to be asked to participate in this study.

All or part of the research in this study will take place at the following location(s): Boston University Medical Center.

Your research blood draw will take place at the Framingham Heart Study located at 73 Mount Wayte Avenue in Framingham, MA, or the place where you reside. A laboratory technician will draw a sample of your blood (16 cc or about 1 tablespoon) for the preparation of DNA (genetic material) and for the creation of a living sample of white blood cells (cell line).

Risks and Discomforts

Minimal bruising, pain, or bleeding may occur as a result of the blood draw. A latex allergy can occur from the gloves worn by the technician. If you have a known latex allergy, inform the technician and he/she will use another form of protection.

There may be unknown risks/discomforts involved. Study staff will update you in a timely way on any new information that may affect your health, welfare, or decision to stay in this study

Potential Benefits

You will receive no direct benefit from your participation in this study. However, your participation may help the investigators better understand the cause and prevention of cardiovascular disease and other health conditions, including the possibility of how genetic factors influence health status.

Alternatives

Your alternative is to not participate in the study.

Subject Costs and Payments

You will not be charged for the examination. If the examination finds any medical problems requiring medical diagnosis or treatment, you will be so advised and that information will be provided to the

physician or clinic that you choose.

In the event that your physician decides that follow up clinical tests or treatments are necessary, payment must be provided by you or your third party payer, if applicable (for example, health insurance or Medicare). No special arrangements will be made by the Framingham Heart Study for compensation or for payment of treatment solely because of your participation in this study. This does not waive any of your legal rights.

Costs that you might incur the day of your participation include, but are not limited to, transportation costs (gas, tolls, etc). You will not receive payment for your participation. However, if necessary, we will provide transportation to the clinic and your return home at no cost.

Confidentiality

Information obtained during this study will be treated as strictly confidential. A code number will be assigned to you and to your personally identifying information. Cell lines will be stored at a central site. Files linking names to samples will be kept locked and accessible only to the Framingham Heart Study (FHS) data managers. The coded samples will be stored securely and kept until no longer of scientific value. The risk in providing this sample is minimal.

Data and DNA will be distributed to the FHS researchers and other qualified researchers interested in the genetics of heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, joint disease, bone loss, deafness, cancer, and other major diseases and health conditions. The researchers will be given the DNA without any personally identifying information. Information gained from research on your DNA may be used for the development of diagnostic procedures or new treatments for major diseases. Your DNA will not be sold to any person, institution, or company for financial gain or commercial profit. However, neither you nor your heirs will gain financially from discoveries made using the information and/or specimens that you provide.

When study results are published, your name and any other identifying information will not be revealed. You will be informed through periodic publications from the FHS of some findings about genetics, cardiovascular disease or other health conditions generated from the DNA analyses.

To help us further protect your privacy, the investigators have obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be

RESEARCH CONSENT FORM

Blood Draw Consent for Cell Line Creation

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necessary, however, upon request of DHHS for audit or program evaluation purposes. You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. Note however, that if an insurer or employer learns about your participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy. Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

You may choose to withdraw your blood samples and your samples would be destroyed after the request is received. If you choose to withdraw your samples, you should call the Framingham Heart Study at [redacted] and ask for the lab manager.

The FHS is a medical research project sponsored by the National Institutes of Health. It is authorized under 42USC 285b-3. The system of records which applies to the FHS is documented in the Federal Register: September 26, 2002 (Vol. 67, No. 1879) pages 60776-60780.

Please check the appropriate box below:

1) |___| YES |___| NO (Office Code 1)

I agree to allow a cell line to be made from my blood to provide a renewable supply of DNA. (A cell line is a frozen sample of specially processed white cells from your blood that allows us to grow more white cells and obtain more DNA from them as needed for future research projects).

Subject's Rights

By consenting to participate in this study you do not waive any of your legal rights. Giving consent means that you have heard or read the information about this study and that you agree to participate. You will be given a copy of this form to keep.

If at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled.

You may obtain further information about your rights as a research subject by calling the Office of the

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Institutional Review Board of Boston University Medical Center at [redacted].

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury while participating in this research, contact [redacted].

Compensation for Research Related Injury

If you think that you have been injured by being in this study, please let the investigator know right away. If your part in this study takes place at Boston Medical Center, you can get treatment for the injury at Boston Medical Center. If your part in the study is not at Boston Medical Center, ask the investigator where treatment for injury would be available locally. You and your insurance company will be billed for this treatment. Some research sponsors may offer a program to cover some of the treatment costs which are not covered by your insurance. You should ask the research team if such a program is available.

Right to Refuse or Withdraw

Taking part in this study is voluntary. You have the right to refuse to take part in this study. If you decide to be in the study and then change your mind, you can withdraw from the research. Your participation is completely up to you. Your decision will not affect your being able to get health care at this institution or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get.

If you choose to take part, you have the right to stop at any time. If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them as soon as possible.

The investigator may decide to discontinue your participation without your permission because he/she may decide that staying in the study will be bad for you, or the sponsor may stop the study.

Protection of Subject Health Information

N/A

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Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

_____

Subject (Signature and Printed Name) Date

_____

Legally Authorized Representative (LAR) (Signature and Printed Name) Date

_____

Person Obtaining Consent (Signature and Printed Name) Date

FORMA DE CONSENTIMIENTO PARA INVESTIGACION

Consentimientoparacrearunalínea de células de sumuestra de sangre

ESTUDIO DEL CORAZON DE FRAMINGHAM N01-HC-25195 1910G

Antecedentes

Una línea de células es una muestra congelada de células blancas de su sangre, que han sido especialmente procesadas para que el Estudio del Corazón de Framingham pueda reproducir más células blancas y así obtener más ADN, según se vaya necesitando para futuros estudios.

Propósito

Una línea de células será creada de una muestra de sangre que usted nos dé, para estudiar las causas de enfermedades del corazón y otras condiciones de salud, cómo prevenirlas y la posibilidad de estudiar la influencia delos factores genéticos para la salud.

Que Sucede en este Estudio de Investigación

Usted será una de las aproximadamente 1080 personas a quienes se les pedirá que participen en este estudio. Todo o parte del estudio se realizará enEl Centro Médico de la Universidad de Boston (Boston University Medical Center o BUMC por sus siglas en Inglés).
La muestra de su sangre será tomada en el Estudio del Corazón de Framingham, localizado en 73 Mt. Wayte Ave. enFramingham, MA, o en su lugar de residencia. Un técnico tomará una muestra de su sangre (16 cc o alrededor de 1 cucharada) para la preparación de ADN (material genético) y para la creación de una muestra de células blancas vivas (línea de células).
Los riesgos de dar la muestra de sangre incluyen un pequeño moretón, dolor o sangrado.También puede ocurrir una alergia al látex. Si sabe que es alérgico al latex, por favor dígaselo al técnico para que use otro tipo de protección.

Riesgos y molestias

Pudiera haber riesgos y molestias hasta ahora desconocidos. Los empleados del estudio le actualizarán sobre cualquier información nueva que pudiera afectar su salud, su bienestar y su decisión de seguir participando en el estudio.

Posibles Beneficios

Usted no recibirá ningún beneficio directo de su participación en este estudio. Sin embargo, su participación puede ayudar a los investigadores a comprender mejor las causas y prevención de enfermedades cardiovasculares y otras condiciones de la salud, incluyendo la posibilidad de saber cómo los factores genéticos influencian el estado de salud.

Alternativas

Tiene la alternativa de no participar en el estudio.

Costos y pagos

BUMC/BMC Institutional Review Board
IRB NUMBER: H-32132
IRB APPROVAL DATE: 01/16/2013
IRB EXPIRATION DATE: 01/15/2014

No se le cobrará por este examen. Si en su examen se descubriera algún problema médico que requiera más diagnóstico o tratamiento, se le avisará a usted y a su doctor o a la clínica que usted nos indique.

En caso de que su doctor decida que usted debe someterse a más exámenes clínicos o más tratamientos, estos deberán ser pagados ya sea por usted o por una tercera persona (por ejemplo su seguro médico o Medicare). No se harán arreglos especiales por compensaciones o pagos de tratamientos por el solo hecho de haber participado en este estudio. Este párrafo no cancela sus derechos legales.

Los gastos que puede incurrir el día de su participación incluyen(pero no se limitan) a costos de transportación (gasolina, peaje, etc.). A usted no se le pagará por participar en el estudio. Sin embargo, si fuera necesario, le proveeremos con transportación a la clínica y de vuelta a su hogar sin costo para usted.

Confidencialidad

La información obtenida durante el estudio será tratada con estricta confidencialidad. Se le asignará un código a usted y a cualquier información personal que pudiera identificarle. Las líneas de células serán guardadas en un lugar central. Los documentos que vinculen los nombres con las muestras serán guardados bajo llave y serán accesibles solo a los administradores de bancos de datos del Estudio del Corazón de Framingham. Las muestras con códigos serán guardadas hasta que ya no tengan valor científico. El riesgo en proveer esta muestra es mínimo.

La información de datos y el ADN será distribuido a los investigadores del Estudio del Corazón de Framingham y a investigadores calificados interesados en la genética de enfermedades del corazón y las venas, enfermedades del pulmón y la sangre, accidentes cerebro-vasculares, pérdida de memoria, enfermedades de las articulaciones, pérdida de densidad ósea, sordera, cáncer, y otras enfermedades graves y condiciones de salud. A los investigadores se les dará el ADN sin ningún dato que pudiera identificar a los donadores. La información obtenida de su ADN puede ser utilizada para el desarrollo de procedimientos para diagnosticar o para nuevos tratamientos de enfermedades graves. Su ADN no será vendido a ninguna persona, institución o compañía por ganancia financiera ni por beneficio comercial. Sin embargo, ni usted ni sus familiares ganarán provecho financiero de los descubrimientos hechos usando la información o especímenes que usted nos dé.

Cuando los resultados sean publicados, su nombre y cualquier otra información que lo pudiera identificar, no serán revelados. Se le mantendrá informado a través de publicaciones periódicas del Estudio del Corazón de Framingham sobre descubrimientos de genética, enfermedades cardiovasculares y otras condiciones de salud que hayan sido generadas de los análisis del ADN.

BUMC/BMC Institutional Review Board
IRB NUMBER: H-32132
IRB APPROVAL DATE: 01/16/2013
IRB EXPIRATION DATE: 01/15/2014

FORMA DE CONSENTIMIENTO PARA INVESTIGACION

Consentimientoparacrearunalínea de células de sumuestra de sangre

ESTUDIO DEL CORAZON DE FRAMINGHAM N01-HC-25195 1910G

Para ayudarnos a proteger su privacidad, los investigadores calificados han obtenido un Certificado de Confidencialidad del Departamento de Salud y Derechos Humanos (DHHS). Con este certificado, los investigadores no pueden ser forzados (por ejemplo por la corte) a divulgar ninguna información que le pueda identificar en ningún procedimiento federal, estatal, local civil, criminal, administrativo, legislativo o ningún otro procedimiento. Sin embargo, el suministro de información será necesario si fuera requerido para una auditoría o evaluación del programa por parte del Departamento de Salud y Derechos Humanos. Por favor comprenda que un Certificado de Confidencialidad no lo previene a usted ni a su familia de voluntariamente suministrar información de usted mismo, ni de su participación en este estudio. Por ejemplo, si un asegurador o empleador sabe que usted es participante de este Estudio, y obtiene el consentimiento de usted mismo para obtener más información, en ese caso el investigador no podrá usar su Certificado de Confidencialidad para no divulgar su información. Esto significa que usted y su familia también deben actuar para proteger su propia privacidad.Finalmente, por favor comprenda que el investigador no está prevenido de tomar las medidas necesarias (incluyendo reportar a autoridades) para prevenir daños severos a usted mismo y a otros.

Tiene la opción de retirar su muestra de sangre en el futuro, en cuyo caso la muestra será destruida. Si elije retirar sus muestras, deberá comunicarse con la encargada del laboratorio del Estudio del Corazón de Framingham al [redacted].

El Estudio del Corazón de Framingham es un proyecto de investigación médica patrocinado por los Institutos Nacionales de la Salud. Autorizado bajo 42USC285b-3. El sistema de registros aplicado al Estudio del Corazón de Framingham, está documentado en el Registro Federal: Septiembre 26, 2002 (Vol. 67, No. 1879) páginas 60776-60780.

Por favor cheque en la casilla apropiada si está o no está de acuerdo con el siguiente estatuto:

1. |___| SI |___| NO (Office Code 1)

Estoy de acuerdo en permitir la formación de una línea de células hecha con mi sangre para proveer un suministro renovable de ADN. (Una línea de células es una muestra de células blancas de su sangre, congeladas y procesadas, para poder reproducir más células blancas y así obtener más ADN para futuros estudios).

Derechos del Participante

Al darnos su consentimiento para participar en este estudio, usted no renuncia a ninguno de sus derechos legales. Dar consentimiento significa que usted ha escuchado o leído la información sobre este estudio y que está de acuerdo en participar. Se le dará una copia de

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esta forma.

Si en cualquier momento decidiera no seguir participando en este estudio, no sufrirá ningún tipo de penalidad ni perderá ningún beneficio al que tuviera derecho.

Puede obtener más información sobre sus derechos como sujeto en el estudio llamando a la Oficina de Revisión Institucional del Comité de Protección de Derechos Humanos del Centro Médico de la Universidad de Boston al [redacted].
El investigador o algún miembro del equipo de investigadores tratará de responder a todas sus preguntas. Si en cualquier momento tiene preguntas o dudas, o si necesita reportar alguna herida ocurrida durante su participación en esta investigación, por favor comuníquese con el [redacted].

Compensación por daños relacionados con la Investigación

Si piensa que ha sido herido por participar en este estudio, por favor déjeselo saber al investigador inmediatamente. Si su participación es en el Centro Médico de Boston, puede obtener tratamiento por la herida en el Centro Médico de Boston. Si su participación NO es en el Centro Médico de Boston, pregúntele a su investigador dónde puede obtener tratamiento localmente para la herida. Usted y su seguro médico recibirán la cuenta por el tratamiento recibido. Algunos patrocinadores de investigación ofrecen un programa para cubrir parte de los costos del tratamiento que no son cubiertos por su seguro médico. Debería preguntarle al equipo de investigación si tal programa está disponible.

Sus Derechos a Rehusar o Descontinuar

Su participación en este estudio es voluntaria. Tiene el derecho de rehusar tomar parte en el estudio. Si decide participar y después cambia de opinión, puede salirse del estudio. Su participación es totalmente opcional. Su decisión no afectará el cuidado médico que pueda recibir en esta institución ni el pago de su cuidado médico. No afectará su inscripción a seguros médicos o beneficios que pudiera obtener.

Si decide tomar parte, tiene el derecho a descontinuar su participación en cualquier momento. Si hubiera nuevos descubrimientos durante la investigación que pudieran afectar su voluntad de participar, se lo harán saber lo máspronto posible.

Es posible que el investigador decida descontinuar su participación sin su permiso, porque pudiera decidir que continuar en el estudio será malo para usted o porque nuestro patrocinador interrumpa el estudio.

Firmar esta forma de consentimiento indica que usted ha leído esta forma (o se la han leído), que sus preguntas han sido contestadas a su satisfacción y que usted voluntariamente accede a participar en este estudio de investigación. Usted recibirá una copia de esta forma de consentimiento firmada.

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_____

_____|_____ _____

Firma del Participante y Nombre con Letra de Molde Fecha

_____|_____ _____

Representante legal autorizado (LAR) firma y nombre con Letra de Molde Fecha

_____|_____ _____

Firma de la Persona que Obtiene el Consentimiento y Nombre Fecha

_____

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RESEARCH SUBJECT'S AUTHORIZATION

FOR RELEASE OF HEALTH INFORMATION FOR RESEARCH PURPOSES

Name of Research Study: Framingham Heart Study

IRB Number: H-32132

Subject's Name: _____ Birth Date: _____

We want to use your private health information in this research study. This will include both information we collect about you as part of this study as well as health information about you that is stored in your medical record. The law requires us to get your authorization (permission) before we can use your information or share it with others for research purposes. You can choose to sign or not to sign this authorization. However, if you choose not to sign this authorization, you will still be able to take part in the research study. Whatever decision you make about this research study will not affect your access to medical care.

Section A:

I authorize the use or sharing of my health information as described below:
Who will be asked to give us your health information:

Who will be able to use your health information for research:

- ***The researchers and research staff conducting this study at the Framingham Heart Study***

We may also be asked or required by law to share your health information with the following people if they request it. Once we give it to them, your information is no longer protected under the federal Privacy Rule. However, its use and further disclosures remain limited as stated in your Informed Consent Form as part of BUMC Institutional Review Board oversight.

- ***Boston University Medical Center Institutional Review Board***
- ***Other governmental agencies that oversee research***

Section B: Description of information:

(1)If you choose to be in this study, the research team needs to collect information about you and your health. This will include information collected during the study as well as information from your existing medical records
from _____ through_____

(2) Your health information will be used and shared with others for the following study-related purpose(s):

- ***Data Analysis of Results***

(3) Specific description of information we will collect:

- Face sheet
- Discharge Summary
- ER Reports
- Admission Notes
- Progress Notes
- Operative Reports
- Pathology Reports
- Echocardiograms
- X-Rays
- EKGS
- EEGs
- CT Scans
- MRI/MRAs
- Mammograms
- Lab Reports
- Consults
- Cardiac Catheterization Reports
- Exercise Tolerance Tests
- Nursing Home notes
- Notes Near Time of Death
- Arteriography
- PA gram
- Other: For example Venous Ultrasound, V/Q Scan etc.

Section C: General

(1) Expiration:

- ***This authorization expires at the end of the study***

(2) Right To Revoke:
You may revoke (take back) this authorization at any time. To do this, you must ask us the Framingham Heart Study for the names of the Privacy Officers at the institutions where we got your health information. You must then notify those Privacy Officers in writing that you want to take back your Authorization. If you do, we will still be permitted to use and share the information that we obtained before you revoked your authorization but we will only use and share your information the way the Informed Consent Form says.

- **If you revoke this authorization, we may still need to share your health information if you have a bad effect (adverse event) during the research.**

(3) Your Access to the Information:
You have the right to see your medical records, but you will not be allowed to review your Framingham Heart Study research record until after the study is completed.

……..

I have read this information, and I will receive a signed copy of this form.

_____ _____
Signature of research subject or personal representative **Date**

Printed name of personal representative: _____

Relationship to research subject: _____

Please describe the personal representative's authority to act on behalf of the subject:

1. PRINCIPLE/PURPOSE

The Buccal Brush procedure is used to collect buccal or cheek cells that will be used for DNA analysis. Ideally the participant will be fasting at the time of collection. In the case of a non-fasting participant a minimum of one hour wait time is recommended after eating before the cells are collected.

2. MATERIALS

Materials	Order Number	Manufacturer/Vendor
Cytology Brush	CYB-1	Medical Packaging Corp
Cell Lysis Solution	158908	Qiagen
Nunc Cryotube Vials 1.0 ml	366656	Thermo Scientific
Heavy Duty Scissors	AH-184	Allheart.com
Sterile Alcohol Swabs	1103C	Samuel Perkins or equivalent
Disposable Non- Latex Gloves	74396	Moore Medical
2 Bar Code Labels		Framingham Laboratory

3. SPECIMEN COLLECTION/ PROCEDURE

3.1. Two buccal brushes will be collected for each participant. This will require two brushes and two cryotube vials per subject.
3.2. Prior to collection- wearing gloves, wipe the blades of the scissors with two separate alcohol pads and leave open to air dry.
3.3. Wearing gloves, role the brush through the fingers while moving the brush up and down on the inside of the participants' cheek. Ten complete passes (up and down count as one) is usually equivalent to the "30 second" collection time necessary to collect the cells.
3.4. Put the brush tip into the cryovial tube.
3.5. With the scissors, cut the tip so that the tube can be closed, concealing the brush with the cheek cells. The remainder of the brush (the long handle) can be discarded.
3.6. Repeat the procedure using the second brush on the other cheek. This second brush will be placed in the second cryovial.
3.7. After collection of both brushes is complete, clean the blades of the scissors with an alcohol pad again and set it aside to dry.
3.8. Label both cryovials with the participant barcode stickers.
3.9. Buccal brush samples are transported back to the laboratory for cell lysis and freezing.

4. BUCCAL BRUSH STORAGE

4.1. Keep the two brushes per subject separate. Each participant will have two samples to freeze.
4.2. Add 300ul of cell lysis solution to each cryovial that contains the buccal brush.
4.3. Vortex each tube for 15 seconds.
4.4. Place samples in a -80 degree freezer until samples are shipped out for DNA extraction.

Phlebotomy Protocol
Offspring Exam 9 / Omni Exam 4

Blood samples are collected from an antecubital vein with participants in a supine position after a 12-hour fast. The following tubes are drawn.

5 x 10 mL lavender tops (EDTA)
1 x 5 mL lavender top (EDTA)
2 x 10 mL red tops (serum)
1 x 4.5 mL blue top (citrate)
1 x 8 mL blue tiger top (CPT [cell preparation tube])
1 x 8.5 mL yellow top (ACD [acid citrate dextrose])
2 x 2.5 mL PAXgene tube

Total volume of blood drawn is 101 mL (3.4 ounces).

If participant needs a cell line, add: 2 x 8 ml CPT tubes.
Total volume of blood drawn is 117 ml (4.0 ounces).

EDTA

1. EDTA whole blood is used for HbA1c, which is measured daily at the Heart Study.
2. EDTA whole blood is used for a CBC, which is performed daily at the Heart Study.
3. EDTA plasma is used for cholesterol, HDL cholesterol, triglycerides and glucose which are measured daily at the Heart Study.
4. Buffy coat samples are collected from the EDTA Vacutainers.
    a. One aliquot is shipped daily to the iPS Core Facility at Harvard University for transformation into induced pluripotent stem cells.
    b. Two aliquots are stored at -80C for future extraction of DNA at the Framingham Heart Study Genetics Laboratory at Boston University Medical Center.
3. EDTA plasma and red cells are saved in several aliquots for future measurements; stored at –80 C.

Serum

1. Serum is used for creatinine, albumin, ALT, AST, total bilirubin, calcium, GGTP, phosphorus and CRP, which are measured daily at the Heart Study.
2. Serum is saved in several aliquots for future measurements; stored at –80 C.

Citrate

1. Citrate plasma saved in several aliquots for future measurements; stored at –80 C.
2. Buffy coat samples are collected from the citrate Vacutainer and stored at -80C for future use.

ACD

Buffy coat samples are collected from the ACD Vacutainer and stored at -80C for future extraction of DNA at the Framingham Heart Study Genetics Laboratory at Boston University Medical Center.

CPT

CPT tubes are shipped daily to the laboratory of [redacted] at Boston University Medical Center for isolation of platelets and peripheral blood mononuclear cells. Cells are stored for future extraction of miRNA.

CPT tubes for cell lines are shipped daily to the University of Minnesota Medical Center at Fairview, in Minneapolis. Lymphocytes are cryopreserved in preparation for future immortalization.

PAXgene

Whole blood drawn into a PAXgene tube will be saved for future extraction of RNA; stored at -80C.

Urine

As part of the Offspring Exam 8 clinic visit, participants are asked to provide a random urine sample.

1. Urine is saved in several aliquots for future measurements; stored at –80 C.

Note: Blood and urine samples are not done during offsite visits.

Weight Measurement

Clinic

1. Ask participant to remove own robe (if wearing own robe over the FHS gown). The participant should remove slippers or shoes. If participant is barefoot, supply participant with socks.

2. Prior to asking the participant to step onto the scale, lift the counter poise and position it at zero.

3. Ask the participant to step onto the scale, facing measurement beam.

4. Instruct the participant to stand in the middle of the scale platform with head erect and eyes looking straight ahead. Weight should be equally distributed on both feet. The participant's hands should be down by their side. The participant should not touch or support him/herself.

5. With the participant standing still in the proper position, lift the counterweight (larger weight), and slide it to the right until the beam approaches balance.

6. Adjust the top poise until the beam is evenly balanced.

7. Have the participant step off the scale. The technician should stand directly in front of the scale and read the weight with eyes level to the point of measurement.

8. Record the weight to the nearest pound; **round up if ≥ 0.5, round down if < 0.5**.

Weight Offsite Visits

1. The participant should remove slippers or shoes.

2. Prior to asking participant to step on the scale, turn scale on, check to make sure it reads 0.0. The scale should be on a flat, hard surface.

3. Ask the participant to step onto the scale.

4. Instruct the participant to stand in the middle of the scale platform with head erect and eyes looking straight ahead. Weight should be equally distributed on both feet, and participant should not touch or support himself/herself.

5. Read the digital display while participant is on the scale.

6. Have the participant step off the scale.

7. Record the weight to the nearest pound; round up if ≥ 0.5, round down if < 0.5.

9. If participant is unable to stand for weight measurement at a nursing home, record the last weight in nursing home chart and the date the weight was obtained. If the participant is unable to stand on a scale during a home visit, record the weight measurement as 999.

10. Calibrate the scale monthly with 50lb weight

Standing Height Measurement

(Clinic only)

Clinic

1. The participant should be wearing socks so positioning of the body can be seen. Ask participant to stand erect with his/her back to vertical mounted stadiometer.

2. Heels should be together and against the vertical ruler, both feet flat on the floor, with weight distributed evenly across both feet. Check to make sure both feet are back against the wall.

3. Participant faces straight ahead with his/her head positioned in the Frankfort horizontal plane. The lower margin of the bony orbit (the socket containing the eye) should be on the same horizontal plane as the most forward point in the supratragal notch (the notch just above the anterior cartilaginous projections of the external ear).

4. Ask participant to let arms hang freely by the sides of the trunk, palms facing the thighs. Ask participant to inhale deeply and maintain a fully erect position.

5. Bring the level down snugly (but not tight) on top of participant's head. Use an extension board for proper measurement of severely kyphotic subjects.

6. Record measurement to the **nearest 1/4 inch, rounding down.**

Note: Measurement is not taken during offsite visits.

Waist Girth at Umbilicus

1. Participant stands erect, arms hanging loosely at sides, feet together and weight equally distributed on both feet, facing straight ahead. The technician will take the gown from the back and place it over the left shoulder of the participant. The technician will ask the participant to cross their arms over their chest with hands at shoulders and hold the gown in place

2. Apply anthropometric tape at the level of the umbilicus. Roll underpants down below umbilicus if underwear is covering umbilicus.

3. Apply tape snugly but not tightly.

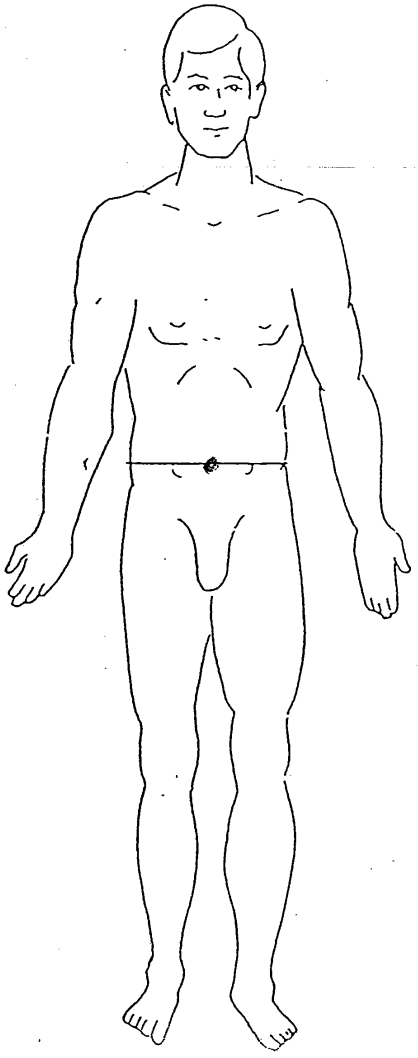
4. Make sure the tape is horizontal and not twisted, checking from both the front and back by using 2 mirrors mounted to the wall.

5. Before recording measurement ask the participant to fully relax their shoulders.

6. Record measurement **to the nearest 1/4 inch, rounding down.**

Note: Measurement is not taken during offsite visits.

Waist Girth



Waist Girth at level of umbilicus.

Hip Circumference Measurement

1. Participant stands erect, arms hanging loosely at sides, feet together and weight equally distributed on both feet, facing straight ahead. The technician will take the gown from the back and place it over the left shoulder of the participant. The technician will ask the participant to cross their arms over their chest with hands at shoulders and hold the gown in place.

2. The examiner stands on the participants left side and applies the measuring tape around the maximum extension of the buttocks (see figure on next page).

3. The examiner should be squatting or kneeling so that their eyes are at the level of the maximum extension of the buttocks.

4. Make sure the tape is horizontal and not twisted, checking from both the front and back by using 2 mirrors mounted on the wall.

5. The zero end of the tape is held under the measurement value.

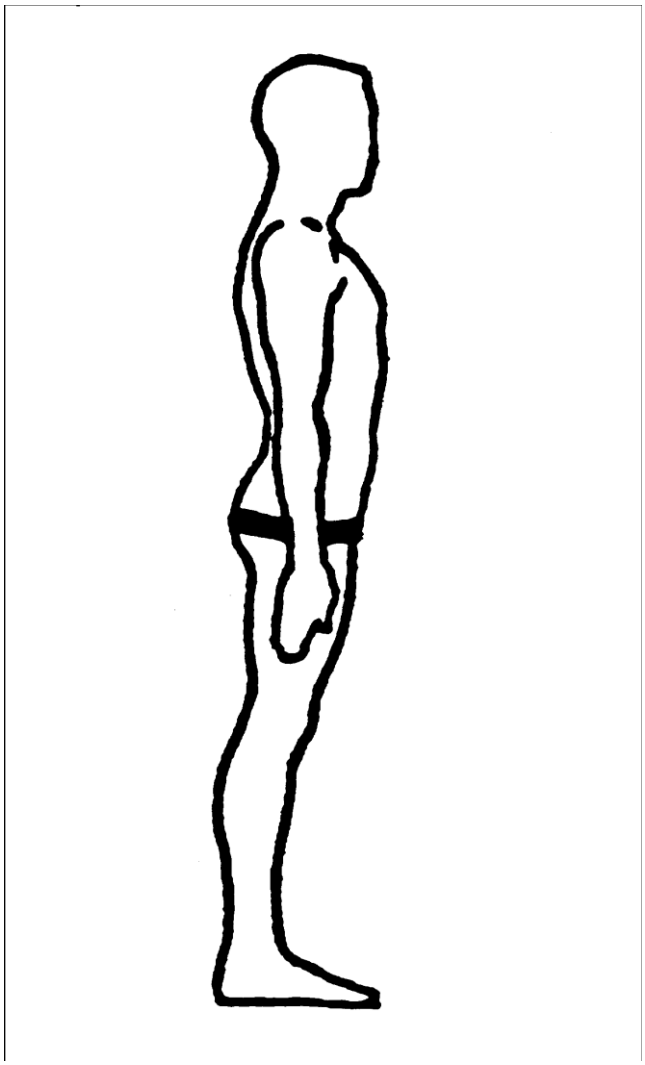
6. Apply tape snugly but not tightly.

7. Record measurement **to the nearest ¼ inch, rounding down.**

8. If the participant is wearing baggy underpants then the examiner stands in back and gathers the side seams together and places the thumb in the fabric to make a fold.

Note: Measurement is not taken during offsite visits.

Protocol from: National Health and Nutrition Examination Survey III – Body Measurements (Anthropometry)
http://www.cdc.gov/nchs/data/nhanes/nhanes3/cdrom/NCHS/MANUALS/ANTHRO.PDF



Protocol from: National Health and Nutrition Examination Survey III – Body Measurements (Anthropometry)
http://www.cdc.gov/nchs/data/nhanes/nhanes3/cdrom/NCHS/MANUALS/ANTHRO.PDF

Thigh Circumference - from the Health ABC Study

Background and Rationale

1. Thigh circumference

Thigh circumference may be a useful indicator of adiposity or lean body mass. Mid-thigh circumference will be measured using the right thigh at the midpoint between the inguinal crease and the proximal border of the patella.

2. Equipment and Supplies

- A flexible inelastic fiberglass tape
- Grease pencil

3. Thigh Measurement Procedures

1) Measure the thigh on the right side. If the right side cannot be used measure the left thigh and mark as a protocol modification and document reason for the modification. The measurement will be taken over bare skin. Participants should be dressed in a clinic gown so that appropriate landmarks can be located.

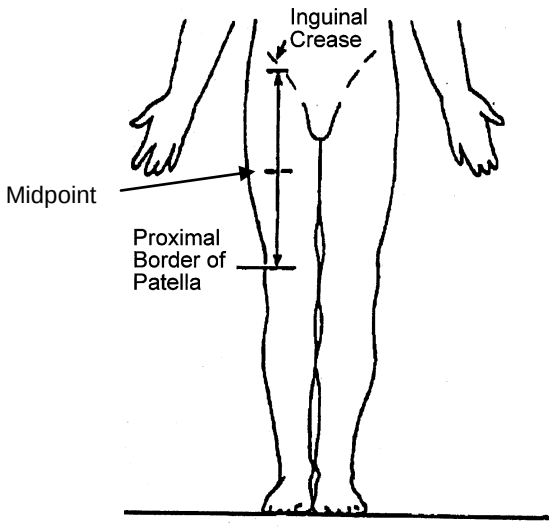
2) The participant should start out sitting on the exam bed, with the knees flexed to about 90 degrees and the thighs horizontal.

   Script: "I am going to measure your right thigh circumference. In order to do that I first have to mark your thigh with a cosmetic pencil to determine where to do the measurement. Is that OK with you?"

3) Mark the proximal border of the patella (knee cap). To help locate the landmark, ask the participant to straighten their leg to about a 120 degree angle while keeping their heel on the floor with the thigh muscles relaxed.

4) Locate the midpoint of the inguinal crease (see figure below). This is easily located if the hips are flexed as they will be with the participant seated. To help locate the landmark, ask the participant to lift the thigh about 1 cm. The point where the muscle and tendon contract is the midpoint of the crease.

5) With the participant seated and the thigh muscles relaxed, measure the distance between the inguinal crease and the proximal border of the patella (**rounding down to the nearest ¼ inch**) and divide by two to get the midpoint. Mark the location with a grease pencil.



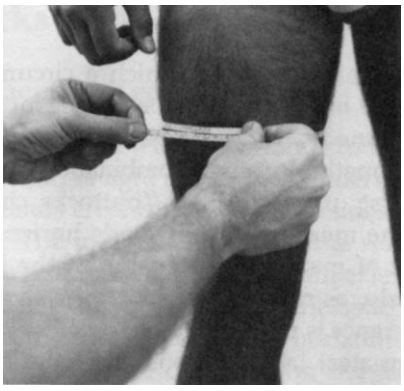
6) Ask the participant to stand up and place the heels about 20 cm apart.

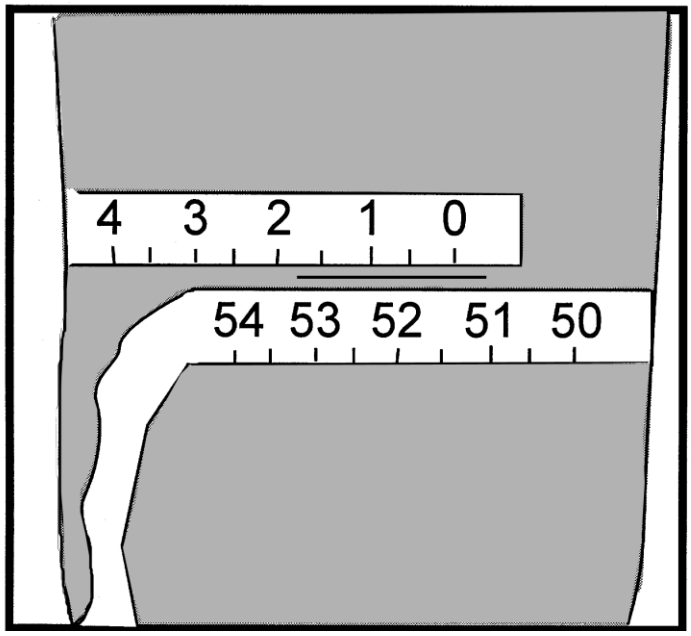
7) The weight should be evenly distributed over both feet, both feet flat on the floor. If balance is a problem, the participant may hold onto a chair or wall. The examiner should be squatting so that their eyes are at the level of the mid thigh.

8) The circumference is measured at the marked midpoint with the measuring tape placed horizontally (that is, perpendicular to the long axis of the thigh) around the thigh. View the thigh from the front and both sides to check this.

9) The tape should be in complete contact with the skin, without compressing the soft tissue.

10) The midpoint mark should be visible in the gap made by the upper and lower wrap of the tape. Make sure that the lower edge of the tape at the zero mark sits directly at the top of the midpoint mark. Make sure that the top edge of the lower wrap of the tape sits directly below the midpoint mark. Read the value directly below the zero mark (see example in figure on next page).





11) Record the circumference to the nearest 1/4 inch (**rounding down to the nearest 1/4 inch**)

Note: Measurement is not taken during offsite visits.

4. Quality Assurance

Training Requirements:

No special qualifications or experience are required to perform this assessment. Training should include:

- Read and study protocol
- Attend training session on techniques (or observe administration by experienced examiner)
- Practice on volunteers with a special emphasis on obese participants
- Compare measurements with those made by experienced colleagues
- Discuss problems and questions with clinic manager

Ongoing quality control:

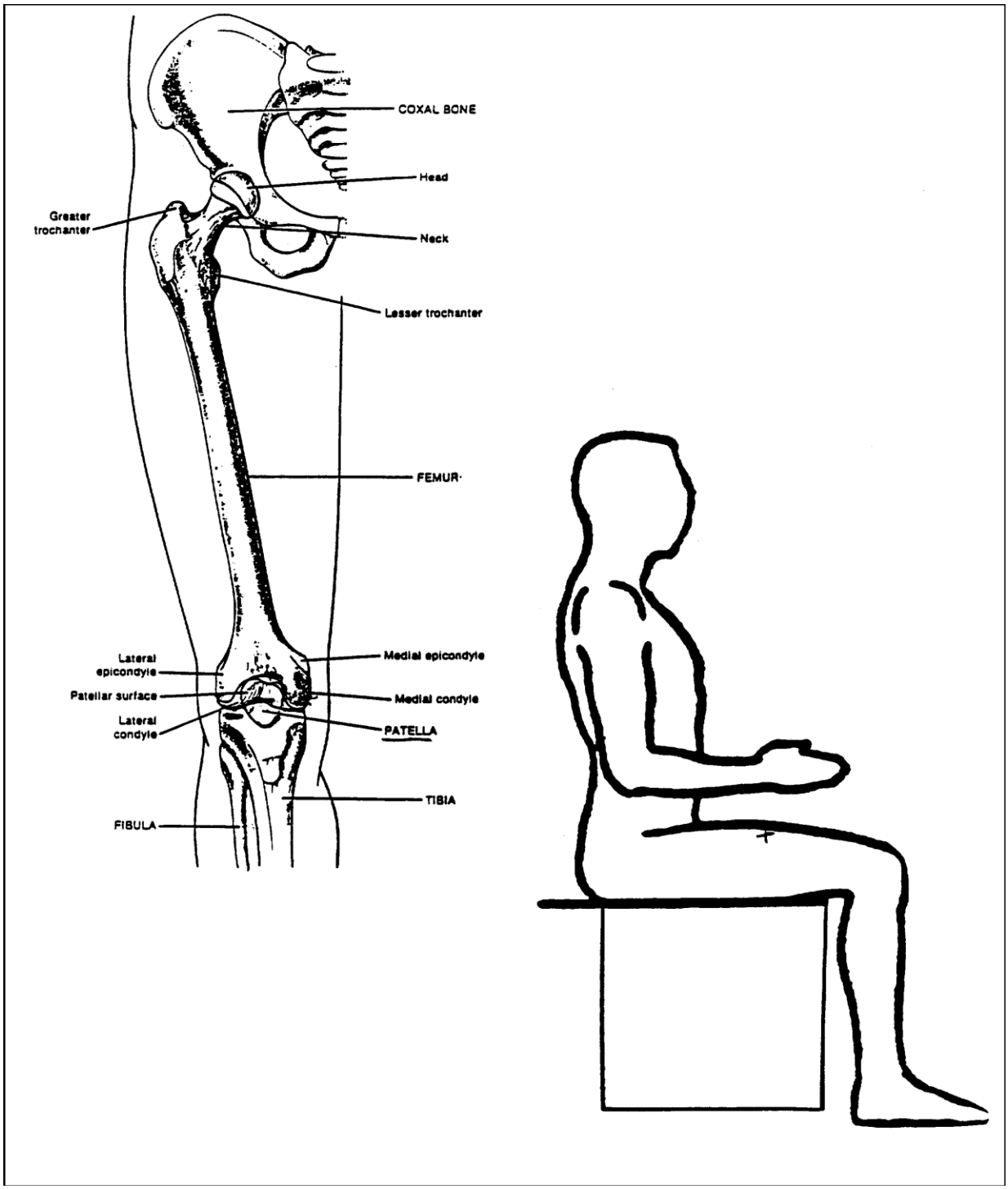
Inter-technician measurements
Supervisor observations
QC reports

Information on the Thigh Circumference Measurement found in this section was obtained through:
Health ABC Operations Manual Vol. III Chapter 2K, pages 1-8 Version 1.0 8/1/02
Health ABC Operations Manual Vol. III Chapter 3N, pages 1-7 Version 1.2 9/15/97

Health ABC Study: http://www.grc.nia.nih.gov/branches/ledb/healthabc/index.htm

[redacted]

Exhibit 3-3. SP position for upper leg length location and upper leg midpoint



http://www.cdc.gov/nchs/data/nhanes/nhanes3/cdrom/NCHS/MANUALS/ANTHRO.PDF

Neck Circumference

1. Participant stands erect, arms hanging loosely at sides, weight equally distributed on both feet, head positioned in the Frankfort horizontal plane.

2. Standing to face the left side of the participant, identify the thyroid cartilage by gentle palpation of the neck. Gently place your left index and second fingers on the front of the neck and ask the subject to swallow to help find the correct spot. You should feel a slight depression.

3. Place the superior border of the anthropometric tape just inferior to the laryngeal prominence.

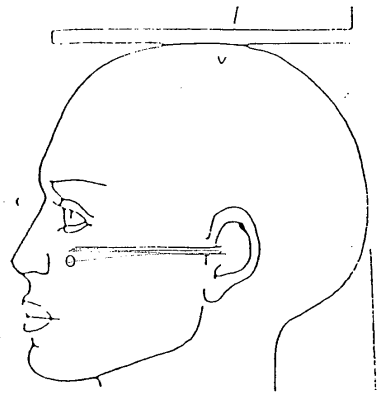
4. Apply the tape snugly, but not tightly, perpendicular to the long axis of the neck, which is not necessarily in the horizontal plane at approximately a 90 degree angle.

5. Record the neck circumference to the nearest 1/4 inch, rounding down.

6. The pressure on the tape should be the minimum required to maintain skin contact.

Note: Measurement is not taken during offsite visits.

Neck Girth



ORBITALE: Lower margin of eye socket
TRAGION: Notch above tragus of ear or at upper margin of zygomatic bone at that point
FRANKFORT PLANE: Orbitale-tragion horizontal line

Measurement of minimal neck circumference.

ECG Lead Placement

1. **V1:** The first intercostal space is palpated just below the clavicle. Count down and identify the 4th intercostal space just below the fourth rib. **Point V1** is just to the right of the sternum in the ***fourth*** intercostal space. Make a small line with a marking pencil here to show where the ECG lead should be placed.

2. **V2:** Should be at the same level as **Point V1** and immediately to the left of the sternum. Make a small line with a marking pencil to show where the ECG lead should be placed.

3. To locate the horizontal reference level for electrodes **(Point E)**, starting from **V2**, locate the **fifth** intercostal space. Move your finger in the **5th** intercostal space laterally to where the midclavicular (center of the chest where you feel a bend in the clavicle) line intersects the **fifth** intercostal space. Make a horizontal line at this point.

   Mark the exact transverse (horizontal) level at this spot with the midsternal line. It should be about one inch (1") below **V1** and **V2** placements.

4. **V6:** Move the participant's elbow laterally away from the body. Mark the midaxillary line in the exact vertical center plane of the thorax down to the intersection of the horizontal plane marked by the location of **E**. This is the exact location of **V6**. (***NOTE:*** It is a common mistake to locate the midaxillary line too far anteriorly, toward the **V5** location).

5. **V4:** Place the # arm of the Heart Square firmly across the lower sternum at the level of **Point E** (as you face the participant, the writing on the Heart Square will appear upside down and backwards). Adjust the **E** and **V6** arms of the Heart Square so they are both perpendicular to the long axis of the thoracic spine at the level of the **E** position. The **E** arm should be exactly horizontal. If the participant is lying flat, the **V6** arm should be exactly vertical.

   Slide the **V6** arm so the **0** point (the *arrow* labeled **V6**) is at the marked location for **V6**. Double check that the **E** arm is still in the correct spot.

   V4: On the **V6** arm (the slide), find the number corresponding to the **E** measurement. Following the corresponding 45 degree line to the surface (e.g. 16) and mark the location following the inside of the square. Place electrodes on ***TOP*** of the breast.

   The participant may now lower the left arm in a more comfortable position.

6. **V3:** Exactly halfway between **V2** and **V4**.

7. **V5:** Exactly halfway between **V4** and **V6**.

8. If he/she is known to be allergic to alcohol wipes, prepare the areas of electrode placement by rubbing with water and drying with a washcloth. If allergies are denied, prepare the areas by wiping with an alcohol wipe and drying with a washcloth.

> *NOTE:* Place the electrodes on the participant and hook up the leads before entering the data in the ECG machine. This will allow ample time for the participant to relax and the machine interference to smooth out.

9. Attach limb leads in the following order: right leg (RL), left leg (LL), right arm (RA), left arm (LA) parallel to the limb with tabs facing toward the heart. This will avoid lead reversal.

10. The body of the electrode is placed centrally at the pencil mark with the tab extending downward. Precordial electrodes are attached in the following order: V1, V2, V3, V4, V5, V6. Recheck all leads for proper placement.

11. Ask the participant to lie still and relax. In the computer, enter the participants Name, ID, Age, Height (clinic only), Weight, and Gender. Enter the Exam Cycle, Location (1=clinic 2=offsite), and your Tech ID.

12. The ECG is printed and reviewed for errors. If ECG needs to be run at **5 mmHg** because of high voltage (if the standard **10 mmHg** is beyond the lines of the ECG paper), highlight (yellow or orange highlighter) the **5 mmHg** on the bottom of the printed ECG. On the top margin of the tracing write " *1/2* ***STANDARD***" using a bold magic marker.

13. Leads are checked again for proper placement and disconnected. Electrodes are carefully removed.

14. After each use, wash the Heart Square gently with soap and water (1 part detergent to at least 20 parts water, approximately 3 drops of detergent to one cup of water) and gently wipe dry with a soft cloth.

Standard ECG & P-Hi Res Protocol

1. Ask the participant to lie supine on the examination table.

2. Inform them you will be performing an ECG and read the following script:

   An ECG is made up of waves showing the electrical activity in different parts of the heart. This new research test is an ECG that looks at a specific wave, the P wave, which shows activity in the top part of the heart. In order to get an accurate test please try to lie still. The test takes approximately 10 minutes.

3. Tell the participant you will be placing electrodes on their arms, legs, chest and back. Inform them you will be cleaning those areas with alcohol wipes as well as making marks on their chest with a cosmetic pencil.

4. If he/she is known to be allergic to alcohol wipes, prepare the areas of electrode placement by rubbing with water and drying with a washcloth. If allergies are denied, prepare areas V1, E, V2-V6, RL, RA, LL, LA, and I by wiping with a Tens Cote Cleaner. Let dry.

5. **V2**: The first intercostal space is palpated just below the clavicle. Count down and identify the 4th intercostal space just below the fourth rib. Point V2 is just to the left of the sternum in the fourth intercostal space. Make a small line with a marking pencil here to show where the ECG lead should be placed.

6. **V1**: Is at the same level as Point V2 and immediately to the right of the sternum. Make a small line with a marking pencil to show where the ECG lead should be placed.

7. **E**: To locate the horizontal reference level for electrodes (Point E), starting from V2, locate the fifth intercostal space. Move your finger in the 5th intercostal space laterally to where the midclavicular (center of the chest where you feel a bend in the clavicle) line intersects the fifth intercostal space. Make a horizontal line at this point.

   Mark the exact transverse (horizontal) level at this spot with the midsternal line. It should be about one inch (1") below V1 and V2 placements. **This is point E**.

8. **V6**: Move the participant's left elbow laterally away from the body. Mark the midaxillary line in the exact vertical center plane of the thorax down to the intersection of the horizontal plane marked by the location of E. **This is the exact location of V6.** (NOTE: It is a common mistake to locate the midaxillary line too far anteriorly, toward the V5 location).

9. **V4**: Place the # arm of the Heart Square firmly across the lower sternum at the

level of Point E (as you face the participant, the writing on the Heart Square will appear upside down and backwards). Adjust the E and V6 arms of the Heart Square so they are both perpendicular to the long axis of the thoracic spine at the level of the E position. The E arm should be exactly horizontal. If the participant is lying flat, the V6 arm should be exactly vertical.

Slide the V6 arm so the 0 point (the arrow labeled V6) is at the marked location for V6. Double check that the E arm is still in the correct spot.

On the V6 arm (the slide) find the number corresponding to the E measurement. Following the corresponding 45 degree line to the surface (e.g. 16) and mark the location following the inside of the square. **This is point V4**. Make mark on TOP of the breast. Note: For women with smaller breasts the measurements may land directly below the breast tissue.

The participant may now place their left arm in a more comfortable position next to their body.

10. **V3**: Exactly halfway between V2 and V4.

11. **V5**: Exactly halfway between V4 and V6.

12. **I**: While standing on the participant's right side move the participant's right elbow laterally away from the body. Mark the midaxillary line in the exact vertical center plane of the thorax down to the intersection of the horizontal plane marked by the location of E. **This is the exact location of I**.

    The participant may now place their right arm in a more comfortable position next to their body.

13. Place the electrodes on the participant in the following order: **LA, LL, RA, RL, V1, E, V2-V6, I, H, M.** For limb leads, the body of the electrode is placed parallel to the limb with tabs facing toward the heart. The rest of the leads have the tab extending downward on the body.

    Leg leads should be placed on the calf midway between the knee and ankle. If the participant has an amputation, the lead should be placed above this.

14. Place the Acquisition Module on the participants lap and ask them to hold it. Separate the leadwires. While holding wires 1 and 4 (the two longest wires) ask the participant to sit up. Move robe to expose the participant's back. Be sure to keep the participants chest as covered as possible

15. Ask the participant to sit up straight and prepare the skin by cleaning areas H and M with a Tens Cote Cleaner.

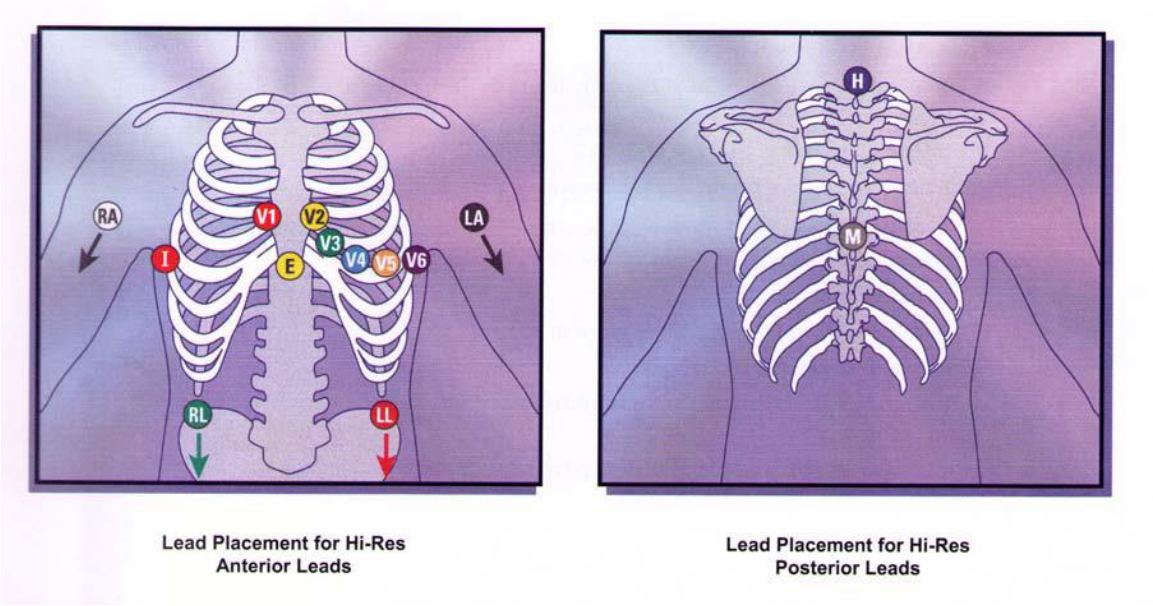
16. Place electrode H on the back of neck tab facing downward, on the bony prominence. If necessary, have the participant put his/her head forward to identify the bony prominence

17. Place electrode M at the center of spine tab facing downward, on the same horizontal level as lead E.

18. Connect leads H and M

19. Bring the wires over the participants left shoulder and ask the participant to lie down. Make sure the lead connections are not disrupted.

20. The remaining leads should be connected in the following order: **LA, LL, RA, RL, V1-V6, E, I**



Lead Placement for Hi-Res Anterior Leads

Lead Placement for Hi-Res Posterior Leads

21. Ask the participant to lie still and relax. In the computer, enter the participants Name, ID, Age, Height, Weight, and Gender. Enter the Exam Cycle, Location (1=clinic) and Technician ID Number.

    Note: When entering Height and Weight round up if the weight is ≥.5 or ≥ .50 for height.

22. Double check that all leads are connected properly.

23. Offer to cover the participant with a blanket or their robe. Note: If the participant is cold this could interfere with the quality of the ECG.

24. When a quality ECG is displayed on the computer screen hit ECG to store.

25. The ECG is reviewed and printed for errors

26. Verify ECG Data Storage to Mac 5000

    a) Press File Manager
    b) Highlight the Participants Name
    c) Press Display
    d) View and Verify the Participants Name and ECG Recording
    e) If ECG needs to be run at 5 mmHg because of high voltage (if the standard 10 mmHg is beyond the lines of the ECG paper), highlight (yellow or orange highlighter) the 5 mmHg on the bottom of the printed ECG. On the top margin of the tracing write "1/2 STANDARD" using a bold magic marker.

27. After the completion of the standard ECG again ask the participant to lay quietly and still during the acquisition of signal to decrease noise. Turn off the lights.

28. Begin the ECG P Hi Res by following the steps below in the computer:

    Hit Main → More → More (to get to P Hi-Res). Do NOT select Hi-Res.
    Same patient
    Press TEMPLATE
    Computer responds that it is acquiring template data and prints it out.
    Press AVERAGE
    After 250 beats have been averaged the acquisition will end.
    Press STORE

29. Leads are checked again for proper placement and disconnected after all leads are checked. Electrodes are carefully removed.

30. Click back on the Main Menu and next on Resting ECG. When it asks you if you want to use the information for the last participant hit no. The machine will be ready for the next participant.

31. Stamp both standard ECG and P Hi-Res ECG with #2.

32. Place standard ECG in participant's file for MD to review during exam.

33. Place paper copy of P Hi-Res ECG in folder in room.

P-Wave Signal Averaged Electrocardiogram Notes:

Parameters: Keep on 250 qualified beats.
During testing keep noise level less than 1 mv (if possible) it is normal for the noise to start out high and then diminish during the averaging process.
Do not change the QRS complexes settings.

When and how to abort test:

A decision not to complete the test may be made when a participant has:

1=atrial fibrillation
2=paced rhythm
3=frequent PVCs or APCs
4=tremor

If the P Hi-Res ECG runs more than 10 minutes abort the test.

Computer instructions to abort test:

Patient data
Template
Prints it
Average
Press "Pause" to abort test.
STORE

If you press Pause by mistake, then press Resume.

Troubleshooting Tips

Problems	Potential Causes	Approaches
Noisy signal	Cream on the body	Wash with washcloth
	Hair on body	Separate hair
	Problem with leads	Check procedure & lead placement
	Cold; tremulous	Place blanket
	Feet dangling	Feet all the way on table
	Talking patient	Ask patient to lay still and not talk
	Environmental noise Doppler's off	Try to turn off the lights Check Doppler

Adapted from Clinical Education and Development. MAC 5000 Resting ECG Analysis System Clinical Reference Guide, 030-CARD-MAC5000MT, Part No. 2015231-006

ECG CODING FOR FRAMINGHAM HEART STUDY EXAMINATIONS

General Comments

Although the computerized ECGs which are recorded in clinic include measurements of rate, intervals and axis, it is important that the examining MD carefully examine the ECG and record these features on the coding forms. Your measurements (not those made by the computer) form the basis of the official ECG interpretation.

An important rule to remember: Please ask for help when you are unsure about interpretation of ECGs or our methods of coding. Be sure to always look at the old ECG for interim changes.

HEART RATE

Each exam room is equipped with a rate stick with which heart rate can be measured. (The computer does a good job with this measurement).

INTERVALS

PR, QRS and QT intervals are measured in thousandths of a second based upon examination of the ECG recording. (Lead II should be used when possible for these measurements). A QRS of 0.080 seconds is coded as 080.

QRS ANGLE

This refers to frontal plane axis in degrees. Each exam room is equipped with a hexaxial device for measuring QRS axis. (The computer does a good job with this measurement).

CONDUCTION ABNORMALITY

IV BLOCK

This refers to right and left bundle branch block. Note that the code 1 is used for incomplete BBB and 2 is for complete BBB. For complete BBB the QRS interval should be .120 sec or greater. When the QRS is prolonged, but the pattern is not that of right or left BBB, the indeterminate IV block is coded as follows: 1=QRS .120 or greater, 2=QRS of .110 or .100. Remember that the measurements of QRS duration are those made by the examining physician and not by the computer. An RSR' pattern in the absence of QRS prolongation should be coded as normal. When an RSR' pattern occurs with a QRS duration of .090 sec or greater it represents incomplete RBBB.

HEMIBLOCK

1=left anterior. This is present when the QRS axis is -30 or less and small q wave is present in lead I.
2=left posterior. QRS axis is >90 and small q is present in AVF, in absence of evidence of right ventricular hypertrophy.

FASCICULAR BLOCK

1=bifascicular. A) If complete RBBB + (1st degree AV block or a hemiblock) are present. B) Complete LBBB.
2=trifascicular. If RBBB + hemiblock + 1st degree AV block. Or LBBB + 1st degree AV block.

AV BLOCK

1st degree when QRS duration is .20 seconds or greater (measured in lead II).
2nd degree when some P waves are not conducted. This comes in tow forms a) Mobitz I. When progressive PR prolongation precedes the dropped P wave and b) Mobitz II when QRS complexes are dropped without prior PR prolongation. AV dissociation occurs when P waves are QRS complexes march out independent of each other.

WPW

A short PR intervals is present (typically .12 seconds or less) and a slurred upstroke of the QRS is present (so called delta wave). When these features are both fulfilled, WPW=1. When the PR is .12 or less and a delta wave is possibly present, or when a delta wave is present but the PR is marginally short .13 to .14 seconds, WPW=2.

ATRIAL ENLARGEMENT

Right Atrial Abnormality

The P wave is inferior leads is peaked with a height of 2.5 mm.

Morris P wave

The terminal portion of the V wave in lead V1 is inverted and measures at least 1mm by 1mm (at normal standardization). This reflects left atrial enlargement.

MYOCARDIAL INFARCTION

This is determined on the basis of the appearance of wide (.04 seconds) or deep (1/4 the height or the R wave) q waves. All tracings should be compared to the prior exam ECG which is always provided. The appearance of new, but small q waves should also be regarded as suggestive of MI. Loss of R waves in leads where they were previously present (see prior exam's ECG) should also raise suspicion of MI. A posterior MI is present when R > S in V1, R is .04 seconds in duration, and an upright T wave is recorded in that lead. When criteria are largely, but incompletely fulfilled be sure to code this item as maybe!

MAXIMUM I WAVE AMPLITUDE <-5mm

This refers to giant inverted T waves at least 5mm deep. This condition is occasionally seen in hypertrophic cardiomyopathy.

LEFT VENTRICULAR HYPERTROPHY

Be sure to carefully code each of the voltage criteria individually. Definite LVH is present when increased voltage is present together with a strain pattern (downsloping ST). Possible LVH is present when voltage criteria are fulfilled but only mild ST-T abnormalities (flattening) are noted. For cohort Exam 21, we have a separate code for LVH by voltage only. When complete BBB is present, LVH should be coded as unknown (9).

RIGHT VENTRICULAR HYPERTROPHY

Definite RVH is present when increased R wave voltage is present in V1 and increase S wave voltage is present in V5 in the absence of RBBB. The sum of RV1 + SV5 should be at least 10.5mm.

ARRHYTHMIAS

The presence of rhythm disturbances should be made on the basis of examination of the ½ speed rhythm strip which accompanies each ECG. This represents a simultaneous 3 lead recording of the entire 12-lead ECG.

Ankle-Brachial Doppler Blood Pressure Measurement

Purpose
The ratio of the ankle blood pressure to the arm blood pressure provides a measure of lower extremity arterial disease (circulation problems).

A. Equipment:

1. 9.6 megahertz Doppler pen probe
2. Ultrasonic Doppler Flow Detector
3. Doppler conducting jelly
4. Standard mercury column sphygmomanometer
5. Calibrated V-Lok Cuff® comes in four sizes:
   - 4 large adult cuffs
   - 4 pediatric cuffs
   - 4 regular adult cuffs
   - 2 thigh cuffs
6. Washcloths to remove conducting jelly

Technicians should ask prior to setting up the participant:

1. Have you had any problems with blood clots in your leg?
2. If yes, are you being treated for this problem now?
3. If yes, do not test that extremity.

B. Exclusions

Lower Extremity Exclusions

1. Persons with venous stasis ulceration or other pathology that precludes placing a BP cuff around the ankle (e.g. open wounds).

   Code as 1

2. Persons with leg / arm amputations.

   Code as 2

3. Persons that are being treated for a DVT (deep vein thrombosis) or blood clot in the leg.

   Code as 1

If there is a current problem at the time of the exam then exclude the participant- any question ask the clinic MD.

Upper Extremity Exclusion

1. If a subject has undergone a mastectomy, blood pressure measurement will be excluded in that extremity only, and recorded as 1= mastectomy.

Note: If a subject refuses or does not complete the exam, code as a 3 (Other) and write in the reason.

C. Set-up Procedure:

1. Ask the participant:
   a. Have you had any problems with blood clots in your leg?
   b. If yes, are you being treated for this problem now?
   c. If yes, exclude that extremity.

2. If no, remove participant's shoes and stockings so that the ankles are bare to mid-calf.
3. Lay participant supine on the examining table. The participant should be supine on the exam table with the ankles at heart level not below
4. Keep participant supine for at least five minutes before measuring BP.
5. Place four BP cuffs on the participant (be sure to check for appropriate cuff size). (Note: The order in which the cuffs are placed on the participant is up to the technician.)

   a. Right arm
   b. Right ankle
   c. Left ankle
   d. Left arm

6. Apply ankle cuffs with midpoint of bladder over posterior tibial artery, with lower end of bladder approximately 3 cm above medial malleolus. To check for appropriate size, always start with the adult cuff. If that size is not correct, use either the adult large or pedi cuff, whichever is the correct size.

D. General Guide to Blood Pressure Readings:

For each participant, determine the maximal inflation level, or the pressure to which the cuff is to be inflated for blood pressure measurement. This assures that the cuff pressure at the start of the reading exceeds the systolic blood pressure and thus allows the first Kortokoff sound to be heard.

1. Attach the cuff tubing to the sphygnomanometer.

2. Palpate the brachial artery for right arm pulse, place the pen probe over the site to listen to the pulse.
3. Inflate the cuff rapidly until the brachial artery pulse is no longer heard by inflating rapidly to 70 mmHg, then inflating by 10mmHg increments.
4. The examiner's eyes should be level with the mid-range of the manometer scale and focused at the level to which the pressure will be raised.
5. Deflate the cuff quickly and completely.
6. The maximal inflation level is 30 mmHg **above** the systolic pressure.
7. Repeat procedure for right posterior tibial artery in the ankle.
8. Following any previous inflation, wait at least 30 seconds after cuff has completely deflated.

E. <u>Right Arm Systolic Blood Pressure Measurement</u>:

1. Attach right arm cuff tubing to manometer.
2. Apply ultrasound jelly over brachial artery.
3. Locate brachial artery using Doppler pen probe.
4. **Hold the Doppler probe *absolutely* still.** It can easily slip off the artery.
5. Measure the systolic blood pressure:
   a. Inflate cuff quickly to maximal inflation level (30 mmHg above systolic pressure).
   b. Deflate at 2 mmHg/second, to appearance of systolic pressure.
   c. Follow down for 10 mmHg. Two subsequent beats should be heard for any valid systolic blood pressure reading.
   d. Remove Doppler pen probe.
   e. Deflate cuff quickly and completely.
6. Neatly record systolic blood pressure.

F. <u>Right Ankle Systolic Blood Pressure Measurement</u>:

1. Connect right ankle cuff to the manometer.
2. Apply ultrasound jelly over posterior tibial artery.
3. Locate posterior tibial artery using Doppler pen probe.
4. **Hold the Doppler probe *absolutely* still.** It can easily slip off the artery.
5. Measure the systolic blood pressure:
   a. Inflate cuff quickly to maximal inflation level (30 mmHg above systolic pressure).
   b. Deflate at 2 mmHg/second to appearance of systolic pressure.
   c. Follow down for 10 mmHg. Two subsequent beats should be heard for any valid systolic blood pressure reading.
   d. Remove Doppler pen probe.
   e. Deflate cuff quickly and completely.
6. Neatly record ankle systolic blood pressure.
7. If a systolic pressure is unable to be obtained (beats can be heard to 300mmHg) than record the reading as 300.

G. Repeat Section F for Left Ankle

H. Repeat Section E for Left Arm

IMPORTANT: If the blood pressure differs by ≥ 20mmHg in the right and left arms, the technician should notify the clinic physician. Also notify the physician if the ankle BP(s) are much lower than the arm(s).

NOTE: If the posterior tibial pulse cannot be found with palpation or Doppler pen probe, use the dorsalis pedis artery for the measurement. Have another examiner verify the absent posterior tibial pulse.

I. Repeat of Ankle and Arm Blood Pressure Measurements:

1. Repeat the sequence of measures in reverse order:

    a. Left arm
    b. Left ankle
    c. Right ankle
    d. Right arm

NOTE: If initial and repeat blood pressures measured at any one site (Right arm, Left arm, Right ankle or Left ankle) differ by more than 10 mmHg, please take a third measurement at that site and record it.

J. For Ankle Measurements record which site the measurement was taken from

0= posterior tibial (ankle)
1=dorsalis pedis (foot) Have second tech. verify that pulse cannot be heard on posterior tibial

K. Record any lower or upper extremity exclusions on data form

L. Note any protocol modifications on data form

M. Completion:

1. Review form for completeness and legibility.
2. Remove cuffs and conducting jelly.

N. Resources:

http://hearthub.org/index.htm?VideoLibrary=1

http://www.medmovie.com/mmdatabase/MediaPlayer.aspx?ClientID=65&TopicID=665

Ankle-Brachial Blood Pressure is not done on Offsite Visits

Observed Physical Performance

A. Overview:

An objective performance measure of physical functioning is an assessment instrument in which an individual is asked to perform a specific task and is evaluated in an objective, standardized manner using predetermined criteria, which may include counting of repetitions or timing of the activity as appropriate. Two theoretical models of the pathway from disease to disability have been developed. The first comes from the World Health Organization and goes from disease to impairment to disability, to handicapped. The second, which is being used more now by geriatricians and aging researchers, progresses from disease, to impairment, to functional limitations to disability.

B. Methods:

During all tests, participant safety is paramount. Participants who do not feel safe or who are unable to perform a test should not be pressed. All procedures should be clearly demonstrated to the participant prior to performing any test and the participant should be queried to ensure that they understand the instructions. If it is obvious that the participant has not understood the directions, reread the standard instructions. You will be demonstrating each maneuver. Someone who may not completely understand the verbal instructions may still be able to perform the test following the demonstration.

C. Equipment:

1. Data sheets
2. Pen
3. Stopwatch
4. 1 armless straight back chair approximately 18" high from floor to top of seat
5. Masking Tape
6. JAMAR Dynamometer
7. Straight back chair with arm rests
8. Measured 4 meter walking course (3-4 meters for offsite exams)
9. Gait Measurement Device
10. Gait Timer

D. A note on encouragement:

If a participant expresses doubt as to whether he or she can perform the task, ask the participant whether they would like to try. If they say yes, proceed with the task but if they say no, honor the participant's choice to decline the testing.

E. Introductory script:

We are going to try to do different physical activities.

I will first explain what I would like you to do, then I will demonstrate it for you and then I will ask you to try it for me.

F. Performance Measures:

1. Hand Grip Strength Test

2. Repeated Chair Stands (5)

3. Measured Walks

JAMAR Hand Grip Strength Test

1. *Script*: ***This instrument will measure your grip strength. The instrument is a little heavy, so be careful. When I tell you, I want you to squeeze the instrument as hard as you can. Do not expect the handle to move very much.***

2. Participant is seated in chair with feet flat on the ground and forearms resting on chair arms, elbows are at about a 90 degree angle.

3. Participant should hold JAMAR in upright position and the wrist is in neutral position. The hand grip can be adjusted for those with larger hands.

4. The examiner should be close enough to the participant to be able to catch the JAMAR in case it is dropped.

5. Make sure that red peak-hold needle is set to zero.

6. Tell participant to squeeze as hard as s/he can, and squeeze until you tell s/he to stop.

7. Say "Ready, Squeeze" once. Have participant hold squeeze for a 3 to 5-1000 second count.

8. Take back JAMAR, hold at eye level, about a foot from your eyes, and record reading on the kilogram scale. If directly in the middle of the scale then the reading is the odd number between the two even hash marks; otherwise record as the closest hash mark.

7. Repeat steps until three measurements are recorded with the right hand.

8. Repeat steps for three trials with the left hand.

9. If only one hand is completed then test is still coded as completed.

Repeated Chair Stands (5)

Description:

The participant will first observe the examiner completing one chair stand. Arms will be folded across chest; feet flat on the floor and the chair should be placed up against the wall. The participant will then attempt to stand up once from his chair without using his or her arms. This is not timed. If he or she is able to do this, then proceed to the timed five consecutive chair stands.

If participant feels it is unsafe, skip the chair stands

Do you think it is safe to try to stand up from a chair without using your arms?

The next tests measure the strength in your legs. First, I will ask you to fold your arms across your chest and sit so that your feet are flat on the floor. Then I will ask you to stand up without using your arms.

Please watch while I demonstrate.

Please fold your arms across your chest and begin when I say, "Ready, Begin."

Stand in front of the participant before he or she begins. Be prepared to supply physical support if the participant's safety requires it, but do not stand so close as to impede the task.

If he or she cannot get up from the chair the first time without using their arms, ask them to try standing up using their arms. If arms are needed then the test is stopped and not continued.

Do you think it is safe to try and stand up from a chair five times without using your arms?

If participant does not feel that it would be safe, abort the five chair stands and record on data sheet.

I will ask you to stand up straight, as quickly as you can, five times without stopping in between. After you stand up each time, sit down and then stand up again. Keep your arms folded across your chest. I will be timing you.

Please watch while I demonstrate.

Please fold your arms across your chest and begin when I say, "Ready, Begin".

Procedure:

1. Start timing on the word “Begin”.

2. Count out loud and only when the participant has straightened up so that you do not pace the test with your counting.

3. If the participant appears to be fatigued before completing all five stands, ask if they can continue. Only if they say “no” should the examiner stop timing and stop the procedure.

4. If the participant did not use his or her hands during the initial chair stand, but begins to use them during the repeated stands, then stop.

5. If, after one minute has elapsed, the participant has not completed all five stands, then stop.

6. Stop timer on the end on the fifth raise when they are standing up completely.

7. Do not coach the participant or encourage then during the test. You may do so after.

The following questions should be answered for each stand:

1. Time to complete five stands in seconds
2. If less than five stands, enter the number
3. If Offsite visit, chair height
4. Check if this test not completed or attempted
5. If not attempted or completed, why not?
   1=Physical Limitation
   2=Refused
   3=Other_____write in
   9=Unknown

Observed Performance Scoring:

If a participant has an actual measured time of 9.99, make a note on the exam stating that the figure represents an actual time as opposed to unknown, and flag the variable so that when it gets cleaned, whoever is cleaning can make a point of changing the person's time back from missing.

Otherwise, round the time up to ten seconds and code that the participant was able to hold their position for 10 seconds.

Measured Walks

Description:

The participant will first observe while **the examiner demonstrates** how to walk the measured course at a normal pace. The participant will then be asked to walk the measured 4 meter course at their normal walking pace. Next, he or she will repeat this normal pace while being timed twice. The examiner will then demonstrate the fast pace walk and the participant will be asked to walk the course at a fast pace while being timed.

In Clinic only, the participant must be wearing socks or shoes they cannot be barefoot. If Offsite, a 3 meter course may be used if a 4 meter course is not available (this will be marked on the data sheet).

A cane or walker may be used during the walk, but if participants with such devices can walk short distances without them, they should be encouraged to do so. Many people with assistive devices use them only when they walk outdoors or for long distances indoors. Doing the test without the device provides a much more accurate assessment of the functional limitation of the participant. Ask the participant if he/she ever walks at home without the device. Then ask the participant if s/he thinks he/she can walk a short distance for the test. Participants who normally use assistive devices should be watched particularly closely during the test to prevent falling.

If a walking aid is used, this will be recorded:

Coding

0 = No aid	**2** = Walker	**4** = Other
1 = Cane	**9** = Unknown	

Training Note: we do not do timed walks for participant in a wheelchair.

Methods:

The walking course should be unobstructed and include at least an extra one-half meter on each end. You will need a measuring tape to measure the distance of the walking course and masking tape to mark the starting and finish lines. An X should be made at the end of the course approximately one foot after the finish line. At each end of the course there will be laser that will also be timing the participant.

Before starting the walk test, turn the power switch that is located on the timer box to "On". Make sure that a solid red light is lit on top of each of the 2 photoelectric diodes.

Note: If the red light is not on or if it is flickering this means that the reflected beam of the diode is not properly lined up with the reflector, simply adjust the diode (slowly move it back and forth) until a solid red light persists.

Procedures:

1. Have the participant line their toes up with the starting line.

2. Hit the "Reset" Button on the Timer Box.

3. Wait at least 2 seconds for the Laser Walk Test screen to read "Ready."

4. The examiner should be standing at the end of the course outside of the laser field to the side with a clear view of the start and finish line and the laser devices.

5. Have the stop watch set at zero and say "*Ready, begin*".

6. Start timing with the stopwatch when you see the participant start to move keeping an eye on the laser for a blink at the start. Stop timing when the participant breaks the plane and the laser blinks at the end of the course*. The laser walk will automatically record the test time using the laser.

7. Record both the stop watch time and the laser time in seconds to the thousandths place on the data collection form. If the laser time and hand timer differ by more than 0.30 repeat the laser walk.

8. If the test needs to be repeated due to participant or staff error, hit the "Reset" button on the timer box and start over.

***If the laser device does not blink at the start and end of the participant walk redo the laser walk. This will ensure there are no false start or end times.**

1. <u>Walk #1</u>:

Script: Now I am going to observe how you normally walk, if you use a cane or other walking aid and would be more comfortable with it, you may use it.

This is our walking course. I want you to walk to the other end of the course at your usual speed, just as if you were walking down the street. Keep walking until I tell you to stop. Please ignore the tape on the floor.

Please watch while I demonstrate. After the demonstrations ask, do you think this will be safe? If they say yes, proceed. If not, abort test.

Have the participant line up his or her toes behind the line on the floor. Start the laser box and start timing with the stopwatch when you see the participant start to move and stop timing when the participant breaks the plane at the end of the course. Record the stopwatch & laser time on the data sheet.

2. Walk #2:

Script: Now I want you to repeat the walk. Remember to walk at your usual pace, and keep walking until I tell you to stop.

Ready? Begin.

3. Walk #3:

Script: Now I want you to repeat the walk again, but this time, I would like you to walk at a rapid pace, as fast as you can. Make sure you continue walking until I tell you to stop.

Please watch while I demonstrate. Do you think this will be safe for you to do?

Ready? Begin.

Coding:

For each walk, the following questions will be answered:

1. Walk time
2. Course in Meters (3 or 4) for Offsite visits only
3. Walking Aid used (0=No aid, 1= Cane, 2= Walker, 3=Other, 9=Unknown)
4. Check if this test not completed or attempted
5. If not attempted or completed, why not?
   1=Physical Limitation
   2=Refused
   3=Other_____write in
   9=Unknown

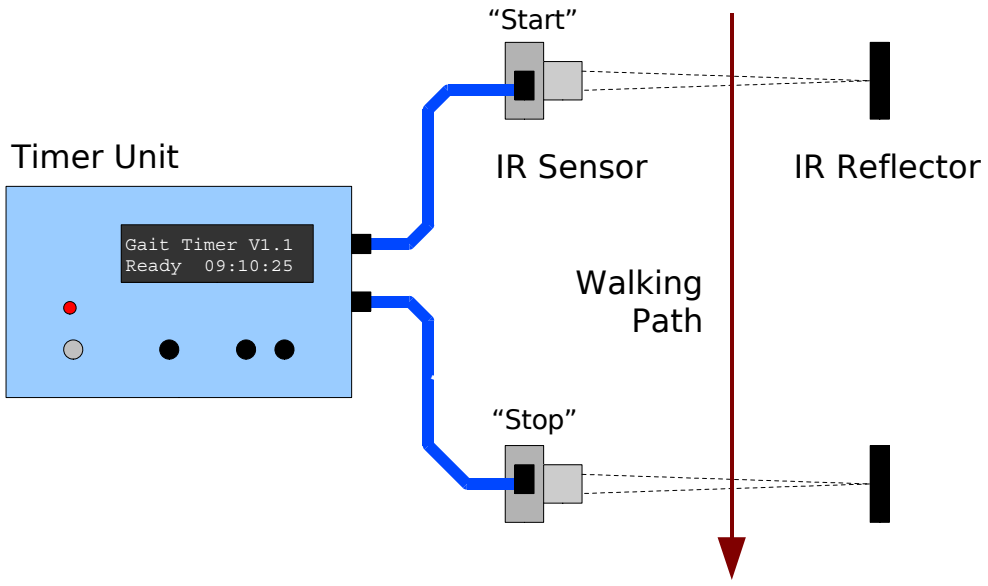
Information on Observed Physical Performance found in this section was obtained through:
Guralnik MD, PhD, Jack. Assessing Physical Performance in the Older Patient: An overview of the Short Physical Performance Battery (SPPB). CD-ROM. 2003
Timed Laser Walk(s) were obtained through: ***FHS Laser Walk Test Manual 6/23/06***
Handgrip protocol was obtained through*:* ***Performance-Based Measures of Physical Function for High-Function Population. Curb, David et al.***

Framingham Heart Study

Gait Measurement Timer
User's Guide

1/27/2009

This device is designed to measure the walking speed of a person over a fixed distance. It consists of two IR (infra-red) sensor boxes with companion reflectors and a central timer unit.



A diagram of the system is shown above. The two infrared (IR) sensors are placed on one side of the walking path pointing at right angle to the path. A reflector is mounted directly across from each sensor. A cable connects each sensor to the timer unit.

Operation

The unit may be powered by batteries or an AC power adapter. When the AC adapter is plugged in to the unit, the batteries are disconnected. To set up the system, plug a cable into each IR sensor, and plug the other end into one of the

connectors (it doesn't matter which connector is chosen they are both equivalent) on the timer unit. Plug the AC adapter (if using) into a wall outlet and into the timer unit. Turn the power switch to “ON” (down). The red LED above the power switch should light and the LCD display light up.

Sensor Alignment

The IR sensors send a beam of infra-red (invisible) light to a reflector, which is received by a detector in the sensor box. Each sensor must be carefully aligned with a reflector before use.

Mount each IR sensor securely to a fixed object, with the sensor head (metal block with three holes) pointing directly across the walking path. Test the sensor by holding your hand or a piece of paper in front of the head a few inches away. The red LED light on the sensor should come on. This light indicates that the IR beam is actively being received.

Mount the reflector directly across from the sensor, and carefully position it such that the red LED is on. Move it around a bit to find the center of the region where the LED is lit, and attach the reflector securely to a fixed object.

Perform the same procedure with the other sensor. Double-check that the LEDs are lit on both sensors. Wave your hand between the sensor and reflector, and observe that the led goes off momentarily when the beam is interrupted.

Timer Operation

Turn the unit on. With both sensors connected, press the **RESET** button. The display should look like this:

```
Gait Timer V1.3
Ready  10:24:45
```

If the display shows changing numbers in place of “Ready” then one of the sensors is not properly aligned or the timer has been falsely triggered. The current time of day should be displayed. If the time is incorrect, it may be set by pressing the HOUR and MIN buttons.

Interrupt the one of the sensor beams (this is now the **start** sensor). The display should look like this:

```
Gait Timer V1.3
##.#   10:43:21
```

where ##.# shows the elapsed time. Interrupt the other sensor sensor beam. The display should look like this:

```
04.425 10:45:20
Ready  10:43:55
```

The top line of the display shows that the elapsed time between **start** and **stop**

was 4.425 seconds, and that the **stop** occurred at 10:45:20.

Interrupt the two beams beams again. The display should look line this:

```
04.425 10:45:20
02.361 10:48:37
```

This indicates that the elapsed time for the second measurement was 2.361 seconds and that the second **stop** occurred at 10:48:37.

If the time between **start** and **stop** exceeds 30 seconds, the display will show "30.0". In this case, press RESET and start the measurements again.

After the first measurement is completed, the second measurement cannot start until *two seconds have passed*. This should prevent false triggers due to (for example) the subject's trailing foot interrupting the beam immediately after the leading foot. The display will momentarily show "`Wait`" during the delay.

Timer Operation Tips

- The operator should occupy a position where both sensor lights (red LED beam indicating) and the gait timer display is visible.
- The operator should ensure that the timer starts and stops as the patient crosses the two beams. To do this, monitor the timer display, and beam indicating lights on the sensors. The first sensor light will blink as the patient crosses the beam. This will initiate the timer. The second sensor light will blink as the patient crosses the beam. This will stop the timer. If something goes wrong, hit the RESET button and restart the trial.
- Note that the internal timer electronics operate at a much faster rate than that of the display. The display may seam sluggish to respond although the internal timing is still accurate.

Battery Replacement

The timer will operate on AA batteries if the AC power is unplugged. The unit requires 6 AA batteries, which are mounted inside the timer unit. To replace the batteries, remove the six screws around the lid of the unit and carefully remove the lid. Avoid disconnecting any of the wires if possible.

Replace the 6 batteries with new ones, making sure that the negative (-) terminal of each battery is against the spring in its holder.

Replace the lid, being careful that all the wires are completely inside and replace the six screws.

Service Contact Information

Mailing Address:

Boston University Electronics Design Facility

590 Commonwealth Avenue, Physics Room 255

Boston, MA 02215

Location:

The EDF is located at 3 Cummington Street (Physics Research Building) in Room 461. The building is behind Morse Auditorium, and across from the Metcalf Science Center (SCI) at 590 Commonwealth Ave.

Phone: (617) 353-4117

Fax: (617) 353-3331

Email: info@edf.bu.edu

Website: http://edf.bu.edu/

Detailed Project Documentation:

http://ohm.bu.edu/cgi-bin/edf/Gait_Measurement_Timer

Gait Speed and Survival in Older Adults

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Context Survival estimates help individualize goals of care for geriatric patients, but life tables fail to account for the great variability in survival. Physical performance measures, such as gait speed, might help account for variability, allowing clinicians to make more individualized estimates.

Objective To evaluate the relationship between gait speed and survival.

Design, Setting, and Participants Pooled analysis of 9 cohort studies (collected between 1986 and 2000), using individual data from 34 485 community-dwelling older adults aged 65 years or older with baseline gait speed data, followed up for 6 to 21 years. Participants were a mean (SD) age of 73.5 (5.9) years; 59.6%, women; and 79.8%, white; and had a mean (SD) gait speed of 0.92 (0.27) m/s.

Main Outcome Measures Survival rates and life expectancy.

Results There were 17 528 deaths; the overall 5-year survival rate was 84.8% (confidence interval [CI], 79.6%-88.8%) and 10-year survival rate was 59.7% (95% CI, 46.5%-70.6%). Gait speed was associated with survival in all studies (pooled hazard ratio per 0.1 m/s, 0.88; 95% CI, 0.87-0.90; $P < .001$). Survival increased across the full range of gait speeds, with significant increments per 0.1 m/s. At age 75, predicted 10-year survival across the range of gait speeds ranged from 19% to 87% in men and from 35% to 91% in women. Predicted survival based on age, sex, and gait speed was as accurate as predicted based on age, sex, use of mobility aids, and self-reported function or as age, sex, chronic conditions, smoking history, blood pressure, body mass index, and hospitalization.

Conclusion In this pooled analysis of individual data from 9 selected cohorts, gait speed was associated with survival in older adults.

JAMA. 2011;305(1):50-58 www.jama.com

REMAINING YEARS OF LIFE VARY widely in older adults, and physicians should consider life expectancy when assessing goals of care and treatment plans.[1] However, life expectancy based on age and sex alone provides limited information because survival is also influenced by health and functional abilities.[2] There are currently no well-established approaches to predicting life expectancy that incorporate health and function, although several models have been developed from individual data sources.[3-5] Gait speed, also often termed *walking speed*, has been shown to be associated with survival among older adults in individual epidemiological cohort studies[6-12] and has been shown to reflect health and functional status.[13] Gait speed has been recommended as a potentially useful clinical indicator of well-being among the older adults.[14] The purpose of this study is to evaluate the association of gait speed with survival in older adults and to determine the degree to which gait speed explains variability in survival after accounting for age and sex.

For editorial comment see p 93.

METHODS

Overview

We used individual participant data from 9 cohort studies, baseline data for which were collected between 1986 and 2000 (TABLE 1).[8,15,16,18-23] Each study, which included more than 400 older adults with gait speed data at baseline, monitored survival for at least 5 years. Analyses performed herein were conducted in 2009 and 2010. All studies required written informed consent and institutional review board approval.

Populations

All studies recruited community-dwelling older adults. Although some sought representative samples,[8,15,20,23] others focused on healthier participants,[16,17] single sex,[19,22] or older adults from primary care practices.[21] Only

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Table 1. Characteristics of Participants in the 9 Cohort Studies

	No. (%) of Participants by Study								
Study	CHS[8]	EPESE[15]	Health, ABC[16,17]	Hispanic EPESE[8]	Invecciare in Chianti[18]	Osteoporotic Fractures in Men[19]	NHANES III[20]	PEP[21]	Study of Osteoporotic Fractures[22]
Sample size, No.	5801	2128	3048	1905	972	5833	3958	491	10 349
Women	3336 (57.51)	1404 (65.98)	1575 (51.67)	1098 (57.64)	541 (55.66)	0	2044 (51.64)	216 (43.99)	10 349 (100)
Race/ethnicity									
White	4854 (83.68)	2126 (99.91)	1783 (58.50)	0	972 (100)	5223 (89.54)	2535 (64.05)	394 (80.24)	9662 (93.36)
Black	909 (15.67)	2 (0.09)	1265 (41.50)	0	0	235 (4.03)	699 (17.66)	89 (18.13)	654 (6.32)
Hispanic	0	0	0	1905 (100)	0	122 (2.09)	623 (15.74)	0	0
Other	38 (0.66)	0	0	0	0	253 (4.34)	101 (2.55)	8 (1.63)	33 (0.32)
Age mean (SD), y	72.81 (5.58)	78.85 (5.52)	73.62 (2.87)	74.74 (5.96)	74.58 (7.08)	73.61 (5.84)	75.17 (6.93)	74.08 (5.74)	71.81 (5.21)
Age group, y									
65-74	3852 (66.40)	559 (26.27)	1912 (62.73)	1083 (56.85)	555 (57.10)	3401 (58.31)	2033 (51.36)	279 (56.82)	7486 (72.34)
75-84	1732 (29.86)	1204 (56.58)	1136 (37.27)	668 (35.07)	302 (31.07)	2183 (37.42)	1484 (37.49)	188 (38.39)	2596 (25.08)
≥85	217 (3.74)	365 (17.15)	0	154 (8.08)	115 (11.83)	249 (4.27)	441 (11.14)	24 (4.89)	200 (1.93)
Missing	0	0	0	0	0	0	0	0	67 (0.65)
Gait speed, mean (SD), m/s	0.86 (0.22)	0.83 (0.13)	1.12 (0.23)	0.56 (0.23)	1.00 (0.28)	1.19 (0.23)	0.68 (0.23)	0.88 (0.24)	0.95 (0.22)
Gait speed class, m/s									
<0.4	149 (2.57)	0	4 (0.13)	515 (27.03)	35 (3.60)	11 (0.19)	480 (12.13)	20 (4.07)	33 (1.19)
≥0.4 to <0.6	526 (9.07)	78 (3.67)	20 (0.66)	621 (32.60)	59 (6.07)	54 (0.93)	897 (22.66)	40 (8.15)	466 (4.50)
≥0.6 to <0.8	1887 (32.53)	791 (37.17)	189 (6.20)	467 (24.51)	110 (11.32)	206 (3.53)	1368 (34.56)	110 (22.40)	1752 (16.93)
≥0.8 to <1.0	2076 (35.79)	1105 (51.93)	705 (23.13)	220 (11.55)	246 (25.31)	875 (15.00)	887 (22.41)	166 (33.81)	3768 (36.41)
≥1.0 to <1.2	1077 (18.57)	135 (6.34)	1093 (35.86)	77 (4.04)	305 (31.38)	1774 (30.41)	294 (7.43)	116 (22.63)	3054 (29.51)
≥1.2 to <1.4	0	17 (0.80)	684 (22.44)	4 (0.21)	170 (17.49)	1911 (32.76)	32 (0.81)	36 (7.33)	970 (9.37)
≥1.4	86 (1.48)	2 (0.09)	353 (11.58)	1 (0.05)	47 (4.84)	1002 (17.18)	0	3 (0.61)	217 (2.10)
Mobility aid use									
None	NA	1962 (92.20)	3048 (100)	1817 (95.38)	881 (90.64)	5792 (99.30)	3664 (92.57)	463 (94.11)	10 165 (98.22)
Cane	NA	87 (4.09)	0	49 (2.57)	8 (0.82)	38 (0.65)	201 (5.08)	21 (4.27)	All aids
Walker	NA	67 (3.15)	0	23 (1.21)	3 (0.31)	0	74 (1.87)	5 (1.01)	Combined
Other/missing	NA	12 (0.56)	0	16 (0.84)	80 (8.23)	3 (0.05)	19 (0.48)	3 (0.61)	184 (1.78)
BMI, mean (SD)	26.68 (4.71)	26.63 (4.64)	27.40 (4.82)	27.91 (5.13)	27.51 (4.11)	27.39 (3.83)	26.66 (5.11)	27.53 (5.12)	26.61 (4.57)
BMI category									
<25	2237 (38.65)	803 (38.24)	983 (32.25)	555 (29.13)	276 (28.40)	1593 (27.31)	1544 (39.01)	156 (31.77)	4352 (42.05)
25-30	2407 (41.49)	886 (42.64)	1288 (42.26)	758 (39.79)	437 (46.96)	2991 (51.28)	1559 (39.39)	211 (42.97)	3842 (37.12)
>30	1144 (19.72)	411 (19.31)	777 (25.49)	577 (30.29)	243 (25.00)	1247 (21.38)	852 (21.53)	123 (25.05)	2155 (20.82)
Missing	13 (0.22)	28 (1.32)	0	15 (0.79)	16 (1.65)	2 (0.03)	3 (0.08)	1 (0.20)	0
Hospitalized past year	NA	395 (18.57)	456 (14.98)	304 (15.96)	129 (13.27)	NA	775 (19.58)	97 (19.76)	1116 (11.51)
Diseases									
Cancer	830 (14.33)	486 (22.84)	575 (18.91)	115 (6.04)	95 (9.77)	1697 (29.09)	387 (9.78)	113 (23.01)	NA
Arthritis	2977 (51.94)	2055 (96.57)	1706 (56.72)	812 (42.62)	304 (31.31)	2764 (47.39)	1827 (46.16)	286 (58.25)	6003 (63.10)
Diabetes	690 (11.90)	335 (15.74)	453 (14.88)	455 (23.88)	106 (10.91)	624 (10.70)	607 (15.34)	84 (17.11)	681 (7.04)
Heart disease	1230 (21.20)	312 (14.66)	652 (22.03)	155 (8.14)	49 (5.05)	1379 (23.64)	484 (12.23)	89 (18.13)	NA
Self-reported health excellent/ very good	2177 (37.61)	542 (74.48)	1343 (44.12)	870 (45.67)	591 (62.61)	5012 (85.95)	1204 (30.47)	229 (46.64)	8537 (82.49)
Total deaths during follow-up	3851 (66.39)	1955 (91.87)	848 (27.82)	972 (51.02)	187 (19.24)	1073 (18.40)	2837 (71.68)	293 (59.55)	5512 (53.26)
Median survival years (95% CI)	13.25 (13.00-13.56)	9.57 (9.17-9.92)	NE	11.70 (11.11-NE)	NE	NE	9.86 (9.53-10.19)	11.15 (9.82-11.92)	17.23 (16.97-17.47)
Follow-up period, median (range), y	13.25 (0.01-18.06)	9.57 (0.10-20.65)	9.00 (0.02-9.00)	11.54 (0.07-12.29)	6.00 (0.18-6.00)	6.84 (0.04-8.26)	9.86 (0.08-17.75)	11.15 (0.12-13.76)	15.03 (0.02-21.00)
Length of walk	15 feet	8 feet	6 m	8 feet	4 m	6 m	4 m	4 m	6 m
Year of baseline data collection	1989-90, 1992-93	1987-1989	1997-1998	1995-1996	1998-2000	2000-2002	1988-1994	1996	1986-1988, 1997
Year of most recent mortality follow-up	2007	2008	2007	2007	2006	2008	2006	2010	2008

Abbreviations: ABC, Aging and Body Composition; BMI, body mass index, calculated as weight in kilograms divided by height in meters squared; CHS, Cardiovascular Health Study; CI, confidence interval; EPESE, Established Populations for the Epidemiological Study of the Elderly; NA, not applicable; NE, not estimable due to insufficiently long follow-up and resulting in low mortality rate less than or close to 50%; NHANES III, Third National Health and Nutrition Examination Survey; PEP, Predicting Elderly Performance.

participants 65 years and older with baseline gait speed data were included in this study. Individual study goals, recruitment methods, and target populations have been published.[8,15-23]

Measures

Gait speed was calculated for each participant using distance in meters and time in seconds. All studies used instructions to walk at usual pace and from a standing start. The walk distance varied from 8 ft to 6 m. For 8 ft, we converted to 4-m gait speed by formula.[24] For 6 m, we created a conversion formula (4-m speed = –0.0341 + (6-m speed) × 0.9816 with R^2 = 0.93, based on a cohort of 61 individuals with concurrent 4- and 6-m walks). For 15 feet (4.57 m),[23] speed was simply meters divided by time. Where available, data on fast gait speed (walk as fast as comfortably able[25]) and the Short Physical Performance Battery were obtained.[26] Survival for each individual used study monitoring methods, including the National Death Index and individual study follow-up. Time from gait speed baseline to death was calculated in days. Five-year survival status was confirmed for more than 99% of participants.

Additional variables include sex, age, race/ethnicity (white, black, Hispanic, other, defined by participant), height (centimeters), weight (kilograms), body mass index (BMI), calculated as weight in kilograms divided by height in meters squared (<25, 25-30, and >30), smoking (never, past, current), use of mobility aids (none, cane, walker), systolic blood pressure, self-reports of health (excellent or very good vs good, fair, or poor), hospitalization in the past year (yes/no), and physician-diagnosed medical conditions (cancer, arthritis, diabetes, and heart disease, all yes/no). Measures of self-reported functional status were not collected in all studies and varied in content and form. We created a dichotomous variable reflecting dependence in basic activities of daily living (ADLs) based on report of being unable or needing help from another person to perform any basic activity, including eating, toileting, hygiene, transfer, bathing, and dressing. For individuals independent in ADLs, we created a dichotomous variable reflecting difficulty in instrumental ADLs based on report of difficulty or dependence with shopping, meal preparation, or heavy housework due to a health or physical problem. Participants were then classified into 1 of 3 groups; dependent in ADLs, difficulty with instrumental ADLs, or independent. Physical activity data were collected in 6 studies, but time frames and items varied widely. Two studies used the Physical Activity Scale for the Elderly (PASE).[27] We dichotomized the PASE score at 100.[28] We created operational definitions of other covariates that were reasonably consistent across studies. Covariates were identical for height, weight, BMI, and systolic blood pressure. Hospitalization within the prior year was determined largely by self-report, and chronic conditions were by self-report of physician diagnosis, with heart disease encompassing angina, coronary artery disease, heart attack, and heart failure.

Statistical Analysis

Descriptive statistics summarized participant characteristics, follow-up period, and median survival from baseline. A study-wide a priori *P* value of .002 provides a conservative Bonferroni correction accounting for at least 25 individual statistical comparisons. Kaplan-Meier product-limit survival curves graphically summarize lifetimes for each gait speed category.[29] For graphical purposes, gait speed was categorized into 0.2-m/s increments with lower and upper extremes being grouped as less than 0.4 m/s and higher than 1.4 m/s.

Cox proportional hazards regression models were used to assess associations between gait speed and survival, adjusting for age at baseline, for which hazard ratios (HRs) correspond to a 0.1-m/s difference in gait speed. The analyses were repeated adjusting for height, sex, race, BMI, smoking history systolic blood pressure, diseases, prior hospitalization, and self-reported heath. Proportionality of hazards was verified by examining Schoenfeld residual plots.[30] Appropriateness of using gait speed as a continuous predictor was confirmed by observing linearity in Cox models with ordered 0.2-m/s gait speed categories. To examine the influence of early deaths, we repeated analyses excluding deaths within 1 year of gait speed measurement and moved up the 0 time for survival assessment (results were similar; eTable 1 available at http://www.jama.com). Subgroup analyses were repeated in strata by age (65-74, 75-84, or ≥85 years), sex, race, self-reported health status, smoking history, BMI, functional status, use of mobility aids, and hospitalization and by report of cancer, arthritis, diabetes, and heart disease.[29] Results were pooled across sex because no substantial sex differences existed in HRs within subgroup strata.

To obtain simple and clinically usable estimates of survival probability based on sex, age, and gait speed, we fit logistic regression models separately for each sex with dichotomized 5- and 10-year survival as the response variable and age, gait speed, and their interaction as continuous predictors. To obtain estimates of median survival (further life expectancy), we fit Weibull accelerated failure–time models separately for each with time to death as the response variable, and age, gait speed, and their interaction as continuous predictors. To compare ability to predict survival among candidate variables and to determine whether gait speed improves predictive accuracy beyond other clinical measures, we fit logistic regression models with dichotomized 5-year or 10-year survival as the response variable and various combinations of predictors as independent variables with both linear and squared terms for BMI. The area under the receiver operating characteristic (ROC) curve or C statistic was used as a measure predictive of accuracy for mortality. All study-specific statistical analyses were performed using SAS version 9.2 (SAS Institute Inc, Cary, North Carolina).

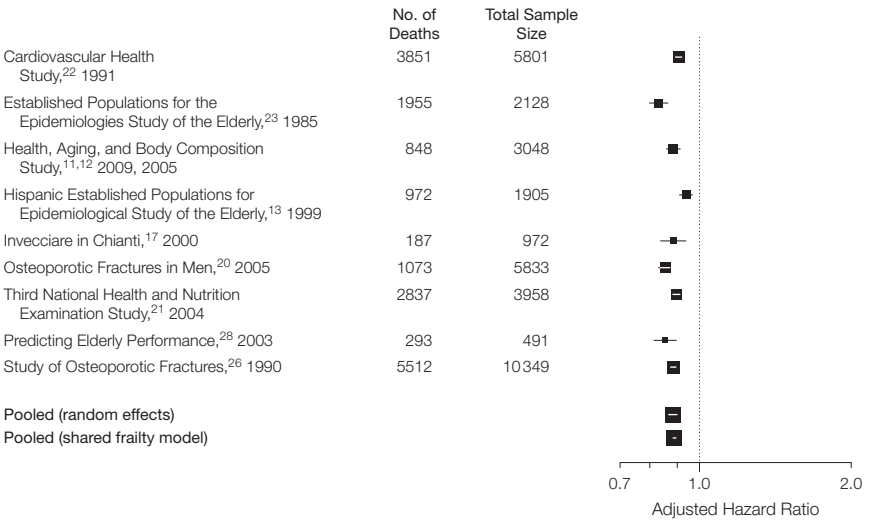
Age-adjusted HRs were pooled from all studies using standard meta-analytic statistical methodology. Heterogeneity of HRs across studies was assessed using the *Q* and I^2 statistics.[31,32] We used a random-effects model to appropriately pool the HRs on the log scale while incorporating any heterogeneity among study estimates

and then transform back to obtain an overall HR, along with a 95% confidence interval (CI) and *P* value.[33] Sensitivity of the results was assessed by fitting a shared frailty[34] (unrelated to the geriatric syndrome frailty) model to individual participant data with a -distributed frailty parameter to account for study effect (results similar; not shown).[34,35] Five- and 10-year pointwise survival rates from the Kaplan-Meier curves for each sex, age-group, and gait speed category combination were pooled across studies using a random-effects model on the complementary log-log scale[36] and then appropriately inverted to obtain overall estimates of survival, as presented in the tables. We further used the standard random effects meta-analytic model to combine sex-specific regression coefficients for age, gait speed, and their interaction from logistic regression models for 5- and 10-year survival and used the overall estimates to construct clinically usable survival probability nomograms; combine sex-specific regression coefficients for age, gait speed, and their interaction from accelerated failure time models for time to death and used the overall estimates to construct clinically usable life-expectancy nomograms; and combine areas under ROC curves obtained from 9 studies. An increase of 0.025 in overall area under ROC curve was interpreted as clinically relevant better accuracy.[37] To appropriately combine entire survival curves across the 9 studies, we used the generalized least squares method for joint analysis of survival curves.[38] We used a random-effects model with weights obtained by inverse of the variance of the survival function at the median lifetimes to pool the median survival times for each sex, age group, and gait speed category. We used Comprehensive Meta Analysis version 2.2 (Biostat Inc, Englewood, New Jersey) for all meta-analytic methods and Stata SE 8 (StataCorp, College Station, Texas) for fitting shared frailty models.

RESULTS

The 9 participating studies contributed a total of 34 485 participants (Table 1). Although most studies included men and women, 2 were sex specific.[19,22] Of the total, 59.6% were women. There were substantial numbers of African American (n = 3852) and Hispanic (n = 2650) participants. The studies had a wide age range, including 1765 persons older than 85 years. Similarly, there was a wide range of gait speeds, from less than 0.4 m/s (n = 1247) to more than 1.4 m/s (n = 1491). Study follow-up time ranged from 6.0 to 21.0 years, with participants followed up for a mean of 12.2 and a median of 13.8 years. There were 17 528 total deaths across all studies, with rates varying from 18.40% to 91.87% in individual studies. Mortality rates appear to be related to length of follow-up (Table 1).

Figure 1. Age-Adjusted Hazard Ratio for Death per 0.1-m/s Higher Gait Speed



The size of the data markers is proportional to the square root of the number of participants. The error bars indicate 95% confidence intervals. The *Q* statistic for heterogeneity is 45.2 ($P<.001$; I^2, 82.3). Pooled using random effects and shared frailty models.

To assess consistency across studies, risk of death was estimated per 0.1-m/s higher gait speed. Age-adjusted HRs by study ranged from 0.83 to 0.94 and all were significant ($P<.001$; FIGURE 1). We also examined the survival HRs for gait speed by study in subgroups, including age, sex, race/ethnicity, BMI, smoking history, use of mobility aids, prior hospitalization, self-reported health, functional status, and selected chronic diseases. There were consistent associations across studies, although given the large sample sizes, *Q* statistics were often statistically significant (details available in eFigure 1A-M available at http://www.jama.com). For the 3 levels of functional status (independent, difficulty with instrumental ADLs, and dependent in ADLs), the pooled HR per 0.1-m/s increase in gait speed for those who were independent was 0.92 ($P=.005$), for those with difficulty in instrumental activities was also 0.92 ($P<.001$) but was 0.94 ($P=.02$) among those dependent in ADLs. Because physical activity measures were not sufficiently consistent across studies, effects could not be pooled. The Osteoporotic Fractures in Men (MrOS)[19] and Hispanic Established Populations for Epidemiologic Studies of the Elderly (EPESE)[8] used the Physical Activity Scale for the Elderly (PASE). When dichotomized at a score of 100 into low and high activity, MrOS had consistent and statistically significant HRs for low (HR, 0.85; 95% CI, 0.81-0.88) and high (HR, 0.87; 95% CI, 0.84-0.90) physical activity. In the Hispanic EPESE, the HR for low physical activity was significant (0.92; 95% CI, 0.88-0.96) but the HR for higher physical activity was not (0.99; 95% CI, 0.95-1.04). Pooled HRs for all subgroups except functional status were consistently in the range of 0.81 to 0.92 and all were significant ($P<.002$).

The overall HR for survival per each 0.1 m/s faster gait speed was 0.88 (95%

CI, 0.87-0.90; $P<.001$) when pooled across all studies using a random-effects meta-analytic statistical approach (Figure 1 and eFigure 1 available at http://www.jama.com). Further adjustment for sex, BMI, smoking status, systolic blood pressure, diseases, prior hospitalization, and self-reported health did not change the results (overall HR, 0.90; 95% CI, 0.89-0.91; $P<.001$). Using data from all studies, we created for each sex, 5- and 10-year survival tables (**TABLE 2**, data derived from pooled Kaplan-Meier estimates evaluated at 5 and 10 years, presented in 3 age groups) and graphs (eFigure 3 and eFigure 4 predicted survival based on pooled logistic regression coefficients, data presented with age as a continuous variable). Gait speed was associated with differences in the probability of survival at all ages in both sexes, but was especially informative after age 75 years. In men, the probability of 5-year survival at age 85 ranged from 0.3 to 0.88 (eFigure 3A) and the probability of 10-year survival at age 75 years ranged from 0.18 to 0.86 (eFigure 4A). In women, the probability of 5-year survival remained greater than 0.5 until advanced age (eFigure 3B), but 10-year survival at age 75 years ranged from 0.34 to 0.92 and at age 80 years from 0.22 to 0.86 (eFigure 4B). Stratification by sex-specific median height failed to show systematic differences in survival rates between short and tall participants, so results presented are not stratified by height. Stratification by race/ethnicity (non-Hispanic white, black, Hispanic) suggested generally similar survival rates by gait speed among age and sex groups. Confidence intervals were often wide. In some subsets of slow walkers of Hispanic descent, survival rates were 10% to 20% higher than in other groups (eTable 2).

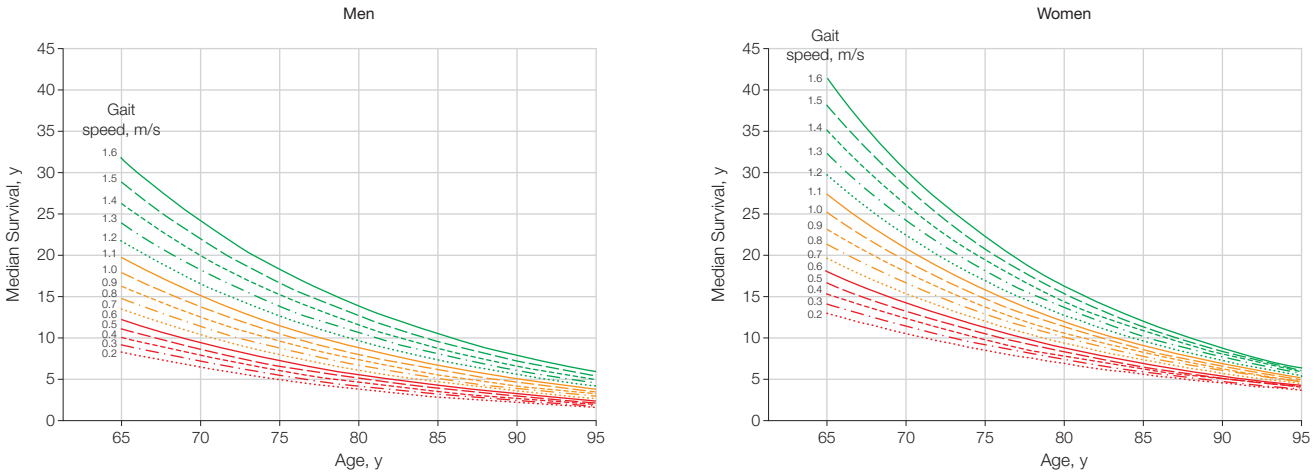
We also used our analyses to estimate median years of remaining life based on sex, age, and gait speed. (**FIGURE 2**, predicted survival data are based on an accelerated failure time model with Weibull distribution, with age as a continuous variable, and eTable 3, data are derived from pooled Kaplan-Meier es-

Table 2. Five- and 10-Year Survival in Men and Women by Age and Gait Speed Group

	5-Year Survival (95% CI), %[a]						10-Year Survival (95% CI), %					
	Men			Women			Men			Women		
Gait Speed, m/s	Age 65-74	Age 75-84	Age ≥85	Age 65-74	Age 75-84	Age ≥85	Age 65-74	Age 75-84	Age ≥85	Age 65-74	Age 75-84	Age ≥85
Speed <0.4	68 (47-82)	60 (38-76)	25 (15-36)	80 (71-86)	69 (58-78)	47 (40-54)	56 (23-80)	15 (4-33)	8 (3-18)	58 (46-69)	35 (24-47)	11 (5-19)
≥0.4 to <0.6	77 (72-81)	57 (49-64)	31 (24-39)	88 (85-90)	75 (68-80)	61 (50-70)	53 (41-64)	23 (15-31)	6 (3-11)	67 (61-72)	42 (36-48)	18 (9-30)
≥0.6 to <0.8	79 (74-83)	65 (57-71)	49 (35-61)	91 (89-93)	82 (78-86)	74 (69-78)	57 (52-62)	31 (24-38)	11 (3-28)	74 (71-77)	52 (46-57)	23 (18-28)
≥0.8 to <1.0	85 (82-88)	75 (69-79)	54 (43-64)	93 (91-95)	89 (86-91)	73 (59-83)	67 (62-71)	43 (36-50)	14 (7-25)	80 (75-83)	62 (56-68)	39 (22-56)
≥1.0 to <1.2	90 (85-93)	83 (76-87)	68 (57-77)	96 (94-98)	91 (87-94)	61 (35-79)	69 (63-74)	53 (46-59)	50 (6-84)	86 (82-89)	73 (70-77)	33 (13-54)
≥1.2 to <1.4	93 (86-96)	85 (79-89)	62 (46-74)	96 (94-97)	93 (87-96)	67 (5-95)	75 (40-91)	51 (16-78)	NE	83 (38-96)	80 (72-86)	NE
Speed ≥1.4	95 (89-97)	93 (86-96)	91 (51-99)	97 (94-99)	95 (72-99)	NE	93 (81-98)	50 (6-84)	NE	87 (71-95)	92 (71-98)	NE
All gait speeds	87 (82-91)	74 (65-81)	46 (39-53)	93 (91-94)	84 (80-87)	64 (58-70)	62 (58-66)	36 (30-42)	10 (8-13)	77 (71-82)	54 (46-60)	22 (15-29)

Abbreviations: CI, confidence interval; NE, not estimable due to small number of participants in categories.
[a]Survival estimates are derived from individual study Kaplan-Meier survival estimates that are pooled across studies using random-effects models with inverse variance weighting.

Figure 2. Predicted Median Life Expectancy by Age and Gait Speed



A PDF of enlarged graphs is available at http://www.jama.com.

timates evaluated at 5 and 10 years in 3 age groups.) In the pooled sample, median survival in years for the age groups 65 through 74 years was 12.6 for men and 16.8 for women; for 75 through 84 years, 7.9 for men and 10.5 for women; and for 85 years or older, 4.6 for men and 6.4 years for women (eTable 3 available at http://www.jama.com). Predicted years of remaining life for each sex and age increased as gait speed increased, with a gait speed of about 0.8 m/s at the median life expectancy at most ages for both sexes (Figure 2; a PDF of enlarged graphs is available at http://www.jama.com). Gait speeds of 1.0 m/s or higher consistently demonstrated survival that was longer than expected by age and sex alone. In this older adult population, the relationship of gait speed with remaining years of life was consistent across age groups, but the absolute number of expected remaining years of life was larger at younger ages. For 70-year-old men, life expectancy ranged from 7 to 23 years and for women, from 10 to 30 years.

To compare the 5-year survival predictive ability between demographics and gait speed vs other combinations of variables, we used areas under the ROC curve (C statistics) in logistic regression models for individual studies and pooled across studies (**Table 3**). Gait speed added substantially[37] to age and sex in 7 of the 9 studies and in the pooled analysis. C statistics for age, sex, and gait speed were greater than those for age, sex, and chronic diseases in 4 of 9 studies, approximately equivalent in 5 studies and inferior in no studies. C statistics for age,

Table 3. Predictive Accuracy for 5- and 10-Year Survival by Individual Study and Pooled Data Presented as Area Under the Receiver Operating Characteristic Curves

	C Statistic (95% Confidence Interval)									
Outcome and Predictors	CHS[8]	EPESE[15]	Health, ABC[16,17]	Hispanic EPESE[8]	Invecciare in Chianti[18]	Osteoporotic Fractures in Men[19]	NHANES III[20]	PEP[21]	Study of Osteoporotic Fractures[22]	Pooled
5-Year Mortality										
Age, sex	0.705 (0.685-0.725)	0.685 (0.658-0.712)	0.606 (0.575-0.637)	0.694 (0.662-0.725)	0.797 (0.754-0.841)	0.700 (0.677-0.723)	0.710 (0.691-0.729)	0.674 (0.616-0.732)	0.646 (0.625-0.667)	0.690 (0.662-0.717)
Age, sex, diseases	0.711 (0.692-0.731)	0.692 (0.665-0.719)	0.616 (0.586-0.647)	0.703 (0.671-0.725)	0.793 (0.747-0.838)	0.704 (0.681-0.727)	0.719 (0.700-0.737)	0.694 (0.737-0.750)	0.662 (0.639-0.684)	0.698 (0.673-0.723)
Age, sex, diseases, BMI, systolic BP, prior hospitalization	0.736 (0.717-0.755)[b,c]	0.702 (0.676-0.728)	0.650 (0.620-0.680)[b,c]	0.728 (0.698-0.755)[b,c]	0.808 (0.765-0.850)	0.728 (0.706-0.749)[b]	0.744 (0.727-0.762)[b,c]	0.728 (0.674-0.781)[b,c]	0.665 (0.643-0.686)	0.719 (0.693-0.745)[b]
Age, sex, use of mobility aid, functional status[a]	NA	NA	NA	0.735 (0.705-0.765)	0.803 (0.756-0.851)	NA	0.738 (0.720-0.757)	0.720 (0.663-0.776)	NA	0.747 (0.720-0.774)
Age, sex, gait speed	0.734 (0.716-0.753)[c]	0.711 (0.685-0.737)[c]	0.642 (0.612-0.673)[b,c]	0.710 (0.679-0.741)	0.803 (0.760-0.846)	0.729 (0.707-0.751)[b,c]	0.737 (0.719-0.755)[b]	0.718 (0.664-0.771)[c]	0.682 (0.662-0.703)[b,c]	0.717 (0.694-0.740) 0.741 (0.706-0.775)[d]
10-Year Mortality										
Age, sex	0.721 (0.707-0.734)	0.725 (0.704-0.746)	NA	0.700 (0.677-0.724)	NA	NA	0.741 (0.726-0.757)	0.674 (0.627-0.721)	0.689 (0.676-0.703)	0.712 (0.692-0.731)
Age, sex, diseases	0.728 (0.715-0.742)	0.738 (0.716-0.759)	NA	0.709 (0.685-0.733)	NA	NA	0.749 (0.734-0.764)	0.698 (0.652-0.744)	0.706 (0.692-0.719)	0.724 (0.707-0.740)
Age, sex, diseases, BMI, systolic BP, prior hospitalization	0.745 (0.732-0.759)	0.749 (0.729-0.770)	NA	0.733 (0.710-0.756)[b]	NA	NA	0.768 (0.754-0.783)[b]	0.723 (0.678-0.727)[b,c]	0.709 (0.696-0.722)	0.739 (0.719-0.759)[b]
Age, sex, functional status, walking aid use[a]	NA	NA	NA	0.722 (0.699-0.746)	NA	NA	0.761 (0.746-0.776)	0.702 (0.655-0.748)	NA	0.732 (0.698-0.767)
Age, sex, gait speed	0.740 (0.727-0.754)	0.753 (0.733-0.774)[b]	NA	0.709 (0.685-0.732)	NA	NA	0.766 (0.751-0.780)[b]	0.723 (0.679-0.768)[b,c]	0.719 (0.706-0.731)[b]	0.737 (0.718-0.755)[b,] 0.734 (0.692-0.777)[d]

Abbreviations: ABC, Aging and Body Composition; BMI, body mass index, calculated as weight in kilograms divided by height in meters squared; BP, blood pressure; CHS, Cardiovascular Health Study; CI, confidence interval; EPESE, Established Populations for the Epidemiological Study of the Elderly; NA, not applicable; NHANES III, Third National Health and Nutrition Examination Survey; PEP, Predicting Elderly Performance.

[a] Functional status was operationally defined for 3 levels: (1) activities of daily living (ADLs) dependence is defined as report of needing help from another person or being unable to perform any of 6 basic ADLs, 2) Instrumental ADL difficulty is defined as report of no ADL dependence but difficulty performing shopping, meal preparation, or heavy housework, and (3) Independent is defined as no report of ADL dependence or instrumental ADL difficulty.

[b] Value is the pooled estimate of the area under the receiver operator characteristic curve for age, sex, and gait speed for the studies that were used in the comparisons of gait speed with use of mobility aids and functional status. Four studies were included in the estimates of 5 y mortality and three in the estimates of 10 y mortality. Values are reported as the C statistic representing area under the receiver operator characteristic curve; values that differ by 0.025 or more are considered substantially different.[37]

[c] C statistic is greater than for age and sex alone.

[d] C statistic is greater than for age, sex, and diseases.

sex, and gait speed were approximately equivalent to those for age, sex, chronic diseases, BMI, systolic blood pressure, and prior hospitalization in all 9 studies and in the pooled analysis. There were 4 studies that had sufficiently consistent data on functional status to create 3 categories: dependent in ADLs, difficulty with instrumental ADLs, and independent. For these studies, gait speed, age, and sex yielded a C statistic (0.741) that was not significantly different ($P = .78$) from age, sex, mobility aids, and functional status ($P = .75$; Table 3).

For 10-year survival, 6 studies had sufficient follow-up time to perform many of the analyses (Table 3). Gait speed added predictive ability to age and sex in 4 of 6 studies and in the pooled analysis. C statistics for age, sex, and gait speed were not significantly different from C statistics with all the other factors for any study nor for the pooled analysis. Three studies had sufficiently consistent data on functional status at baseline to allow pooling. Gait speed, age, and sex yielded a C statistic (0.734) that was not significantly different from age, sex, mobility aids, and functional status (0.732; ($P = .95$; Table 3).

In addition, we used C statistics to assess the ability of usual gait speed to predict survival compared with other physical performance measures, such as fast gait speed and the Short Physical Performance Battery (SPPB), a brief measure that includes walk speed, chair rise ability, and balance. We assessed usual vs fast gait speed in the single study with both measures (Invecciare in Chianti[18] study: usual, 0.727 [95% CI, 0.678-0.776]; fast, 0.684 [95% CI, 0.630-0.739]), suggesting that fast walks did not have an advantage in survival prediction over usual-paced walks. Gait speed was superior to the SPPB in the Hispanic Established Populations for the Epidemiological Study of the Elderly[8] (gait speed, 0.617; 95% CI, 0.585-0.649; SPPB, 0.574; 95% CI, 0.539-0.649); was equivalent in the following 3 studies: Health, Aging, and Body Composition (ABC) study and ABC[16] (gait speed, 0.579; 95% CI, 0.548-0.610; SPPB, 0.560; 95% CI, 0.528-0.592); Invecciare in Chianti (gait speed, 0.727; 95% CI, 0.678-0.776; SPPB, 0.738; 95% CI, 0.690-0.735); Predicting Elderly Performance study[18] (gait speed, 0.667; 95% CI, 0.610-0.724; SPPB, 0.691; 95% CI, 0.637-0.744); and worse than SPPB in the Established Populations for the Epidemiological Study of the Elderly[15] (gait speed, 0.638; 95% CI, 0.610-0.777; SPPB, 0.663; 95% CI, 0.636-0.691).

COMMENT

Gait speed, age, and sex may offer the clinician tools for assessing expected survival to contribute to tailoring goals of care in older adults. The accuracy of predictions based on these 3 factors appears to be approximately similar to more complex models involving multiple other health-related factors, or for age, sex, use of mobility aids, and functional status. Gait speed might help refine survival estimates in clinical practice or research because it is simple and informative.

Why would gait speed predict survival? Walking requires energy, movement control, and support and places demands on multiple organ systems, including the heart, lungs, circulatory, nervous, and musculoskeletal systems. Slowing gait may reflect both damaged systems and a high-energy cost of walking.[13,39-54] Gait speed could be considered a simple and accessible summary indicator of vitality because it integrates known and unrecognized disturbances in multiple organ systems, many of which affect survival. In addition, decreasing mobility may induce a vicious cycle of reduced physical activity and deconditioning that has a direct effect on health and survival.[6]

The association between gait speed and survival is known.[6,7,9-12,55,56] Prior analyses used single cohorts and presented results as relative rather than absolute risk, as done herein. Similarly, mortality prediction models have been developed.[3-5,57-60] Some models use self-reported information but others also include physiological or performance data, for a total of 4 to more than 10 predictive factors. Only a few models assess overall predictive capacity using C statistics; the reported values are in the range found in the present study (published area under the curve range, 0.66-0.82[61] vs this study, 0.717 and 0.737).

The strengths of this study are the very large sample of individual participant data from multiple diverse populations of community-dwelling elders who were followed up for many years and use of consistent measures of performance and outcome. We provide survival estimates for a broad range of gait speeds and calculate absolute rates and median years of survival. Compared with prior studies that were too small to assess potential effect modification by age, sex, race/ethnicity, and other subgroups, we were able to assess multiple subgroup effects with substantial power. This study has the limitations of observational research; it cannot establish causal relationships and is vulnerable to various forms of healthy volunteer bias. The participating study cohorts, while large and diverse, do not represent the universe of possible data. Our survival estimates should be validated in additional data sets. Only 1 of the 9 studies was based in clinical practice,[21] and advanced dementia is rare in populations who are competent to consent for research. However, median years of survival in this study resemble estimates for US adults across the sex and age range assessed.[62] We were unable to assess the association of physical activity with survival in pooled analyses because measures of activity were highly variable across studies. Also, participants in these studies had no prior knowledge about the meaning of walking speed. In clinical use, participants might walk differently if they are aware of the implications of the results. Although this study provides information on survival, further work is needed to examine associations of other important pooled outcomes such as disability and health care use and to examine effects in populations more completely based in clinical practice.

Because gait speed can be assessed by nonprofessional staff using a 4-m walkway and a stopwatch,[21] it is relatively simple to measure compared with many medical assessments. Nevertheless, methodological issues such as distance and verbal instructions remain.[63,64] Self-report is an alternative to gait speed for reflecting

function. However, significant challenges remain in the use of self-report as well, such as choice of items and reliability, some of which can be addressed by emerging techniques such as computer adaptive testing based on item-response theory.[65] The results found herein suggest that gait speed appears to be especially informative in older persons who report either no functional limitations or only difficulty with instrumental ADLs and may be less helpful for older adults who already report dependence in basic ADLs. The research studies analyzed herein used trained staff to measure gait speed. Staff in clinical settings would need initial training and may produce more variable results. Long-distance walks have become accepted in some medical fields and may contribute information beyond short walks.[66-68] However, the longer distance and time to perform the test may limit feasibility in many clinical settings. Although the sample size of very slow walkers was small, our data suggest that there may be a subpopulation who walk very slowly but survive for long periods. It would be valuable to further characterize this subgroup.

Although the gait speed–survival relationship seems continuous across the entire range, cut points may help interpretation. Several authors have proposed that gait speeds faster than 1.0 m/s suggest healthier aging while gait speeds slower than 0.6 m/s increase the likelihood of poor health and function.[7,21] Others propose one cutoff around 0.8 m/s.[13] In our data, predicted life expectancy at the median for age and sex occurs at about 0.8 m/s; faster gait speeds predict life expectancy beyond the median. Perhaps a gait speed faster than 1.0 m/s suggests better than average life expectancy and above 1.2 m/s suggests exceptional life expectancy, but additional research will be necessary to determine this relationship.

How might gait speed be used clinically? First, gait speed might help identify older adults with a high probability of living for 5 or 10 more years, who may be appropriate targets for preventive interventions that require years for benefit. Second, gait speed might be used to identify older adults with increased risk of early mortality, perhaps those with gait speeds slower than 0.6 m/s. In these patients, further examination is targeted at potentially modifiable risks to health and survival. A recommended evaluation and management of slow walking includes cardiopulmonary, neurological and musculoskeletal systems.[6,18] Third, gait speed might promote communication. Primary clinicians might characterize an older adult as likely to be in poor health and function because the gait speed is 0.5 m/s. In research manuscripts, baseline gait speed might help to characterize the overall health of older research participants. Fourth, gait speed might be monitored over time, with a decline indicating a new health problem that requires evaluation. Fifth, gait speed might be used to stratify risks from surgery or chemotherapy. Finally, medical and behavioral interventions might be assessed for their effect on gait speed in clinical trials. Such true experiments could then evaluate causal pathways to determine whether interventions that improve gait speed lead to improvements in function, health, and longevity.

The data provided herein are intended to aid clinicians, investigators, and health system planners who seek simple indicators of health and survival in older adults. Gait speed has potential to be implemented in practice, using a stop watch and a 4-m course. From a standing start, individuals are instructed to walk at their usual pace, as if they were walking down the street, and given no further encouragement or instructions. The data in this article can be used to help interpret the results. Gait speed may be a simple and accessible indicator of the health of the older person.

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Acquisition of data: Studenski, Faulkner, Nevitt, Visser, Kritchevsky, Badinelli, Harris, Newman, Cauley, Ferrucci, Guralnik.
Analysis and interpretation of data: Studenski, Perera, Patel, Rosano, Faulkner, Inzitari, Brach, Chandler, Cawthon, Barrett-Connor, Nevitt, Visser, Harris, Newman, Cauley, Guralnik.
Drafting of the manuscript: Studenski, Perera, Inzitari, Badinelli.
Critical revision of the manuscript for important intellectual content: Studenski, Perera, Patel, Rosano, Faulkner, Brach, Chandler, Cawthon, Barrett-Connor, Nevitt, Visser, Kritchevsky, Harris, Newman, Cauley, Ferrucci, Guralnik.
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Online-Only Material: A PDF of enlarged Figure 2 graphs; eTables 1-3, and eFigures 1A-M, 2, 3, and 4 are available at http://www.jama.com.

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Seated Blood Pressure

A. Equipment:

1. One standard Littman stethoscope tubing and earpieces with bell: Classic II 3M

2. One standard mercury column sphygmomanometer: Baumanometer (clinic)

3. Aneroid sphygmomanometer (offsite)

4. BP cuffs in four sizes (all Latex free)

    Thigh adult cuff
    Large adult cuff
    Regular adult cuff
    Pediatric cuff

B. Blood Pressure Cuff Placement:

1. Bare participant's left arm to the point of the shoulder.

2. Determine correct cuff size using guidelines inside the cuff.

3. Palpate the brachial artery.

4. With participant seated, place the appropriate cuff around the upper left arm. The midpoint of the length of the bladder should lie over the brachial artery. Each cuff has an artery marker. The mid-height of the cuff should be at heart level.

5. Place the lower edge of the cuff, with its tubing connections, about one inch (1") above the natural crease across the inner aspect of the elbow.

6. Wrap the cuff snugly about the arm, with the palm of the participant's hand turned upward.

7. If the subject has had a left-sided mastectomy, the right arm may be used for blood pressure measurement. If right arm is used, note it on the form.

C. Determination of Maximal Inflation Level

For each participant, determine the maximal inflation level, or the pressure to which the cuff is to be inflated for blood pressure measurement. This assures that the cuff pressure at the start of the reading exceeds the systolic blood pressure and thus allows the first Kortokoff sound to be heard.

1. Attach the cuff tubing to the sphygmomanometer.

2. Palpate the radial pulse.

3. Inflate the cuff rapidly until the radial pulse is no longer felt (palpated systolic pressure) by inflating rapidly to 70 mmHg, then inflating by 10mmHg increments.

4. Deflate the cuff quickly and completely.

5. The maximal inflation level is 30 mmHg **above** the palpated systolic pressure.

D. Guidelines for Accurate Blood Pressure Readings:

1. The participant should be in a seated position for at least 5 minutes before the blood pressure is measured with both feet remaining flat on the floor.

2. All readings are made to the nearest even digit.

3. Any reading which appears to fall exactly between marking on the mercury column should be read to the next higher marking (i.e. 2, 4, 6, 8, or 0).

4. All readings are made to the top of the meniscus, the rounded surface of the mercury column.

5. When the pressure is released quickly from a high level, a vacuum is formed above the mercury and the meniscus is distorted. Allow a few moments for it to reappear before reading the manometer.

For offsite Blood Pressures: Check that the needle is at the zero mark at the start and the end of the measurement. Place the manometer in direct line of sight with the eye on a line perpendicular to the center of the face of the gauge.

E. Blood Pressure Readings:

1. Following any previous inflation, wait at least 30 seconds after the cuff has completely deflated.

2. By closing the thumb valve and squeezing the bulb, inflate the cuff at a rapid but smooth continuous rate to the maximal inflation level (30 mmHg above palpated systolic pressure).

3. The examiner's eyes should be level with the mid-range of the manometer scale and focused at the level to which the pressure will be raised.

4. Open the thumb valve slightly. Allow the cuff to deflate, maintaining a constant rate of deflation at approximately 2 mmHg per second.

5. Using the bell of the stethoscope, listen throughout the entire range of deflation, from the maximum pressure past the systolic reading (the pressure where the FIRST regular sound is heard), until 10 mmHg BELOW the level of the diastolic reading (that is, 10 mmHg below the level at which the LAST regular sound is heard).

6. Deflate the cuff fully by opening the thumb valve.

7. Remove the stethoscope. Neatly enter systolic and diastolic readings in the spaces provided on the form.

Mini-Mental State Exam (MMSE)

Tech-Administered

Background and Rationale:

Cognitive function may decline as a result of certain risk factors (e.g. hypertension, elevated cholesterol, cardiac arrhythmias). This in turn could adversely impact the physical functioning and quality of life of older adults. Dementia is a major illness and cause of disability among the elderly. Cerebrovascular disease or multi infarct dementia is the second leading cause of dementing illness among Caucasians, preceded only by Alzheimer's disease. The Mini-Mental State Exam (MMSE) is a widely used test of cognitive function among the elderly; it includes tests of orientation, attention, memory, language and visual-spatial skills.

The MMSE is a 30 point test that was designed as a short screening measure of cognitive status. The goal of the test was to determine if people show signs of cognitive impairment. It has come to be used widely as a screening test for progressive dementing disorders, such as Alzheimer's disease.

Within Framingham, it is used to determine if someone is showing changes in cognitive function, and we do so by looking for a drop in the MMSE score compared to previous exams. If there is a drop of 3 points or more from the immediately preceding exam, we would invite the participant into the Dementia study for further neuropsychological testing and a neurological exam. If there is a drop in 5 points of more across all exams, this will also trigger a request for further follow up by the Neuro group.

While the MMSE has been useful in serving as a screening tool, it also has some significant limitations. One major issue is that younger and/or highly educated people are likely to score the maximum score of 30. This is known as a ceiling effect - even when people might be starting to experience real changes in cognition, the MMSE might not pick it up until much later on. The other major limitation with the MMSE is that the test is not diagnostic and a poor score does not always indicate the presence of. dementia. Or even if your score suggests you have dementia, it's hard to tell what type of dementia. It is very hard to determine with any level of confidence what areas of cognition are impaired based on MMSE performance. Sometimes, researchers do try to look at specific items on the test, and determine cognitive-domain specific deficits. For example, poor performance on the recall item may lead some to decide there is a memory problem.

If there are any concerns regarding the participant's memory, notify the Clinic physicianand refer the participant for for further assessment with the Neuro group. The Clinic physician should complete a Referral Form and give to the Neuro Project Coordinator, [redacted], after the exam. Referral forms can be found in the appendices.

If a participant has been seen by the Neuro group previously, it is indicated on the PTS Roster screen. Sometimes a family member will tell the recruiters that there is a memory issue.

During the admitting process, if the participant has trouble answering questions (i.e., children's names, sibling's names, etc.) the Admitter will notify the Clinic staff who will then notify the Clinic physician.

Methods:

1. The MMSE asks questions to ascertain cognitive status. Responses are scored:
   0=incorrect
   1=correct
   6=item administered, participant does not answer
   9=test item not administered/unknown

2. If a response is ambiguous, the interviewer records the response in the margin so a decision can be made on its appropriateness. Please refer all questionable responses to the neuropsychologists [redacted]

3. When a participant is incapacitated by blindness, has a functional disability, is illiterate, or is otherwise unable to respond to a question, the interviewer should specify the problem and questions involved (see "Factors Potentially Affecting Mental Status Testing" later in the section).

Expanded Scoring Instructions for Mini-Mental Exam:

Important note: Sometimes a participant might produce a response that is not a word (i.e. a neologism) but has been responding with intelligible responses on previous items (right or wrong). In this case the items should be scored **0**. The key to differentiating a **0** or a **9** is consistency within test. If a person has a speech abnormality, such as aphasia or dysarthria, across all items, most (or many) responses will be unintelligible. If a person is, for example, demented, he/she may produce a flow of intelligible responses with occasional unintelligible responses. A "**9**" must represent situations in which the EXAMINER is not sure whether (1) the participant responded correctly (because of slurred speech, severe stuttering, etc.), or (2) if the participant has some other factor that prevents test item administration (such as an inability to administer *copy this figure* test

item to a right-handed person who has right-handed paralysis, or to someone who has a visual impairment or inability to hear).

Scoring for Administered Individual Items: (applies only if a test item is administered)

Score **0** for the following reasons:

- Incorrect response
- I don't know
- Unintelligible response in context of other intelligible responses

Score **9** for the following reason:

- When test item was not administered (refused or inability because of physical limitations), or
- When the subject's response is uninterpretable (response could be correct, but tester is unable to discern the response).

Important note: The single exception to scoring **6** for no response is if a participant is in a coma (this circumstance would be encountered in a nursing home visit) In this instance, administer the first item (to establish no response -- give a **0** to the first item if there is no response). (This exception is made to conform with the stroke protocol.)

Questions: Scripts and Procedures for Each Question:

Introductory Script: *I'm going to start by asking questions that require concentration and memory. Some questions are more difficult than others and some will be asked more than one time.*

Read each question on the form.
Record the response on the form.

1. *What is the date today?* (**3** = correct score for month (1 pt), day (1 pt) and year (1 pt))

    a. Ask for the date. Then ask specifically for parts omitted (e.g. *Can you also tell me what month, year it is?*)
    b. If participant supplies part or all of the date (e.g. month and day, or month, day, and year), record as appropriate and do not ask those questions again.

2. *What is the season?*

Since distinctions between seasons can be difficult during certain months, one week leeway is allowed on either side of the actual date.

MMSE ACCEPTABLE ANSWERS FOR "WHAT IS THE SEASON"?

2011

Month	Correct Response	Acceptable Dates (2 Seasons)
April	Spring	n/a
May	Spring	n/a
June	Spring or Summer	6/14/11 – 6/28/11
July	Summer	n/a
August	Summer	n/a
September	Summer or Fall/Autumn	9/16/11 – 9/30/11
October	Fall/Autumn	n/a
November	Fall/Autumn	n/a
December	Fall/Autumn or Winter	12/15/11 – 12/29/11

2012

Month	Correct Response	Acceptable Dates (2 Seasons)
January	Winter	n/a
February	Winter	n/a
March	Winter or Spring	3/13/12 – 3/27/12
April	Spring	n/a
May	Spring	n/a
June	Spring or Summer	6/13/12 – 6/27/12
July	Summer	n/a
August	Summer	n/a
September	Summer or Fall/Autumn	9/15/12 – 9/29/12
October	Fall/Autumn	
November	Fall/Autumn	

December	Fall/Autumn or Winter	12/14/12 – 12/28/12

2013

Month	Correct Response	Acceptable Dates (2 Seasons)
January	Winter	n/a
February	Winter	n/a
March	Winter or Spring	3/13/13 – 3/27-13
April	Spring	n/a
May	Spring	n/a
June	Spring or Summer	6/14/13 – 6/28/13
July	Summer	n/a
August	Summer	n/a
September	Summer or Fall/Autumn	9/15/13 – 9/29/13
October	Fall/Autumn	
November	Fall/Autumn	
December	Fall/Autumn or Winter	12/14/13 – 12/28/13

2014

Month	Correct Response	Acceptable Dates (2 Seasons)
January	Winter	n/a
February	Winter	n/a
March	Winter or Spring	3/13/14 – 3/27/14
April	Spring	n/a
May	Spring	n/a
June	Spring or Summer	6/14/14 – 6/28/14
July	Summer	n/a
August	Summer	n/a
September	Summer or Fall/Autumn	9/16/14 – 9/30/14
October	Fall/Autumn	
November	Fall/Autumn	
December	Fall/Autumn or Winter	12/14/14 – 12/28/14

3. *What day of the week is it?*

4. *What town, county, and state are we in? (Town, County, State, correct score = 3)*

    a. Ask the participant what town, county, and state we are in.
    b. If the participant is from out of town or out of state, it is acceptable for them to respond with the county they live in. It is okay to prompt them if they live out of the area.
    c. For offsite visits, refer to the section of the manual titled "New England Counties" for a complete list of all counties.

5. *What is the name of this place?*

    a. Ask the participant where they are. Any appropriate answer is okay. (possible acceptable responses = FHS, Perini, Mt. Wayte).
    b. On home visits, the examiner can ask, *What is the address of this place?(possible acceptable responses = Nursing Home, my house, or their address).*

6. *What floor of the building are we on?*

    a. Clinic Visit = 1st Floor. If they say "Main Floor", repeat the question adding "now".

7. *I am going to name 3 objects. After I have said them I want you to repeat them back to me. Are you ready?* ***Apple, Table, Penny.*** *Could you repeat the three items for me? Remember what they are because I will ask you to name them again in a few minutes:*

    a. Make sure participant is attentive when beginning the question.
    b. Read the list of objects slowly. DO NOT REPEAT ITEMS UNTIL AFTER THE FIRST TRIAL.
    c. If participant asks you to repeat the 3 items, respond, *Can you tell me the items I just mentioned?* or *Just do the best you can*.
    d. Read *Apple, Table, Penny*.
    e. Script: *Could you repeat the three items for me?*
    f. Record the score for the first trial.
    g. If, after scoring the first attempt, the participant has not learned the 3 objects, repeat the list of objects up to 6 times until he/she has learned them.
    h. If, 3 items are repeated regardless of order, score 3 points. Occasionally hearing impairments prevent subjects from correctly hearing test questions (for example, when asked to repeat three items, *apple, table, penny*, they may repeat *April, tablet, pencil* -- these alternate responses should be accepted both under the repetition and recall conditions).

8. *Now I am going to spell a word forward and I want you to spell it backwards. The word is WORLD. W-O-R-L-D. Please spell it in reverse order.* Write in letters _____ (letters are entered and computer scored later.

    a. Read the question slowly. Where *world* has hyphens between the letters, spell out the word.
    b. Repeat the spelling if necessary.
    c. Record the participant's response. Write in the letter as the participant has spelled the word.
    d. If the participant spells the word forward rather than in reverse, they can be cued once with a reminder to spell it backwards.

9. *What are the 3 objects I asked you to remember a few moments ago?*

    a. Items may be repeated in any order.

10. *What is this called?* (Watch)

    Show the wristwatch to the participant
    Correct responses include: watch, wristwatch, timepiece
    Code 1 = correct answer

11. *What is this called?* (Pencil)

    a. Show the pencil to the participant. NOTE: the pencil should be a standard sharpened wooden pencil with eraser.
    b. Correct responses include: Pencil, number 2 pencil
    c. Code **1** = correct for correct answer.

12. *Please repeat the following: No ifs, ands or buts.*

    a. Enunciate clearly -- include the "**S**" at the end of *if<u>s</u>, and<u>s</u>, or but<u>s</u>,* (if you think the participant heard you but repeated it incorrectly, make a note of what was missed and score **0**).
    b. Allow only **one** attempt.
    c. Code **1** = correct when the participant correctly repeated the phrase.
    d. Code **0** = incorrect when the participant did not repeat the phrase <u>exactly</u>.

    Occasionally hearing impairments prevent participants from correctly hearing test questions. In the case of repeating *no ifs, ands, or buts,* some judgment must be made on the part of the examiner as to whether the participant could hear the "***s***" or not.

13. *Please read the following and do what it says.*

a. Hand participant the "Please Close Your Eyes" card.
b. The participant may read the sentence out loud. The task to be coded is the participant's ability to follow instructions by closing his/her eyes. It is not necessary for the sentence to be read out loud if the participant performs the function properly.
c. Code **1** = correct when the participant closes his/her eyes.
d. Code **0** = incorrect when the participant did not close his/her eyes.

14. *Please write a sentence.*

a. Script: *Write any complete sentence on this piece of paper for me.*
b. Repeat the instructions to participant if necessary.
c. Code **1** = correct if the participant wrote a complete sentence as directed.
d. Written commands, such as *sit down*, where the subject is implied, are considered correct responses.
e. Spelling and/or punctuation errors are not counted as errors.
f. Code **0** = incorrect when the participant did not write a complete sentence as directed.
g. Code **1** = if the participant is cognitively able to dictate a sentence but is physically unable to write it. In this case the examiner should write the dictated sentence and make a note that it was dictated.
Code **6** = Low vision

15. *Please copy this drawing.*

a. Script: *Here is a drawing. Please copy the drawing on the same piece of paper.*
b. If the participant asks if the figures should be drawn separately or together the examiner should respond, *Draw the figures as you see them.*
c. To be correct, each pentagon must have 5 sides, 5 sides that point outward. The two figures must be overlapping.
d. The overlap figures must have 4 sides.
e. Code "**0**" = incorrect when the participant's figure did not match.

16. *Take this piece of paper in your right hand, fold it in half with both hands, and put it in your lap.*

(If participant is unable to use right hand because of physical disability, you can alter instructions to read "Take this piece of paper in your left hand, fold it in half with your left hand, and put it in your lap". The goal is to see whether the subject is able to follow a 3-step command, so this variation to the directions to accommodate subject's physical limitations is allowable.)

Read the full statement **BEFORE** handing the paper to the participant.

a. **DO NOT** direct the paper to participant's right side. Hold the paper in front and have the participant reach out to take it. Observe which hand is used.

b. **DO NOT** repeat instructions or coach participant. Only repeat if the examiner felt it was not heard or if instructions were not given clearly (just repeat the directions in full as they were the first time).

c. Score: This is a 3 step command. Score **one** for each correctly performed act (code **6** if low vision).

Factors Potentially Affecting Mental Status Testing

The examiner's impression for Offspring Exam 9 will include the following:

NO	YES	MAYBE	UNKNOWN	
0	1	2	9	Illiteracy or low education
0	1	2	9	Not fluent in English
0	1	2	9	Poor eyesight
0	1	2	9	Poor hearing
0	1	2	9	Other

Note: Questions cannot be answered by a proxy.

PLEASE CLOSE YOUR EYES

KATZ-Activities of Daily Living

Tech-Administered

A. Background and Rationale:

This section is designed to assess the following spectrum of physical functioning. This section assesses:

- Ability to carry out activities of daily living

s

B. Activities of Daily Living

The activities & examples of each ADL include:

1. Dressing
   - Undressing and redressing
   - Devices such as: velcro, elastic laces.
2. Bathing
   - Including getting in and out of tub or shower
   - Devices such as: bath chair, long handled sponge, hand held shower, safety bars.
3. Eating
   - Devices such as: rocking knife, spork, long straw, plate guard.
4. Transferring
   - Getting in and out of a chair
   - Devices such as: sliding board, grab bars, special seat.
5. Toileting activities
   - Using the bathroom facilities and handling clothing
   - Devices such as: special toilet seat, commode.

NOTE: With a nursing home visit, the participant's chart may be used to verify or to obtain accurate information on ADL's. If information is obtained from the nursing home staff then proxy information on screen must be completed.

Rosow-Breslau Questions

Rationale & Background

This scale is primarily concerned with the *functional* health which people report, i.e., the degree to which they claim they can manage adequately or are restricted in their activities because of their physical condition or capacity. *Breslau, M, Rosow, I: A Guttman Health Scale for the Aged. 556-559*

Methods

The method of assessing physical functioning is **self-report**. This data will enable us to assess the level of independence and function in the study population.

*Note: Do not ask the Rosow-Breslau questions of cognitively impaired participants; their proxy **can** answer these questions.*

Nagi Questionnaire

Tech-Administered

1. Show and explain the answer key *before* administering the questionnaire. The participant is to choose one of the following answers for each activity:

    0 = No Difficulty
    1 = A Little Difficulty
    2 = Some Difficulty
    3 = A Lot of Difficulty
    4 = Unable to Do
    5 = Don't Do on Physician or Health Care Providers Orders
    6 = I don't know
    9 = Unk. (either Tech. forgot to administer or ppt. refused to answer)

2. Start with, *For each activity, tell me whether you have No Difficulty, A little Difficulty, Some Difficulty, A Lot of Difficulty, if you are Unable to do it, if you Do not do it on Physician or Health Care Providers Orders, or if you don't know.*

3. Read each activity separately, and go through the level of difficulty for each one until the participant understands the response choices.

Do not ask these questions if the participant is cognitively impaired; proxy may answer these questions.

No Difficulty

A Little Difficulty

Some Difficulty

A Lot of Difficulty

Unable to Do

Don’t Do on Physicians or Health Care Providers Orders

Sociodemographic Questionnaire

This is a self-reported form. If not self-reported, the Proxy Section of the exam form must be completed.

A. Sociodemographics

1. *Where do you live?*

   Coding
   0 = Private residence
   1 = Nursing home
   2 = Other setting, such as an assisted living facility (i.e., no longer able to live independently)
   9 = Unknown

2. *Does anyone live with you?* (NOTE: Code nursing home resident as NO to these questions.)

   Coding
   0 = No
   1 = Yes
   9 = Unknown

   NOTE: If the answer to the above question was **0** or **9** you may skip the following section. If the answer was yes, the examiner needs to determine who lives in the same household. **It is important to ask whether others live in the same household for < 3 months per year or > 3 months per year**. The list is:

   Spouse
   Significant Other
   Children
   Friends
   Other Relative

   Coding
   0 = No
   1 = Yes, more than 3 months per year
   2 = Yes, less than 3 months per year
   9 = Unknown

B. Use of Nursing and Community Services

1. *Have you been admitted to a Nursing Home (or skilled facility) in the past year?*

Coding
0 = No
1 = Yes
9 = Unknown

2. *In the past year, have you been visited by a nursing service or used home, community or adult day care programs? (examples: home health aid, visiting nurses, etc.)*

Coding
0 = No
1 = Yes
9 = Unknown

20-Item CES-D—Tech Administered

The 20-item CES-D was developed and validated by the Center for Epidemiologic Studies, National Institute of Mental Health (NIMH). (1)

Tech Administered

Script

The questions below ask about your feelings, please say if you felt this way during the past week.

*Indicates that the technician should preface the statement with "During the past week…"

Instructions for Scale Scoring of the CES-D:

Each item has a range of four response options which indicated how often the participant felt that way during the past week:

Code	*Response option*
0	Rarely or none of the time (less than 1 day)
1	Some or a little of the time (1-2 days)
2	Occasionally or a moderate amount of the time (3-4 days)
3	Most or all of the time (5-7 days)

Note: Questions may not be answered by a proxy.

Reference: "Basic Data on Depressive Symptomatology" United States 1974-75 Series 11 Number 216
DHEW Publication No. (PHS) 80-1666
U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Pubic Health Service, Office of Health Research, Statistics, and Technology
National Center for Health Statistics, Hyattsville, MD April 1980

Reference List

(1) National Center for Health Statistics: Basic Data on Depressive Symptomatology United States, 1974-75. DHEW Publication No (PHS) 80-1666. US Department of Health, Education and Welfare. 1980.
Ref Type: Generic

Rarely or none of the time (Less than 1 day)

Some or a little of the time (1-2 days)

Occasionally or moderate amount of time (3-4 days)

Most or all of the time (5-7 days)

Administration of Physical Activity Questionnaire
Rest and Activity for a Typical Day

1. Hand participant a copy of the Physical Activity Questionnaire (24 hour).

2. Explain that the first section is Rest and Activity for a Typical Day (24 hours).

3. The day is broken up into different types of activities and a typical day is considered MOST days of the week.

4. Read through each activity and do NOT clarify.
    - **Sleep**
        - Example: napping during the day and actual night sleep.
    - **Sedentary**
        - Example: sitting in the car, eating meals, TV, computer, etc.
    - **Slight Activity**
        - Example: walking to the car, shopping, standing in line, etc.
    - **Moderate Activity**
    - **Heavy Activity**

    Explain that a total number of hours for a typical day must equal 24 hours.*

5. This should capture over the past year.

6. Make adjustments according to participant until the total number of hours equals 24*.

    * If the total hours the participants states does not equal to 24 on the first pass, please ask the participant where he/she might have underestimated the hours stated. Do not just add missing hours to the last activity automatically. The participant needs to clarify the activity amounts until they add up to 24.

Administration of Physical Activity Questionnaire
Time Spent Doing Sitting Activities

Explain that now you will be asking 2 questions about *sitting* activities, in particular.

1. *Over the past 7 days, how often did you participate in SITING ACTIVITIES such as reading, watching TV, using the computer or doing handcrafts?*

Read through each **response level:**

Never, code as 0
Seldom/1-2 days, code as 1
Sometimes/3-4 days, code as 2
Often/5-7 days, code as 3
If refused to answer, code as 8
If answer **Don't Know/Unknown** code as 9

2. *Over the past 7 days, how many hours per day did you engage in these activities?*

Read through each **response level:**

Less than 1 hour, code as 1
1 hour but less than 2 hours, code as 2
2-4 hours, code as 3
More than 4 hours, code as 4
If refused to answer, code as 8
If answer **Don't Know/Unknown** code as 9

Administration of Physical Activity Questionnaire
Time Spent Actually Doing the Activity

This section of physical activity questions was adapted from the Cardiovascular Health Study (CHS). http://128.208.129.3/chs/forms/4pl.htm They cover physical activity over the past year.

Introductory Script:
Now I am going to read you a list of activities. Please tell me which activities you have done in the past year.

In the past 12 months did you (do) the following activity in any month?

1. Read through each activity.

    a. If answered NO, move to next question.

    b. If answered YES, move below to answer,

        i. In a typical 2 week period of time, how often did do this activity?
        ii. How long did you do this activity on average each session? *(# of hours and/or minutes*)
        iii. How many months out of the year did you do this activity?

    c. If REFUSED, code as 8\

    d. If answered UNKNOWN, code as 9

    e. Regarding the last row for "Other" activity not listed above, it is acceptable to cue the participant to other possibilities, such as skiing, horseback riding, etc.

****NOTE: If golfing is done with a cart, code under light sport or recreational activities.**

Fractures

Yes	No	Fractures
		Since your last clinic visit have you broken any bones? **If yes, code the location of the 1st 3 fractures**

Exam 9 Proxy Form
(clinic & offsite)

Proxy Information

Whenever someone else is providing information about a participant that is collected on the forms, this person is considered a "proxy". When an offsite visit is to a nursing home, frequently a nurse familiar with the participant will be the proxy. Sometimes during offsite exams there will be more than one proxy. For example a Home Health Aid may answer all of the questions relating to ADL's, and the daughter may answer all of the medical questions. In cases like these, record information for both proxies on the proxy sheet in the exam form.

Important: The proxy that is designated by the participant as their FHS proxy does not have to be the same person as the one listed on the exam form.

Blood Pressure Measurement

A. Equipment:

1. One standard Litman stethoscope tubing and earpieces with bell: Classic II 3M

2. One standard mercury column sphygmomanometer: Baumanometer (clinic)

3. Aneroid sphygmomanometer (off-site)

4. BP cuffs in four sizes (all Latex free)

   Thigh adult cuff
   Large adult cuff
   Regular adult cuff
   Pediatric cuff

B. Blood Pressure Cuff Placement:

1. Bare participant's left arm to the point of the shoulder.

2. Determine correct cuff size using guidelines inside the cuff.

3. Palpate the brachial artery.

4. With participant seated, place the appropriate cuff around the upper left arm. The midpoint of the length of the bladder should lie over the brachial artery. Each cuff has an artery marker. The mid-height of the cuff should be at heart level.

5. Place the lower edge of the cuff, with its tubing connections, about one inch (1") above the natural crease across the inner aspect of the elbow.

6. Wrap the cuff snugly about the arm, with the palm of the participant's hand turned upward.

7. If the subject has had a left-sided mastectomy, the right arm may be used for blood pressure measurement. If right arm is used, note it on the form.

C. Determination of Maximal Inflation Level

For each participant, determine the maximal inflation level, or the pressure to which the cuff is to be inflated for blood pressure measurement. This assures that the cuff pressure

at the start of the reading exceeds the systolic blood pressure and thus allows the first Kortokoff sound to be heard.

1. Attach the cuff tubing to the sphygmomanometer.

2. Palpate the radial pulse.

3. Inflate the cuff rapidly until the radial pulse is no longer heard (palpated systolic pressure) by inflating rapidly to 70 mmHg, then inflating by 10mmHg increments.

4. Deflate the cuff quickly and completely.

5. The maximal inflation level is 30 mmHg **above** the systolic pressure.

D. Guidelines for Accurate Blood Pressure Readings:

1. The participant should be in a seated position for at least 5 minutes before the blood pressure is measured.

2. All readings are made to the nearest even digit.

3. Any reading which appears to fall exactly between marking on the mercury column should be read to the next higher marking (i.e. 2, 4, 6, 8, or 0).

4. All readings are made to the top of the meniscus, the rounded surface of the mercury column.

5. When the pressure is released quickly from a high level, a vacuum is formed above the mercury and the meniscus is distorted. Allow a few moments for it to reappear before reading the manometer.

For offsite Blood Pressures: Check that the needle is at the zero mark at the start and the end of the measurement. Place the manometer in direct line of sight with the eye on a line perpendicular to the center of the face of the gauge.

E. Blood Pressure Readings:

1. Following any previous inflation, wait at least 30 seconds after the cuff has completely deflated.

2. By closing the thumb valve and squeezing the bulb, inflate the cuff at a rapid but smooth continuous rate to the maximal inflation level (30 mmHg above palpated systolic pressure).

3. The examiner's eyes should be level with the mid-range of the manometer scale and focused at the level to which the pressure will be raised.

4. Open the thumb valve slightly. Allow the cuff to deflate, maintaining a constant rate of deflation at approximately 2 mmHg per second.

5. Using the bell of the stethoscope, listen throughout the entire range of deflation, from the maximum pressure past the systolic reading (the pressure where the FIRST regular sound is heard), until 10 mmHg BELOW the level of the diastolic reading (that is, 10 mmHg below the level at which the LAST regular sound is heard).

6. Deflate the cuff fully by opening the thumb valve.

7. Remove the stethoscope. Neatly enter systolic and diastolic readings in the spaces provided on the form.

MD BP CERTIFICATION

MD	Cerification Date		Certified by	Recertification Date	Recert by

X = not in clinic anymore

BRIEF REPORT: How Well Do Clinic-Based Blood Pressure Measurements Agree with the Mercury Standard?

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BACKGROUND: Obtaining accurate blood pressure (BP) readings is a challenge faced by health professionals. Clinical trials implement strict protocols, whereas clinical practices and studies that assess quality of care utilize a less rigorous protocol for BP measurement.

OBJECTIVE: To examine agreement between real-time clinic-based assessment of BP and the standard mercury assessment of BP.

DESIGN: Prospective reliability study.

PATIENTS: One hundred patients with an International Classification of Diseases—9th edition code for hypertension were enrolled.

MEASURES: Two BP measurements were obtained with the Hawksley random-zero mercury sphygmomanometer and averaged. The clinic-based BP was extracted from the computerized medical records.

RESULTS: Agreement between the mercury and clinic-based systolic blood pressure (SBP) was good, intraclass correlation coefficient (ICC) = 0.91 (95% confidence interval (CI): 0.83 to 0.94); the agreement for the mercury and clinic-based diastolic blood pressure (DBP) was satisfactory, ICC = 0.77 (95% CI: 0.62 to 0.86). Overall, clinic-based readings overestimated the mercury readings, with a mean overestimation of 8.3 mmHg for SBP and 7.1 mmHg for DBP. Based on the clinic-based measure, 21% of patients were misdiagnosed with uncontrolled hypertension.

CONCLUSIONS: Health professionals should be aware of this potential difference when utilizing clinic-based BP values for making treatment decisions and/or assessing quality of care.

KEY WORDS: blood pressure measurement assessment; clinic method; mercury device.
DOI: 10.1111/j.1525-1497.2005.0105.x
J GEN INTERN MED 2005; 20:647–649.

Obtaining accurate blood pressure (BP) readings is important for the management and assessment of hypertension. Clinical trials implement a strict protocol designed to minimize observer bias.[1] However, in clinical practice and in studies that assess quality of care, a less rigorous protocol is used to obtain BP values.[2] The lack of rigorous BP measurements in the clinical setting may lead to unreliable recordings and misunderstandings of patients' BP control. This may influence medication recommendations as well as assessments of clinic-based quality of care.

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The authors have no conflicts of interest to report.

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Historically, the random-zero mercury sphygmomanometer has been the gold standard for BP measurements. However, owing to concern over mercury spills, the mercury devices are no longer used in the clinical setting.[3] In 1998, the American Hospital Association (AHA) and the Environmental Protection Agency (EPA) signed a memorandum of understanding to eliminate mercury from hospitals by 2005 and launched a program to assist hospitals in this process.[4] Consequently, mercury sphygmomanometers are being replaced with other BP devices. Although these devices have been compared with the mercury sphygmomanometer under strict conditions, their utility in routine clinical practice has not been thoroughly investigated.[5]

Our study evaluated the current state of the clinic-based method of BP measurement. We sought to quantify the degree of agreement between real-time primary care clinic-based assessment of BP and the standard assessment of BP using the random-zero mercury sphygmomanometer.

METHODS

Setting and Patients

The study was conducted in the general internal medicine practice at Duke University Medical Center. Patients of 3 general internal medicine physicians, who had an International Classification of Diseases—9th edition diagnosis of hypertension (401.9) and an upcoming primary care clinic appointment, were contacted for participation in the study. Approximately 392 patients received a letter 2 weeks prior to their appointment. Of these, 227 were reached by telephone for screening 1 week prior to their appointment. Patients were excluded if they were on dialysis; had recently been hospitalized for heart attack, stroke, or metastatic cancer; lived in a nursing home; or received home health care. The exclusion criteria were for a separate study. Eligible patients were scheduled to meet with a research assistant 60 minutes prior to their physician's visit. If patients were unable to meet before, they were scheduled to meet with a research assistant directly after their physician's visit. One hundred patients consented and participated in the study.

Procedure

The protocol was approved by Duke University's Institutional Review Board. A trained research assistant performed all standard BP assessments. First, the patient's arm circumference was measured at the arm's mid-point between the

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acromium and olecranon process. The proper size cuff was placed on the right arm of the patient. Patients were instructed to sit up straight, with their back against the chair, their feet flat on the floor, and the cuffed arm resting on the table at heart level. At this point, the research assistant left the room, allowing the patients to relax for 5 minutes. Upon returning, the research assistant obtained 2 BP measurements with the mercury device. Between measurements, patients were asked to raise their arm for 5 seconds and rest their arm at heart level for an additional 25 seconds. Finally, a brief interview was conducted to obtain demographic information.

Three research assistants were involved in this study. Each research assistant received training and certification for the use of the random-zero mercury sphygmomanometer by successfully completing 4 items: a videotape exam; a written exam; a demonstration of the technique and procedure for proper BP measurement; and a Y-tube stethoscope exam. We examined whether there were differences in systolic (SBP) or diastolic blood pressure (DBP) by aresearch assistant using analysis of variance. The effect of research assistant on diastolic BP (mean of observations 1 and 2) assessed with the mercury device was significant (P=.02). However, further inspection of the data revealed that two patient outliers drove the effect. When the outliers were excluded, there was no longer a significant effect by research assistant (P=.11). Excluding the 2 outliers did not significantly affect the intraclass correlation coefficient (ICC) values; therefore, we retained all patients in the analyses.

Clinic-Based Measurement

The general internal medicine clinic utilized either of the following BP devices: the Welch Allyn vital signs monitor 52000 series (an oscillometric device) or the Tycos wall aneroid sphygmomanometer. Nurses obtained patients' BP in the examination room before the physician's encounter and recorded them in the facility charts and the electronic medical records. We extracted the clinic-based BP from the patients' electronic medical records. Eighty-four percent of the clinic-based assessments occurred within 1 hour of the standard mercury assessment. The mean time difference between the standard assessment and the clinic-based readings was 24 minutes (SD =47 minutes).

Statistical Analysis

Systolic and diastolic readings were obtained for 199 of the 200 possible measurements with the mercury device. The missing datapoint was because of large arm size.

We examined the extent to which two different methods of BP assessment (mercury vs clinic) produce the same BP values in 3 ways. First, we plotted the mean of the 2 methods (X-axis) against the difference between the 2 methods (Y-axis).[6] This Bland–Altman graphical representation permits investigation of the strength of the relationship (i.e., correlation) as well as the extent of agreement (i.e., the extent to which the 2 methods produce the exact same measurements). When 2 methods have high correlation but poor agreement, this nature of disagreement is displayed by the Bland–Altman graph. If agreement between 2 methods is high, then the difference scores should be normally distributed about a mean of zero. Second, we calculated the ICCs, which assess the relationship between 2 or more variables that have the same metric and variance.[7] We used a 2-way mixed model without interaction, treating mode of assessment (i.e., mercury vs clinic) as a fixed variable and subjects as a random variable. Third, we calculated the κ for percent of BPs in control versus out of control according to type of assessment (mercury vs clinic-based) using the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7) guidelines to define control.[8]

RESULTS

Patients' ages ranged from 43 to 86 years. The majority were female (77%), 78% were white, and 20% were black. Approximately one-quarter were diabetic and 94% were prescribed one or more antihypertensive medications (Table 1).

Agreement Between Mercury and Clinic-Based Measurements

The agreement between mercury and clinic-based readings was good for SBP, ICC =0.91 (95% confidence interval (CI): 0.83, 0.94), and satisfactory for DBP, ICC =0.77 (95% CI: 0.62, 0.86). The nature of disagreement is reflected in the Bland–Altman graphs, which show that the clinic-based assessments tended to overestimate both SBP and DBPs obtained by mercury. The mean difference was 8.3 mmHg (SD =13) for SBP and 7.1 mmHg (SD =12) for DBP (see Fig. 1). The ICC estimate of agreement between mercury and clinic-based DBP readings was lower than that for SBP readings because of a smaller range of DBP values.

Table 1. Characteristics and Data of the General Internal Medicine Patients

Characteristics	% (N=100)
Demographics	
Age (y) (M, SD)	64 (11)
Female	77
Male	23
White	78
Black	20
Asian	2
Married	65
Comorbidities	
Kidney disease*	5
Diabetic	26
Prescribed medication	94
Diuretics	73
Calcium channel blocker	35
ACE inhibitor	47
β-Blocker	26
Angiotensin-2 receptor blocker	26
α-1 antagonist	5
α-2 agonist	7
Data	Mean (SD)
Arm circumference (cm) (R: 24 to 49)	34 (5)
BP measurements (mmHg)	
Mercury SBP (R: 84 to 186)	128 (20)
Mercury DBP (R: 30 to 106)	67 (13)
Clinic-based SBP (R: 99 to 188)	136 (18)
Clinic-based DBP (R: 52 to 108)	74 (11)

**Kidney disease defined by serum creatinine > 1.5 for males, > 1.3 for females.*

ACE, angiotensin-converting enzyme inhibitors; BP, blood pressure; SBP, systolic blood pressure; DBP, diastolic blood pressure; R, range.

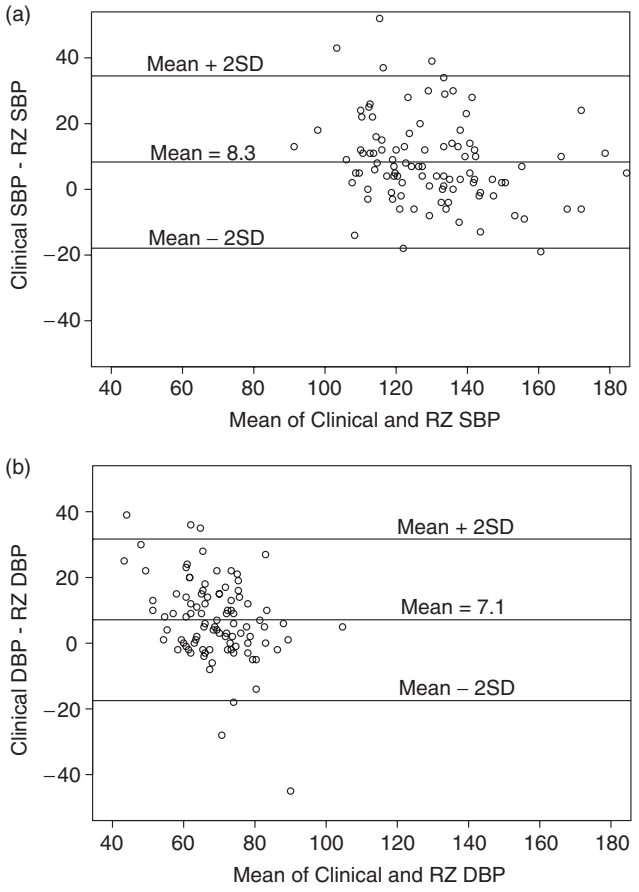

FIGURE 1. Bland–Altman graphs comparing blood pressure values obtained by the random-zero mercury sphygmomanometer versus the clinic-based method: (A) systolic blood pressures; (B) diastolic blood pressures.

We also determined agreement between methods within categories of BP control as defined by JNC 7. Twenty-three percent of the patients were classified with controlled BP ($<140/80$, or $<130/80$ for patients with diabetes or renal disease) based on the clinic as well as the mercury readings. Fifty-two percent were classified with uncontrolled BP based on the clinic as well as the mercury readings. However, 21% of the patients were characterized with uncontrolled BP based on clinic measurements, while their standard mercury assessment of BPs showed that they were in control. When categorized in this manner, agreement between clinic-based and standard methods was only moderate, $\kappa=0.47$ (95% CI: 0.30, 0.64).[9]

DISCUSSION

The gold standard for BP measurement is the utilization of the mercury sphygmomanometer and a strict protocol. In clinical practice, however, an aneroid or a digital device is used under a less stringent protocol. When the two types of assessment were compared, we found that clinic-based readings were generally higher than the values obtained using the more rigorous method. The Bland–Altman graphs specify the nature of disagreement (see Fig. 1). Specifically, clinic-based assessments tended to overestimate both SBP and DBP obtained by mercury. Of note, the clinic overestimation occurred more often with mercury readings categorized as normotensive. Hence, although the patients' BP values may be normal based on the mercury device, the clinic-based readings misdiagnosed 21% of the patients with uncontrolled BP.

Our study had several limitations. First, the clinic-based readings and the standard assessments were not taken at the same time. However, the majority of the readings (84%) occurred within 1 hour of each other. Second, we did not randomize the order of physician's visit and research assistant's meeting. However, patients who met with the research assistant before their physician's visit ($N=86$) did not have more elevated clinic BPs than patients who met with the research assistant after their physician's visit ($N=14$). Third, there was the potential for terminal digit bias by the research assistants when using the random-zero mercury sphygmomanometer. However, each research assistant was trained to perform BP measurements by decreasing the mercury column by 2 mmHg per second to prevent digit preference. On the other hand, the potential for terminal digit preference in the clinic could not be controlled. Therefore, we would consider this a characteristic of the less rigorous protocol carried out in the clinic.

In summary, we show evidence that the assessment of BPs in a primary care clinic fails to provide values that are obtained with a standard method of assessment. Furthermore, clinic-based BP values may overestimate those obtained by a standard method. The degree of overestimation is clinically important and could result in inappropriate treatment decisions. We advocate better standardization of the clinic-based method with implementation of recommended devices and a more rigorous training of the nursing staff.

This study was supported by the Eugene A. Stead Medical Student Research Scholarship to the first author, and an NHLBI Grant R01 HL070713 to the second author. We also thank Drs. Kathleen Waite and Anne Phelps for their assistance with patient recruitment.

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5. **Jones DW, Appel LJ, Sheps SG, et al.** Measuring blood pressure accurately: new and persistent challenges. JAMA. 2003;289:1027–30.
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7. **McGraw K, Wong S.** Forming inferences about some intraclass correlation coefficients. Psychol Methods. 1996;1:30–46.
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9. **Landis JR, Koch GG.** The measurement of observer agreement for categorical data. Biometrics. 1977;33:159–74.

Socio-demographics
Self-Administered Questionnaire/Tech-Administered Offsite

During the examination the participant will be given a clipboard with this questionnaire included to be completed in between testing stations.

Once the questionnaire is completed, the staff should confirm that all boxes have been filled in with a code. Staff members should not fill in any blank information nor ask the participant any leading questions. If any questions are left blank the form should be returned to the participant for completion.

For offsite examinations, this form will be tech-administered

OCCUPATION CODING

01 = HOMEMAKER
02 = RETIRED
03 = SELF EMPLOYED BUSINESS OWNER
04 = M.D./DENTIST
05 = LAWYER/JUDGE
06 = PSYCHOLOGIST/SOCIAL WORKER/MENTAL HEALTH COUNSELOR
07 = SCIENTIST/RESEARCH
08 = ENGINEER/COMPUTER SCIENCE
09 = BANKER/ACCOUNTANT
10 = MANAGER/CONSULTANT (e.g. PRODUCTION MANAGER)
11 = ADMINISTRATIVE (e.g. PERSONNEL)
12 = EDUCATOR
13 = NURSE/MEDICAL PERSONNEL
14 = LABORATORY TECHNICIAN
15 = PHYSICAL/OCCUPATIONAL/SPEECH THERAPIST
16 = SECRETARY/CLERK/DATA ENTRY
17 = RETAIL/CASHIER
18 = SALES/MARKETING/INSURANCE
19 = REALTOR
20 = WRITER/EDITOR
21 = ARTIST/GRAPHIC DESIGNER/CRAFTSPERSON
22 = MUSICIAN
23 = POLICE/FIRE/SECURITY/MILITARY
24 = FACTORY/ASSEMBLY
25 = MECHANIC
26 = RESTAURANT/FOODWORKER
27 = SKILLED LABOR (e.g. PLUMBER, CARPENTER, PAINTER HAIRDRESSER)
28 = GENERAL LABOR (e.g. CUSTODIAN, DELIVERY, MAILMAN, TRUCKDRIVER)
29 = HEAVY LABOR (e.g. CONSTRUCTION, LANDSCAPING)
30 = CLERGY (MINISTER, PRIEST, RABBI)
31 = SPORTS PRO/COACH/EXERCISE INSTRUCTOR
32 = STATISTICIAN
33 = STUDENT
88 = OTHER

SF-12®
Self-Administered

What is the SF-12®?

The SF-12® is a multipurpose short-form (SF) generic measure of health status. It was developed to be a much shorter, yet valid, alternative to the SF-36® for use in large surveys of general and specific populations as well as large longitudinal studies of health outcomes. All SF-12® items came from the SF-36®.

The SF-12® has become one of the most widely used instruments for purposes of monitoring the health of both general and specific populations because it is substantially shorter than SF-36®. It has been adopted for many large population outcomes monitoring efforts that did not include the SF-36® because of its length. More than 1 million SF-12® surveys were administered within a year of its release and the SF-12® has been selected for inclusion in the National Committee for Quality Assurance (NCQA) *Annual Member Health Care Survey* (Version 1.0), which NCQA and many large employers require for accreditation. These trends confirm the expected practical advantage of the SF-12®.

The SF-12® includes one or two items from each of the eight health concepts Thus, the SF-12® measures eight concepts commonly represented in widely used surveys: physical functioning, role limitations due to physical health problems, bodily pain, general health, vitality (energy/fatigue), social functioning, role limitations due to emotional problems, and mental health (psychological distress and psychological well being). Both standard (4-week) and acute (1-week) recall versions are available.

Source: Ware, J., Kosinski, M., Keller, S.
"SF-12®: How to Score the SF-12® Physical and Mental Health Summary Scales" (Third Edition: September 1998)
Quality Metric Incorporated, Lincoln, Rhode Island and The Health Assessment Lab, Boston Massachusetts

Reference: Ware, J., Kosinski, M., Keller, S.
"A 12-Item Short-Form Health Survey – Construction of Scales and Preliminary Tests of Reliability and Validity"
Medical Care, Volume 34, Number 3, PP 220-233 ©1996 Lippincott-Raven Publishers

Note: This form is tech administered on offsite visits. These questions cannot be answered by a proxy.

Sleep Questionnaire

Self-Administered in Clinic/Tech-Administered Offsite

1. For clinic exams the staff must check the form for completeness.
2. If the participant is cognitively impaired the questions will not be asked of the participant or of their proxy due to the length of the examination.

Guidelines for Review of Willett Food Frequency Questionnaire

The purpose of the Willet Food Frequency Questionnaire is to obtain information about what the participant usually eats and drinks. The questions review specific foods and portion sizes, to find out how often, on average, the specified amount was eaten or drunk during the past year. The Willet Food Frequency Form is completed prior to the participant's clinic visit.

Special arrangements may be made if the participant is illiterate, has problems reading, cannot read English, or is unable to answer the questions accurately due to physical or cognitive disabilities. This may be evident for example, the answer sheet has all circles filled out in the first column or is not filled out at all.

1. Check that there are no staples, rips, tears, or writing other than where indicated. If so, the form must be redone.

2. Make sure that the form is completed with a #2 pencil.

3. Check that circles are filled in completely - no Xs, checkmarks, etc.

4. Check that a response has been filled in for every line. If never used, fill in that circle.

5. Check that there is only one response for every line.

6. For vitamins, make sure the brand, the dose and how long taken is written in the spaces provided.

7. Make sure that all extra foods are written in the numbered spaces (up to 4 items) with complete information.

8. Make sure that what is written in the extra foods section is not something that is already in another part of the questionnaire.

9. Make sure to check for completeness of I.D. number.

10. Make sure to stamp the date on top when the participant brings in the form.

PLEASE READ

INSTRUCTIONS FOR COMPLETING THE FOOD FREQUENCY QUESTIONNAIRE

An important part of the Framingham Heart Study is the completion of this Food Frequency Questionnaire. It is designed to measure your dietary pattern over the past year.

Thank you so much for participating in this research study.

Please complete this form and bring it with you at the time of your appointment.

1. Please use a #2 pencil.
2. **Every line must have a circle colored in. Do not leave any questions blank. If the section does not apply to you, please color in a circle that is labeled, "No" or "Never."**
3. Make sure all erasures are complete.

Thank you for taking the time to fill out this form.

Instrucciones para rellenar la forma sobre la dieta "Food Frequency Questionnaire"

Muchas gracias por participar en este estudio. Una parte importante del mismo es el cuestionario sobre su dieta (Food Frequency Questionnaire) que ha sido diseñado para medir su patrón de alimentación durante el último año.
Por favor llene esta forma y tráigala con usted el día de su cita.

Desafortunadamente solo tenemos esta forma en Inglés. Si cuenta con alguien que le pueda ayudar a llenarla se lo agradeceríamos mucho, si no, por favor traiga esta forma a la clínica y con gusto aquí le ayudaremos a completarla. Es muy importante que sea contestada con la mayor exactitud posible!

Por favor:
1.- Use LAPIZ para rellenar los círculos en su totalidad, indicando su respuesta.

2.- No deje ninguna respuesta sin marcar. Si la pregunta o sección de preguntas no aplican a usted, rellene los círculos "never" (nunca).

3.- No separe, engrape ni destruya esta forma.

4.- Si necesita cambiar una respuesta, por favor borre completamente el círculo con la respuesta equivocada.

GRACIAS!

FRAMINGHAM HEART STUDY

Pulmonary Function Testing

MANUAL OF PROCEDURES FOR OFFSPRING EXAMINATION 9

Date: 4/1/11

Table of contents

1. Overview

Participants have undergone spirometry, which measures the ability to force air out of the lungs, at each exam cycle since the earliest days of the Original Cohort. Measurement of diffusion capacity, a measure of the lung's ability to exchange oxygen and carbon dioxide, has been done in the first and second examination of the Generation 3 cohort and in the 8th examination of the Offspring cohort.

A limited number of participants in Offspring (8th examination) and Generation 3 (2nd examination) have undergone post-bronchodilator spirometry, in addition to the pulmonary function testing that all participants undergo. This will be done again in the Offspring 9th examination. Selection of participants to undergo post- bronchodilator testing is based on evidence of airflow obstruction and will help discriminate between participants with reversible airflow obstruction (i.e., asthma) and those with fixed disease (i.e., chronic obstructive pulmonary disease).

For those undergoing post-bronchodilator testing, the time spent in the Pulmonary Function Testing station will be somewhat longer, as a result of the additional spirometry testing and additional time needed to allow onset of medication effect. Subjects **not** performing post-bronchodilator spirometry will proceed through the station as follows:

1) spirometry
2) diffusion effort #1
3) questionnaire
4) diffusion effort #2. At least 4 minutes should pass between diffusion maneuvers

Subjects performing post-bronchodilator spirometry will proceed through the station as follows:

1) spirometry
2) diffusion effort #1
3) questionnaire
4) diffusion effort #2 (at least 4 minutes should pass between diffusion maneuvers)
5) completion of all remaining exam components
6) administration of albuterol (at a time that ensures that post-bronchodilator spirometry will be able to be performed at least 10 minutes and no more than 15 minutes after administration)
7) post-bronchodilator spirometry

The timeline below summarizes the time-lines for these two alternative test protocols:

Table 1. Timeline for pulmonary function testing at FHS

	Start	10 minutes	15 minutes	20 minutes	25 minutes	40 minutes	50 minutes
Those doing only pre-bronchodilator spirometry and diffusion	Pre-bronchodilator spirometry	First Diffusion Capacity	Respiratory Questionnaire	Second Diffusion Capacity			
Those doing pre, post bronchodilator spirometry and diffusion	Pre-bronchodilator spirometry	First Diffusion Capacity	Respiratory Questionnaire	Second Diffusion Capacity	Bronchodilator Administration	15 minute wait	Post-Bronchodilator spirometry

2. Background and Glossary of Terms

Spirometry records the relationship between the rate at which air can be exhaled and the volume of air exhaled during a breathing maneuver called the FVC maneuver (forced vital capacity maneuver). Some common lung diseases reduce the rate at which air can be exhaled during a FVC maneuver. Such "obstructive" lung diseases include asthma, bronchitis and emphysema. The ratio of FEV1/FVC, a measure of how quickly air can be exhaled, is reduced in obstructive lung diseases (e.g. asthma and chronic obstructive lung disease) but may be normal in other conditions that reduce both FEV1 and FVC to the same degree (e.g. surgical removal of part of a lung, pulmonary fibrosis, or severe obesity).

A number of key terms are defined below:

FEV1 is the Forced Expiratory Volume in one second, i.e. the total amount of air that a person can blow out in one second during a maximal forced exhalation. It is reduced in many conditions that cause impairment of lung function.

FVC is the Forced Vital Capacity, the total volume of air that can be exhaled forcefully and as rapidly as possible from the point of maximal inhalation (lungs as full as possible) to the point of maximal exhalation (lungs as empty as possible). The subject takes as deep a breath as possible and then quickly exhales as much air as possible.

FVC maneuver is the maneuver of exhaling as forcefully and as rapidly as possible from the point of maximal inhalation (lungs as full as possible) to the point of maximal exhalation (lungs as empty as possible).

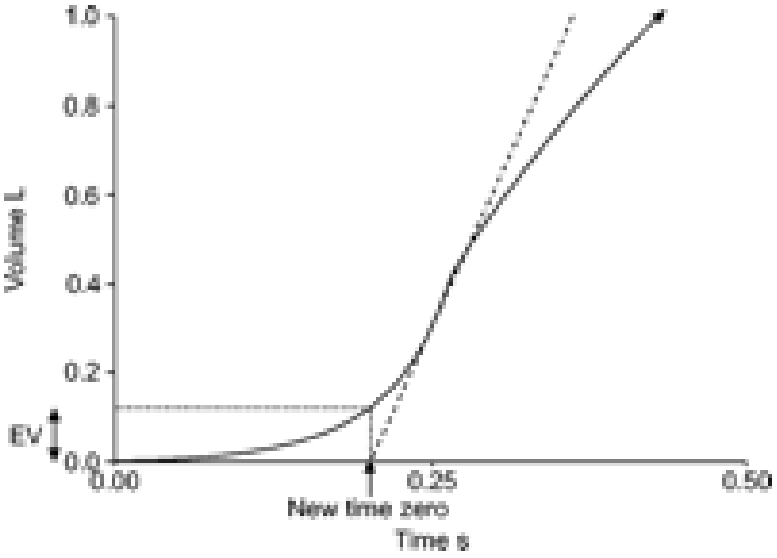
FEV1/FVC RATIO is the ratio of the FEV1 divided by the FVC. It is the proportion of total volume of air exhaled in an FVC maneuver that is exhaled in the first second of the maneuver. It is reduced in obstructive lung diseases such as asthma and chronic obstructive lung disease.

PEF (or PEFR) is the Peak Expiratory Flow Rate, i.e. the highest flow measured during the FVC maneuver.

PRED: is short for the "predicted value" of a pulmonary function parameter. It is determined on the basis of gender, age, and height from a regression equation derived from a large population study of apparently healthy people who have never smoked tobacco.

PERCENT PREDICTED is the value of a given pulmonary function measurement, such as FEV1, when as expressed as a percentage of the value that would be predicted for a healthy never-smoker of the same gender, age, and height as the participant. For example, an FEV1 of 50 percent predicted means that the participant's FEV1 is only 50 percent of what would be predicted for never-smokers of the same gender, age, and height.

BACK EXTRAPOLATION: is the standard method used to determine "time zero" when measuring the FEV1. The amount of slowly exhaled volume at the start of the maneuver excluded from the FEV1 by this technique is called the back extrapolated volume (BEV or EV). The BEV is calculated as shown in the figure below:



The BEV should be less than 5% of the FVC or 0.15 L, whichever is greater, otherwise the maneuver is considered to have started too slowly.

DIFFUSION CAPACITY OF CARBON MONOXIDE: is a measure of the lung's ability to transfer gas into the bloodstream (volume of gas (carbon monoxide) transferred per minute per mmHg of mean pressure gradient). This volume is derived using the total lung capacity derived from a single breath dilution of an inert tracer gas (He, or CH_4).

3. Staff training requirements

A. Training requirements for new staff

1) Read and understand the manual of procedures.
2) Undergo pulmonary function testing.
3) Training session with the physician investigator overseeing lung function testing at FHS.
4) Perform unprompted pulmonary function testing on 5 non-participant volunteers while observed by certified technician.
5) Perform pulmonary function testing on 5 FHS participants while supervised by certified technician.
6) Perform unprompted pulmonary function testing on 1 non-participant volunteer while observed by the physician investigator overseeing lung function testing at FHS.
7) Complete written quiz (and review of correct responses) administered by physician investigator overseeing lung function testing at FHS.

B. Training requirements for staff previously certified to perform pulmonary function testing at FHS

1) Read and understand the manual of procedures.
2. Training session with the physician investigator overseeing lung function testing at FHS.
3) Perform unprompted pulmonary function testing on 1 non-participant volunteer while observed physician investigator overseeing lung function testing at FHS.
4) Complete written quiz (and review of correct responses) administered by physician investigator overseeing lung function testing at FHS.

4. Subject selection for bronchodilator testing

As noted above, in addition to the routine spirometry and diffusion capacity measurements obtained on all participants, some participants will have spirometry measured after inhaling a medication that may relax the airways of those with airflow obstruction. This will help discriminate between participants with reversible airflow

obstruction (i.e., asthma) and those with fixed disease (i.e., chronic obstructive pulmonary disease).

All participants whose current pre-bronchodilator spirometry has **EITHER** a FEV1-to-FVC ratio less than 90 % of the predicted value **OR** a FEV1 less than 85 % of the predicted value will be asked to undergo post-bronchodilator testing.

The % predicted values used to assess eligibility for post-bronchodilator testing are those that are calculated by the Collins CPL pulmonary function system using the NHANES III prediction equations (Hankinson 1999). For any participants who report their race as black or African American, the NHANES III African-American equations should be used. For all other participants, the NHANES III-Caucasian prediction equations should be used. (Note that we are not employing the NHANES "Hispanic" equations because these were derived from Mexican-American subjects, and most Hispanic participants in FHS are not of Mexican ancestry.).

5. Pulmonary function protocol summary

This section provides of summary of the protocol. Detailed step-by-step instructions for specific procedures are provided in later sections.

A. Subjects not undergoing bronchodilator testing

i) Pre-bronchodilator spirometry

During the test, participants will be asked to take a deep breath and then to force the air out as hard and fast as possible. The spirometer will measure these maximal flow rates and also the volume of air that has been exhaled at particular time points. As the results the testing assumes that these values are the maximum levels a participant can do, it is imperative that participants are coached to blast the air out of their lungs as hard and fast as possible.

ii) Diffusion capacity

As mentioned, diffusion capacity measures the lungs ability to exchange oxygen and carbon dioxide. A gas that does not diffuse from the lung into the blood stream (a tracer gas, methane) and carbon monoxide (CO), which is quickly taken up by the blood, are inhaled at trace amounts. Participants will hold their breath for a fixed amount of time (10-12 seconds), and then exhale. The Collins CPL system will then measure the difference between the CO and tracer gas as they are exhaled. This difference is due to the diffusion of CO and, as the time interval is known, we can calculate the rate of transfer. It is important that the participants take a deep breath (at least 90% of their vital capacity). Ideally, at least 2 maneuvers should be performed and should agree within 10%. At least 4 minutes should be allowed between diffusion maneuvers to allow sufficient time for the CO and tracer gas to wash out. If the first two attempts do not produce two acceptable maneuvers with a value for the single-breath diffusion capacity (Dsb) within 10% of the higher value, then a third maneuver should be performed after an additional 4-minute wait.

iii) Respiratory Questionnaire

Technicians will administer a respiratory questionnaire. The questionnaire will help investigators to understand whether the participant has allergies, asthma, COPD, and other pulmonary diseases. Further, the questionnaire will capture information on recent inhaler use, which may affect the spirometry.

Table 2. Common bronchodilator inhalers, Brand names and Generic names

	Short acting	Intermediate
	4-6 hours	12 hours
Drug trade names	*Proventil, Proair, Ventolin, Maxair, Combivent,*	*Serevent, Advair, Foradil, Sybmicort, Dulera, Brovana,*

	Maxair Xopenox, Volmax, Atrovent	*Spiriva*
Generic drug names	*albuterol, levalbuterol, pirbuterol, ipratropium,*	*salmeterol, fluticasone/salmeterol, formoterol arformoterol, budesonide/formoterol, mometasone/formoterol, tiotropium*

B. Subjects undergoing bronchodilator testing

Subjects undergoing post-bronchodilator spirometry will move through the Pulmonary Function Testing station exactly as those not undergoing the post-bronchodilator spirometry, except that after completing all of the exam components they will receive two inhalations of albuterol metered-dose inhaler 90 ug / inhalation, and then repeat the spirometry (which is done exactly as the pre-bronchodilator spirometry). Their schedule is described below.

1) **Pre-bronchodilator spirometry**
2) **Diffusion capacity**
3) **Respiratory Questionnaire**
4) **Post-bronchodilator spirometry** - The post-bronchodilator spirometry should be performed *no less than 10 minutes and no more than 15 minutes after* administering the albuterol.

6. Pulmonary function equipment and technical support contact information

1. nSpire Health 3 Litre Calibration Syringe Model #021156

2. nSpire Health Vitalograph Linearity Syringe Serial #CS4769

3. Contact person for PFT problems

   NSpire Tech Support
   800-574-7374
   Techs: [redacted]

   [redacted]
   NSpire NE Field Service Rep
   [redacted]

   For Supplies:
   [redacted]
   Somerset Medical
   9 Loire Street
   Somerset, MA 02726
   Phone (774) 644-1405
   Fax (508) 567-1225
   [redacted]
   http://www.somersetmed.com

4. Contact person for PFT Contract Issues

   [redacted]
   nSpire Health
   1830 Left Hand Circle
   Longmont, CO 80501
   (800) 574-7374 x3285

7. Supply list

For use with the Collins Comprehensive Pulmonary Laboratory (CPL)
Collins 2000 Plus/SQL Software version 4.8
And the Hewlett-Packard Deskjet 845c Printer

Item	Item Number	Vendor
Lung Diffusion Mix (.3% CO, .3% CH4, 21% O_2, BAL N_2) Size 200	Z04NI7852003060	Airgas East 17 North Western Drive Salem, NH Office (508) 755-6815 [redacted]
APC Smart-UPS Interruptible Power Supply		Mill City Connections
HP 840c Black Ink Cartridge		W.B. Mason

CPL System Catalogue – No. 004010

KoKoFilter w/mouthpiece and nose clips	810580	Somerset Medical
Balloon Kit – Set of 4 (B1, B2, B3, B4)	K70085	Somerset Medical
CPL 1B Balloon Kit	K700889	Somerset Medical
Disposable Hydrous Desiccator Columns	K021501	Somerset Medical
PFT Adaptor for CPL	212147	Somerset Medical
Roll of 100 Segmented Tubing	001426	Cardinal Health

CPL System Catalogue – No. 004000

Nafion Tubing	K381248	Somerset Medical
Disposable CO2 Cannister for CPL	022556	Somerset Medical
White Balloon Stems (refill pack)	K022356	Somerset Medical

8. Pulmonary function equipment daily procedures

1. Turn on: Spirometer switch.

2. Open valves on gases. Turn counterclockwise all the way to open.

3. Calibrate equipment.

4. Print calibration report for log record.

5. Date log book and put ID stickers for each expected participant.

6. Record any/all comments if issues arise or if participant refuses test or has to stop test.

7. Close the gas valves clockwise all the way everyday after testing is done.

Note: the Spirometry computer should NOT be turned off at the end of the day. It is turned off after clinic on Fridays.

8. Pulmonary function equipment calibration protocol

Read all prompts

- Minimize nSight (Patient Information)
- Shortcut to Plus CPLDiag
- Component = CPL (SN: SI0034)
- Balloon check: check all boxes and click on Inflate
- Deflate

LEAK TEST

Put round weight on bell

- Leak Test
- Component = CPL
- S Delay = 20
- Duration = 60
- Start
- $\leq$ -20 is ok. CANNOT HAVE $\geq$ -20. IF DO, REDO CALIBRATION (optimum = 0 to -14)

TOOLS (under nSight)

- (Follow prompts)
- Calibration
- *CPL (click on "+")
- Barometric pressure (highlight and make drop-downs visible)
- Calibrate
- Calibrate
- Temp (leave temp that is shown on screen = machine temp)
- Enter
- Humidity
- Enter
- Barometric pressure (leave barometric press that is shown on screen)
- Enter
- Continue

SPIROMETER

- Calibrate
- Calibrate (bell goes up)
- Attach syringe
- Press space bar
- Pull out syringe at constant pace
- Press space bar
- Push in at constant pace
- Press space bar
- All lines should have a green square = Valid. If not, repeat calibration
- Continue

PNEUMOTAC

- Calibrate
- Calibrate
- Continue
- Continue
- Press space bar
- Pull out syringe
- Press space bar
- Press space bar
- Push in syringe (push in before "4")
- Space bar
- Continue
- Verify
- Close

Take off syringe

DL GAS ANALYZER

- Calibrate
- Next (all must be "Valid" in green)
- Next
- If "Failed" repeat DL Gas calibration ONLY
- If "Passed" press Finish

REPORT

- Check all boxes EXCEPT MOUTH PRESSURE
- Print
- Write initials at bottom of report
- Put printouts in white binder on low shelf in front of scale

END

- Minimize nSight
- Shortcut to Plus CPL Diag
- Component = CPL
- Close
- Enlarge Raptor

9. Participant testing – detailed procedures

a. Exclusion criteria

Prior to all tests, the technician must ask the participant about pulmonary function testing exclusion criteria:

- Any of the following within 3 months: major surgery (chest, abdominal or brain), oral surgery, a heart attack, a stroke, or an aneurysm of the brain or cataract surgery. If the participant has an aneurysm, ask where it is.

- Blood pressure today greater than or equal to 210/110. Check with the MD or Tonometry in clinic for the participant's blood pressure reading. If the MD or Tonometry has not yet obtained a reading, take the participant's blood pressure according to FHS protocol. If either the systolic or diastolic exceeds this limit, do not perform the PFT.

- Ask: Do you currently have any limitations on physical activity prescribed by your doctor? If the participant answers yes to this question the technician will discuss the limitation with the clinic physician. If the clinic physician determines the limitation will not be detrimental to the participant's health if they perform the

PFT, the PFT will be performed per protocol. If the limitation puts their health at risk if they perform the PFT the exam will be aborted and notes will be put in the computer.

On the following page is a flyer that should be printed out and placed on the wall at the pulmonary function testing station to remind the technician to ask about these exclusion criteria.

(To be placed in PFT testing room)

PFT EXCLUSION CRITERIA

IN THE PAST 2 WEEKS HAVE YOU HAD:

- ORAL SURGERY

IN THE PAST 3 MONTHS HAVE YOU HAD:

- MAJOR SURGERY (Chest, abdominal, or brain, requiring hospitalization)?
- HEART ATTACK
- STROKE
- ANEURYSM OF THE BRAIN
- BP>210/110 (Participants blood pressure MUST be taken in clinic prior to performing the PFT)
- CATARACT SURGERY

DO YOU CURRENTLY HAVE ANY LIMITATION ON PHYSICAL ACTIVITY PRESCRIBED BY YOUR DOCTOR?

- Anyone with history of EPISODIC tachycardia, A-Fib ***REQUIRING MEDICAL TREATMENT*** or Ablation should be excluded from doing the albuterol challenge.

Note: Participants with chronic atrial fibrillation should not be excluded unless requested by participant.

b. Entering participant information

From the Windows desktop, double click on the "Plus 2000 Version 4.8" icon. On the Patient Information Screen tool bar click Search. Once the Patient Search box pops up enter the participant's FHS ID Number and click search. Once the computer finds the participants information it will display on the right side of the search box. Click on the participant's ID and hit Add to Cache. Close the search box and confirm that this is the correct participant (verify date of birth). Once this is confirmed click New Study. Update the participants Height & Weight and enter the tech number that is performing the test. Once the information card is appropriately completed, click on "Save" which will put the participant's information in the "Cache" as seen in the navigation bar (top of the screen, next to "Notes").

Date- Before you update the information for the New Study, the computer will ask you (in a pop-up screen) for a date of the pulmonary function test- ensure that the date is correct.

Name – If the participant's name is not in all capital letters, retype the participant's name. Enter the participant's first name, tab to the next field then his last name. Use all capital letters.

Date of birth -Confirm DOB

Height - Enter the participant's measured standing height in inches (including .25-.75)

Weight – Enter the participant's weight in pounds

Gender- Does not need to be changed from exam 1

Race- If the subject self-identifies as black or African American, please select "Black – African American (NHANES)" Otherwise, please select "White – Caucasian (NHANES)"

Editing- If a mistake was made when entering information, use mouse to move the cursor to the error. Then begin typing the information.

Saving the information- Once the data is satisfactorily entered, click on "Save."

c. Spirometry

The technician is the critical part of the pulmonary function testing system, since the technician must guide the participant through breathing maneuvers that are highly dependent on participant effort. The technician must coach the participant to inhale maximally and then to exhale maximally and as rapidly as possible. The technician must also judge the quality of the participant's effort. To obtain accurate results, the testing must be done in a standardized fashion.

Note: This manual refers to the participant as "he" or "him" for easy reading, although participants will be both male and female.

Position the Participant – Testing should be conducted in the sitting position in a chair without wheels. The participant should sit erect with chin slightly elevated.

Explain the Procedure – The technician should explain that the purpose of the next test is to determine how hard and fast he can exhale air, "Like blowing out dozens of candles on a birthday cake." The technician should explain that he should take in as deep a breath as possible, and when his lungs are completely full, blow out all the air as hard and fast as possible, until told to stop.

Dentures, if they are loose, should be removed and placed in a clean cup, since they will prevent a tight seal from being formed around the mouthpiece. If dentures are not loose, leave them in place.

Always Demonstrate the Maneuver. The technician should ask the participant to watch them demonstrate the FVC maneuver. Again demonstrate correct placement of the mouthpiece. If the participant does not adjust well to using the mouthpiece (i.e. strong gag reflex) the participant can use just the neck of the filter for a mouthpiece. His lips must remain tightly sealed using this also. The technician should sit up straight. Take a deep breath, throw back their shoulders, and widen their eyes to emphasize the maximal depth of inhalation. Then dramatically **BLAST** out all of their air as hard and as fast as they can.

The technician's vigorous demonstration will prevent time and effort from being wasted on unacceptable forced expiratory efforts that result from the participant's failure to understand a verbal explanation of the procedure.

FVC Maneuver Test Steps

The technician should do the following:

1) To begin doing the maneuvers, click on "Go to," then on "Forced Vital Capacity." This will bring up the testing page.

2) Ensure that the participant has a clean filter and mouthpiece, but do not connect the participant until prompted by the computer. Click on "Start test."

3) The spirometer will fill the bell and prompt the technician- THEN have the participant connect to the mouthpiece and breathe normally.

4) Ensure that the participant has a nose clip in place. If the nose clip is uncomfortable for a participant, then instruct the participant to tightly pinch his nostrils shut throughout each maneuver.

5) Once the participant is connected to the spirometer, nose clip in place, and is breathing normally, press the space bar. This will prompt the computer to track the regular breathing of the participant.

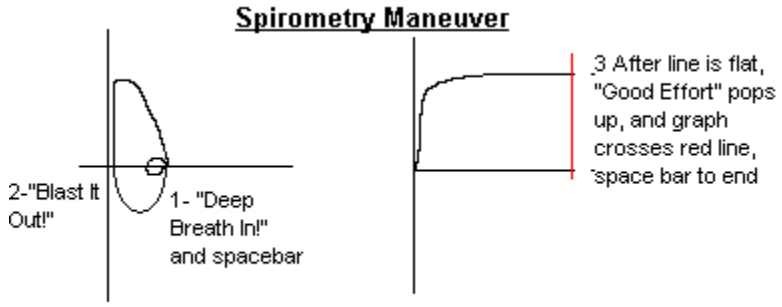
6) Once you are both ready, instruct the participant take in as **deep** a breath as possible and press the space bar while they are inspiring.

7) Coach the participant through the FVC maneuver, encouraging him to blow out as hard as possible for at least 6 seconds (as seen at the red vertical line on the time axis on the screen) **and** until the red line tracking the participant's maneuver (on the right hand graph) becomes flat. Watch the participant inspire deeply and then shout "**BLAST OUT**!!!" Lower your voice a bit and coach the participant by saying "keep going…keep on pushing out all that air…a little bit more…"

8) Watch the body language of the participant as he attempts to follow your instructions. **Pay attention to him, not the instrument**.

9) Once he has "pushed" for at least six seconds and the participant tracking line has become flat and the "Good Effort" message appears over graph, push the space bar again to end the test, have the participant come off the mouthpiece, remove the nose clip and breathe normally.

Example Graph of the Spirometry Maneuver:



To summarize the testing process:

- Once the participant is connected to the spirometer with a nose clip on, push the space bar.
- After a couple of normal breaths, have the participant take as deep a breath as possible.
- **While the participant is inspiring,** press the space bar.
- As soon as the participant has reached maximal inspiration, have him blast out all the air in their lungs.
- Once he has blown out for at least 6 seconds **and** the graph of his breathing has become flat and you see the "Good Effort" message, push the spacebar to end the test. Whether or not the "Good Effort" message is received, end each FVC maneuver once the total expiratory time has exceeded 12 seconds, as indicated on the x-axis of the volume-time curve displayed real-time during the maneuver. (We have added this 12-second rule to reduce the risk of dizziness and syncope in participants with airflow obstruction, in whom end-of-test flow criteria may not be achievable in a reasonable expiratory duration.)

The quality of the effort is seen at the top of the right hand graph- the quality is graded on (1) the initial effort (Extrapolated Volume, or EV), (2) flatness of the line or reaching of RV, Residual Volume, (End of Test, as defined by flow of less than 30mL/sec, or EOT), and (3) total expiratory time (TET).

You can repeat testing by starting again (with the participant off the mouthpiece initially) by going back to #2.

If the participant fails to perform the maneuver correctly, **again** demonstrate both the error and the correct performance yourself. You may have to repeat the demonstration after every maneuver for some participants.

The participant will be coached to perform at least 3 FVC maneuvers and to perform additional maneuvers, up to a maximum of 8, until acceptability and reproducibility goals are met, as described below.

FVC Maneuver Acceptability

According to the ATS-ERS standards, the technician should coach every participant to obtain at least three maneuvers that are "acceptable." FHS uses current ATS-ERS standards to determine acceptability. For each FVC maneuver, the Collins CPL system displays a "+" or a "-" to indicate whether each of three acceptability criteria have been met. These acceptability criteria are:

- Extrapolated volume (EV): "+" = EV less than or equal to 0.15 L
- Total exhalation time (TET): "+" = TET 6 seconds or greater
- End of test criteria (EOT): "+" = expiratory flow is close to zero (less than 30 mL/sec), i.e. the plateau on the volume-time curve appears flat

To be considered acceptable, all three criteria must be met, i.e. three "+" signs (which will appear in green) must appear for the maneuver. If one of more criteria receives a "-" sign (in which case they will appear in red), the maneuver will be considered unacceptable. There will be two exceptions to this rule:

1. An EV of < 5% of the FVC for a given maneuver will be considered acceptable, per ATS-ERS guidelines, even if it is not less than 0.15 L and therefore does not receive a "EV (+)" designation by the CPL system. A table of EV values that are acceptable for a given range of FVC values is posted at the lung function testing station to facilitate this determination by the technicians.

2. Some people with significant airflow obstruction cannot reach the EOT criterion of a flat plateau on the volume-time curve within a reasonable exhalation time that avoids substantial discomfort and a risk of dizziness or even fainting. For this reason, any FVC maneuver that appears otherwise perfect but fails to reach meet the EOT criterion despite a TET of 12 seconds or greater will be considered acceptable.

Reproducibility goal of the test session

The technician should coach every participant to obtain **at least** three maneuvers that are "acceptable," as defined above. Once three acceptable maneuvers have been performed, the technician must assess whether the reproducibility goal has been met. The reproducibility goal has two components:

1) The two largest values of FVC must be within 0.150 L of each other
2) The two largest values of FEV1 must be within 0.150 L of each other

Note that the largest FVC and the largest FEV1 may come from different maneuvers.

If the reproducibility goal is met by the three acceptable maneuvers, then the test session is complete. If the reproducibility goal is not met, then additional maneuvers should be performed, up to a maximum of 8, until the reproducibility goal is met. **Remember that ONLY acceptable maneuvers should be considered when assessing whether the reproducibility goal has been met. Also remember that the reproducibility goal requires that the largest two values (not any two values) of FVC or FEV1 be within 0.150 L of each other.**

Maximum Number of Maneuvers

Don't exhaust the participant by asking him to perform more than **eight** FVC maneuvers. If you haven't obtained 3 acceptable maneuvers and met the reproducibility goal by the time you have done 8 maneuvers, it is unlikely that you will. Click on "Notes" which will bring you to a screen where you may add comments as to why the participant was not able to successfully complete testing.

Saving the Results

Once you have obtained three acceptable maneuvers and have met the reproducibility goal (or failed to do so after 8 tries and documented the why in the "notes" field), testing is complete. Now click on "Save."

d. Diffusion capacity

Setting up

After completing the FVC maneuvers-

- Click on "Go to"
- Click on "Diffusion Capacity"
- Click on "START TEST"

Preparing the participant

While the machine prepares, explain to the participant that he will be asked to breathe normally and then to blow all his air out, just like the Vital Capacity maneuver. Once his lungs are as empty as possible, the participant will be asked to breathe in as deeply and quickly as possible and hold his breath for 10-12 seconds. The machine will close a valve, helping him to hold his breath and making it impossible for air to leak out- he will not be able to breathe while on the mouthpiece until the tester tells the participant to blow all his air out for the second time.

Starting the Test

1) You will get a series of messages as the machine prepares. The machine includes the volume of the filter in the calculations.

2) The computer will then display the following message- "OK." Click OK and then once the next box pops up, have the participant connect to the mouthpiece. "Press the spacebar when the patient is connected to the mouthpiece and breathing normally." Ensure that the participant's lips are tightly sealed around the mouthpiece and that the nose clip is in place. Once the participant is attached and breathing normally, press the spacebar.

3) The graph will show the participant's tidal breathing. Once the participant is comfortable, have him breathe all the way out to Vital Capacity (the point at which the graph of his breathing becomes flat). Coach him, saying "Push, push, push" just as you would for the spirometry.

4) Once he has pushed all the air out, press the spacebar and **IMMEDIATELY** instruct him to take as deep an inspiration as possible. Ideally, the deep inspiration should take one to two seconds.

5) Once the graph of his breath has flattened out again at maximal inspiration, tell him to hold his breath.

6) Push the "V" key, as soon as his breath has flattened out at maximal inspiration, to close the valve and keep air from escaping. He must hold his breath for 10-12 seconds for the maneuver.

7) Once the participant's graph crosses the vertical line on the screen, **IMMEDIATELY** instruct him to blow out all the air (if you closed the valve, it will open automatically at 12 seconds), just as though he was performing spirometry.

8) Have the participant keep blowing until the red line becomes horizontal.

9) Once the red line is horizontal, press the spacebar, ending the test.

10) After each diffusion hit save.

To summarize-

- Once in the Diffusion Capacity menu, Click on "Start Test" and prepare the participant
- Once the machine is set up and you clicked ok, ensure that the participant is comfortable on the mouthpiece, with a good seal, and with a nose-clip in place.
- Press the spacebar.
- After several breaths, have the participant blow out all the air he can.

- Once the graph flattens out horizontally, push the spacebar, then **IMMEDIATELY** have him breathe in as deeply and quickly as possible and hold his breath.
- Once the participant has taken as deep a breath as possible and the graph flattens out again, push the "V" key to keep him from breathing out.
- When the graph of the participant's breath hold crosses the vertical line, **IMMEDIATELY** have him blow out all the air he can, much like with the spirometry maneuvers.
- Once the graph flattens out at maximal expiration, push the spacebar, ending the test.

Grading the Test

The screen will change, and the effort is graded at the top of the graph on the left. Five criteria are applied- Start of Test (SOT), Breath holding Time (BHT), End of Test (EOT), Air leak during breath hold (DRP), and Mouth Pressure (MP). If all five are acceptable, they will be displayed in green. If one criterion is not met, then all three appear in red. The failed criterion will have a (-) sign next to it. Review how to improve this result with the participant.

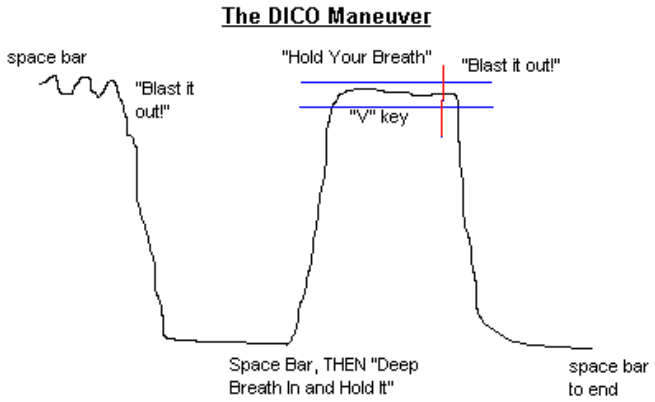
As with spirometry, maneuvers must be reproducible. For DLCO, two acceptable (all green effort marks) maneuvers must be within 10% of each other (i.e. 10% of the higher value).

Per ATS standards allow 4 minutes between tests. Note that the machine takes several minutes to set up. Use the clock on the computer to time the 4 minutes.

Repeat the maneuver from "Starting the Test" until you have two acceptable and reproducible maneuvers.

Limit the number of attempts for DLCO to 3 per participant.

Example Graph of the DICO Maneuver:



e. Respiratory questionnaire administration

The technician administers this questionnaire to the participant before starting the FVC. (Other questionnaires may be administered between diffusions). The questionnaire must be administered exactly as written. The answers are recorded in numbers, as indicated in the answer keys to the right of the questions. The technician follows the prompts on the questionnaire for the progression to follow, based on 'Yes', ("if yes fill in …") and 'No' responses.

If a participant reports that he/she uses an inhaler "as needed" and it was last used more than 48 hours ago, code as 88.

f. Bronchodilator administration and post-bronchodilator spirometry

i) Subject selection

The selection of subjects who will undergo bronchodilator administration and post-bronchodilator spirometry is described earlier in section 4. Briefly, all participants whose current pre-bronchodilator spirometry has **EITHER** a FEV1-to-FVC ratio less than 90 % of the predicted value **OR** a FEV1 less than 85 % of the predicted value will be asked to undergo post-bronchodilator testing.

ii) Bronchodilator administration

A. Albuterol information- We will administer 2 inhalations of albuterol HFA metered-dose inhaler 90 micrograms per actuation. Albuterol is a medication usually used to treat breathing problems like asthma or chronic obstructive pulmonary disease (COPD). The effects of albuterol last 3-4 hours. Participants with a history of adverse reactions to albuterol should not undergo this part of the protocol. Participants with episodic tachycardia or atrial fibrillation or ablation for AF should not be administered albuterol. At the doses we are using for FHS, only a small minority of participants would be expected to have side effects, and these side effects are listed in the "Consent Form." The side effects include: lightheadedness, an increase in heart rate (pulse) or symptoms of jitteriness or shakiness (tremors).
For women who are ≤ 55 years old and they qualify for albuterol (and do not have AF, tachycardia, cardiac ablasion, and have not refused albuterol):
Check physician exam (after ppt has seen physician):
IF the ppt is in menopause, has had a hysterectomy or tubal ligation = does not need pregnancy test prior to abuterol administration
If ppt is NOT in menopause, has NOT had a hysterectomy or tubal ligation: MUST HAVE PREGNANCY TEST PRIOR TO ALBUTEROL ADMINISTRATION

B.

The administration of the albuterol will not take place until the participant has completed all other components of the exam. This will ensure that no other data will be affected by the possible side effects of albuterol.

C. The participant will inhale two puffs of albuterol through a spacer. You should allow the participant to breathe normally for about a minute between inhalations, and there should be *no less than 10 minutes and no more than 15 minutes* between the administration of albuterol and the post-albuterol spirometry.

D. Detailed step-by-step protocol for bronchodilator administration:

1. Take the cap off the inhaler.
2. Shake the inhaler.
3. After shaking the inhaler, activate the inhaler in the air to check that it is operating adequately. Do this at arm's length from the technician and not near a participant, such that neither technician nor participants inhales it.(Note: When a new inhaler is being used for the first time, or if an inhaler has not been used for 2 weeks, activate 4 times before testing the first participant.)
4. Attach the inhaler to one end of a tube spacer. (Note: Each tube spacer, which is disposable and for single participant use, is a 6-inch length of segmented tubing cut from a 100-foot roll.)

5. Have the participant breathe all the way out in a relaxed manner; there is no need to reach maximal exhalation (residual volume) by forcing out the maximum amount of air possible.
6. Insert just the tip of the spacer into the participant's mouth.
7. Have the participant start to take a **slow**, deep breath in.
8. Just as the participant starts to inhale, activate the inhaler **once** while encouraging the participant to keep inhaling all the way until he/she has reached the point of maximal inhalation (total lung capacity).
9. At that point of maximum inhalation, have the participant hold his/her breath for about 10 seconds. After this, instruct the participant to exhale normally and relax.
10. Wait 1 minute and repeat for another inhalation.
11. Following the second inhalation of albuterol, allow at least 10 minutes and no more than 15 minutes before doing post-bronchodilator spirometry.

g. Data Procedures after Participant Testing

Inserting Test Comments
At the end of testing, you may wish to insert comments regarding the ability of the participant to comply with testing. This is added at the end of testing, under the "Reports" menu.

1) Click on "Notes"
2) Type in your comments
3) Save & close

"Notes" Option
There is a tab on the upper left portion of the "Patient Information" page. If the technician has a comment regarding a participant that may be helpful for clinical interpretation (e.g. "patient having pain with deep breath due to bruised ribs after fall yesterday") or for quality review ("e.g. patient refused to go on after two efforts"), then this should be entered under "Technician Notes," followed by clicking "Save and Exit."

Examples of notes that should be put in computer:

- Reasons for unacceptable tests
- Reasons for aborted tests
- Refusals/Physical symptoms affecting performance of PFT

Printing Reports

The PFT report is printed after the test is reviewed and graded by a FHS physician (pulmonologist). After grading the test, this physician will select the "File" tab and click on "Print Report". The HP Deskjet 845c. is selected and 1 copy is printed.

Log Book

All participants are entered into the "PFT Daily Log, Comment, and Calibration" binder. Enter, by date, each participant name. An FHS generated sticker with the name and ID number can be used.

Participants Completing the PFT

Once the PFT is done (or not done), complete Procedures Sheet:

|__|	**Spirometry**	0=Not Done, 1=Done, 2=Attempted, not finished, 3= Attempted, tech aborted ,4=Other
|__|	**Reason Spirometry not done**	1=Medical exclusion, 2=Refused, 3=equipment problems 4=Other
|__|	**Post Albuterol Spirometry**	0=Not Done, 1=Done, 2=Attempted, not finished, 3= Attempted, tech aborted ,4=Other
|__|	**Reason Post Alb. Spir. not done**	1=Medical exclusion, 2=Refused, 3=equipment problems 4=Other 5=Do not qualify
|__|	**Diffusion Capacity**	0=Not Done, 1=Done, 2=Attempted, not finished, 3= Attempted, tech aborted ,4=Other
|__|	**Reason Diffusion not done**	1=Medical exclusion, 2=Refused, 3=equipment problems 4=Other

Participants Not Having a PFT

Participants not having a PFT during their Clinic visit are also put in the "PFT Daily Log" binder with the reason that the PFT was not done.

Participants Refusing Bronchodilator Response Testing

Occasionally a participant who is asked to participate in the post-bronchodilator test refuses to do so. This refusal is recorded next to the participant's identifying sticker in the PFT Daily Log Book and the refusal reason is also noted under "technician notes" in the computer. Before the participant is asked to change and exited from the clinic, a second technician should ask the participant if he/she might be willing to perform the bronchodilator response testing.

Participant and MD Notification – PFT

Once a week the FHS pulmonary specialist comes into FHS and interprets with pulmonary function tests performed in clinic. He types a clinical interpretation on the participant's report and prints and signs one copy. He then delivers them to the Research Clinic Coordinator. The Research Clinic Coordinator makes a copy of each of the reports and gives them to the Statistical Technician.

The Statistical Technician files the original copy in the participant's chart and the second copy is mailed to the participant's physician.

For incorrectly previously entered Data:

*Pull up the participant information by using the incorrect ID number and add to cache.

*Then, enter the correct number and fill in all of the correct information. (name, birth date, height, weight, technician number, gender and race.) **MAKE SURE TO ENTER THE ACTUAL TEST DATE.**

In the composition book PFT Log Book, write in the incorrect information (ID, DOB, etc) and then write in the correct information along with the date of exam.
This log book will be used for any information that data may need (ID changes, machine changes, etc.)

10. Quality control observations of pulmonary function technicians by supervisor

Every three months, the clinic supervisor will observe each technician conduct a full pulmonary function test session on a participant. The supervisor will complete the following checklist for each observed session. Results will be reviewed with the technician and with physician-investigator overseeing pulmonary function testing at FHS. Constructive feedback will be provided as warranted. (Additional quantitative quality-control assessment of all pulmonary function data will be performed by the physician-investigator, with ongoing monitoring of study quality for each technician. Technician-specific feedback will be provided to optimize quality of all test procedures.)

Date: _____ Tech ID#_____ Quarter:_____
Supervisor:_____ Participant Label_____

PFT Supervisor Checklist
Clinic

Check that each procedure is carried out correctly. Check yes if correct or no if incorrect. Provide an explanation of the incorrect item. Items are presented in the sequence of the examination procedure, but may require confirmation before or after the exam.

Yes	No	PFT Instructions
		Ask the participant: In the past 3 months have you had: major surgery (chest, abdominal, or brain, requiring hospitalization), heart attack, stroke, aneurysm of the brain,cataract surgery, check BP(see list on wall) (Participants blood pressure MUST be taken prior to PFT Testing if not done by MD or Tonometry)
		Ask the participant: Do you currently have any limitation on physical activity prescribed by your doctor?
		If the participant is found to be ineligible due to the exclusion criteria the test is aborted and only the respiratory questions are completed & the reason is documented.

Yes	No	Spirometry/Forced Vital Capacity
		Position the Participant – Testing should usually be conducted in the sitting position on a chair without wheels. Ask the participant to sit erect with chin slightly elevated.
		Explain the Procedure - Explain that the purpose of the next test is to determine how hard and fast he can exhale air, "Like blowing out dozens of candles on a birthday cake." Explain that he should take in as deep a breath as possible, and when his lungs are completely full, blow out all the air as hard and fast as possible, until told to stop. Loose dentures should be removed.
		Always Demonstrate the Maneuver. Ask the participant to watch you perform the FVC maneuver. Again demonstrate correct placement of the mouthpiece. If the participant does not adjust well to using the mouthpiece (i.e. strong gag reflex) the participant can use just the neck of the filter for a mouthpiece. His lips must remain tightly sealed using this also. Sit up straight. Take a deep breath, throw back your shoulders, and widen your eyes to emphasize the maximal depth of inhalation. Then dramatically **BLAST** out all of your air as hard and as fast as you can.
		Have the participant connect to the spirometer with a nose clip on, push the space bar.
		After a couple of normal breaths, have the participant take as deep a breath as possible.

		While the participant is inspiring, press the space bar.
		As soon as the participant has reached maximal inspiration, have them blast out all the air in their lungs.
		Once s/he has blown out for at least 6 seconds **and** the graph of his breathing has become flat and you see the **"Good Effort"** message, push the spacebar to end the test.
		If the participant fails to perform the maneuver correctly, **again** demonstrate both the error and the correct performance yourself.
		The participant is not asked to perform more than **eight** FVC maneuvers
		Once the participant has 3 acceptable tests, click Save.
		The technician correctly assessed reversibility of the 3 acceptable tests.
		Staff looks at the FEV1/FVC ratios and, if they are <70%, the staff member asks the participant if he would do a reversibility testing with albuterol and a brief explanation of this is given.

Yes	**No**	**Diffusion Capacity**
		After completing the FVC maneuvers- • Click on "Go to" • Click on "Diffusion Capacity" Click on "START TEST
		Preparing the participant: While the machine prepares, explain to the participant that he will be asked to breathe normally and then to blow all his air out, just like the Vital Capacity maneuver. Once his lungs are as empty as possible, the participant will be asked to breathe in as deeply and quickly as possible and hold his breath for 12 seconds. The machine will close a valve, helping him to hold his breath and making it impossible for air to leak out- he will not be able to breathe while on the mouthpiece until the tester tells the participant to blow all his air out for the second time.
		1 <u>Starting the Test:</u> The box will pop up on the computer, hit ok. Do not have them attach to the mouthpiece until this done. The computer then will display the following message- "Press the spacebar when the patient is connected to the mouthpiece and breathing normally." Ensure that the participant's lips are tightly sealed around the mouthpiece and that the nose clip is in place. Once the participant is attached and breathing normally, press the spacebar

		2 The graph will show the participant's tidal breathing. Once the participant is comfortable, have him breathe all the way out to Vital Capacity (the point at which the graph of his breathing becomes flat). Coach him, saying "Blow it out, blow it out" just as you would for the spirometry
		3 Once he has pushed all the air out, press the spacebar and IMMEDIATELY instruct him to take as deep an inspiration as possible. Ideally, the deep inspiration should take one to two seconds.
		4 Once the graph of his breath has flattened out again at maximal inspiration, tell him to hold his breath. He must hold his breath for 10-12 seconds for the maneuver.
		Push the "V" key, as soon as his breath has flattened out at maximal inspiration, to close the valve and keep air from escaping.
		Once the participant's graph crosses the vertical line on the screen, **IMMEDIATELY** instruct him to blow out all the air (if you closed the valve, it will open automatically at 12 seconds), just as though he was performing spirometry.
		Have the participant keep blowing until the red line becomes horizontal
		Once the red line is horizontal, press the spacebar, ending the test.
		Wait 4 minutes between each maneuver. Do not start the set up until 2 minutes have passed.
		Repeat the maneuver from "Starting the Test" until you have two acceptable and reproducible maneuvers.
		Grading the test: Confirm that both tests are acceptable, they will be displayed in green. If one criterion is not met, then all three appear in red. The failed criterion will have a (-) sign next to it. Review how to improve this result with the participant. Then do another maneuver.
		Limit the number of attempts for DLCO to 3 per participant.
		Once the participant has 2 acceptable test click save.
		If there is a comment regarding a participant that is beneficial and should be saved, enter the comment under "Technician Notes" and then click on "Save and Exit."

Yes	**No**	**Albuterol Participants/Spirometry/FVC**
		Any participant that has a FEV1/FVC ratio of <70% (either pre-identified or identified in clinic) is asked to participate in the albuterol challenge.
		The administration of the albuterol is given after all of the other

		exam components have been completed.
		Getting ready 1. Shake the inhaler. 2. Take the cap off the inhaler. 3. Attach the spacer to the inhaler.
		Using the MDI 1. Have the participant breathe all the way out. 2. Insert just the tip of the spacer into the participant's mouth. 3. Have the participant start to take a deep breath. 4. As the participant starts breathing in **slowly** through their mouth, actuate the inhaler (press down on the inhaler) **one** time. 5. Have the participant keep breathing in **slowly,** as deeply as they can. 6. Have the participant hold their breath as you count to 10 slowly, if they can. 7. Wait about 1 minute between puffs. 8. Allow at least 15 minutes and no more than 30 minutes before doing post-bronchodilator spirometry.
		The spirometry/FVC protocol is performed according to the same protocol above.

Yes	No	PFT Completion
		Respiratory questionnaire is administered. Questions are asked exactly as they are listed on the page.
		All participants are entered into the "PFT Daily Log, Comment, and Calibration" binder. Enter, by date, each participant name. An FHS generated sticker with the name and ID number can be used.
		Once the PFT is done, fill out Procedures Sheet
		Participants not having a PFT during their Clinic visit are also put in the "PFT Daily Log, Comment and Calibration" binder with the reason that the PFT was not done.
		PARTICIPANTS REFUSING THE ALBUTEROL CHALLENGE: Occasionally a participant who is asked to participate in the post-bronchodilator test refuses to do so. This refusal is recorded next to the participant's identifying sticker in the PFT Daily Log Book and the refusal reason is also noted.

Yes	No	Technician Review
		Did the technician introduce the set of questions with clear explanation?

		Did the technician ask the questions exactly as written on the form?
		Did the technician correctly clarify any questions the participant had?
		Did the technician correctly use the answer key?
		Did the technician score the participant's responses correctly?
		Did the technician review the form for completeness?

Yes	**No**	**Deviations**
		Did the tech perform any minor deviations?
		Did the tech perform any major deviations?
Comments/Corrections/Deviations:		
Supervisor Signature:		
Date:		

11. Pulmonary function data back-up

Backing up the PFT Database:
Cumulative backup is performed once a week by the Desktop Support Specialist.

1. Login to the computer as FHS-DT-PFT\Valued Customer.
2. Close the nSight Program, if open.
3. Go to Start →All Programs →nSpire Health → nSight →Database Backup Wizard
4. Select "nSight DB2" from the database list and click Backup.
5. Save the backup on the desktop with the filename "PFTBackupmmddyyy.bak".
6. Once the backup is complete, connect to [redacted] using the FHS\Clinic domain account. (Note: There should be a mapped drive in My Computer to this location.
7. Create a folder called "PFT Backup mmddyyyy".

8. Copy and paste (or drag and drop) the backup file from the desktop to the newly created folder. (Note: This may take a few minutes to copy.)
9. Once you verify the backup is in the proper folder, delete the backup off of the desktop.
10. Log out or lock the computer once you are finished.

Backup Storage:

Data stored in the ClinicUsers folder is backed up weekly to data tape by the FHS IT Department. These tapes are then sent offsite monthly for storage with Retrievex. Please contact [redacted], FHS IT Manager with questions or access to the offsite data.

Other Database Tasks:

Before manipulating the database to do any other tasks except for using the nSight program or database backup, it is recommended that you contact the product's Technical Support to ensure you do not damage the database.

Updated: October 2011 by [redacted] for FHS-DT-PFT.fhs.org

12. Pulmonary function equipment maintenance schedule

Maintenance information taken from:

The Instruction Manual for the Collins Comprehensive Pulmonary Laboratory (CPL)
No. 760096, Version August 2000

Item	**Frequency**
Cleaning of CPL Covers and External Components	As Needed
Replacing CO_2 Absorbent Cartridge	Every 3 Months
Replacing Desiccator Columns	When Blue Granules turn Pink
Replacing Balloon Cuffs in Valve*	As Needed
Cleaning of Balloon Valve	As Needed
Change Nafion Tubing	Every 4 months
3.00 Liter Hans Rudolph	Annually

Send to:
Calibration Syringe
nSpire Health
1830 Lefthand Circle
Longmont, CO 80501

* The balloons must be inflated and deflated 50 times before use. We have an extra balloon valve so that a full set of balloons are prepped and readied for use. The valves are switched with the prepped balloons already attached when needed.

13. Calibration syringe exchange

Once the replacement syringe is received at FHS, remove it from the shipping box for usage and **immediately** insert the syringe FHS has been using into the same box for return to nSpire Health via FHS carrier of choice. It is **important** that RMA 16672 is written on the outside of this box and also insert the fax sheet into the box. Ship the syringe to: nSpire Health, 1830 Lefthand Circle, Longmont, CO 80501. File the enclosed calibration certificate in the FHS logbook or files.

Calibration Syringe Care

The 3.00 liter calibration syringe should be stored next to the spirometer so that it remains at the same temperature as the spirometer. Store the syringe with the plunger pushed all the way in. Take care not to drop the syringes.

ALBUTEROL LOT NUMBERS

EACH TIME A NEW ALBUTEROL INHALER IS OPENED, PLEASE RECORD THE STOP DATE OF THE PREVIOUS ONE AND THE LOT NUMBER AND START DATE OF THE NEW ONE.

LOT NUMBER	START DATE	STOP DATE

Maintenance Tracking Form

PFT PERIODIC MAINTENANCE 2008							
Cleaning CPL Covers (prn)	Replacing C02 Absorbent Cartridge (q.3mos)	Replacing Dessicator Columns (blue pink)	Replacing Balloons (and Prepping) (prn)	Cleaning Balloons Valve (prn)	Change Nafion Tubing (q.4mos)	Collins Syringe Calibra-tion (annually)	Mainte-nance (annually)

Air Gas Order Form

Air Gas
1-800-562-3815

[redacted]

PFT DAILY CALIBRATION

Read all prompts

- Minimize nSight (Patient Information)
- Shortcut to Plus CPLDiag
- Component = CPL (SN: SI0034)
- Balloon check: check all boxes and click on Inflate
- Deflate

LEAK TEST

Put round weight on bell

- Leak Test
- Component = CPL
- S Delay = 20
- Duration = 60
- Start
- ≤ -20 is ok. CANNOT HAVE ≥ -20. IF DO, REDO CALIBRATION (optimum = 0 to -14)

TOOLS (under nSight)

- (Follow prompts)
- Calibration
- *CPL (click on "+")
- Barometric pressure (highlight and make drop-downs visible)
- Calibrate
- Calibrate
- Temp (leave temp that is shown on screen = machine temp)
- Enter
- Humidity
- Enter
- Barometric pressure (leave barometric press that is shown on screen)
- Enter
- Continue

SPIROMETER

- Calibrate
- Calibrate (bell goes up)
- Attach syringe
- Press space bar
- Pull out syringe at constant pace
- Press space bar
- Push in at constant pace
- Press space bar
- All lines should have a green square = Valid. If not, repeat calibration
- Continue

PNEUMOTAC

- Calibrate
- Calibrate
- Continue
- Continue
- Press space bar
- Pull out syringe
- Press space bar
- Press space bar
- Push in syringe (push in before “4”)
- Space bar
- Continue
- Verify
- Close

Take off syringe

DL GAS ANALYZER

- Calibrate
- Next (all must be “Valid” in green)
- Next
- If “Failed” repeat DL Gas calibration ONLY
- If “Passed” press Finish

REPORT

- Check all boxes EXCEPT MOUTH PRESSURE
- Print
- Write initials at bottom of report
- Put printouts in white binder on low shelf in front of scale

END

- Minimize nSight
- Shortcut to Plus CPL Diag
- Component = CPL
- Close
- Enlarge Raptor

Daily PFT Log – Offspring Exam #9/Omni Exam #4

Date	Participant	Comments	Tech

PFT PERIODIC MAINTENANCE

Cleaning CPL Covers (prn)	**Replacing CO2 Absorbent Cartridge (q. 3mos)**	**Replacing Dessicator Columns (blue..pink)**	**Replacing Balloons (and prepping) (prn)**	**Cleaning Balloon Valve (prn)**	**Change Nafion Tubing (q. 4 mos)**	**Collins Syringe Calibration (annually)**
PFT NOTES						

Yearly Maintence by Field Service Tech

ALBUTEROL LOT NUMBERS

EACH TIME A NEW ALBUTEROL INHALER IS OPENED, PLEASE

RECORD THE STOP DATE OF THE PREVIOUS ONE AND

THE LOT NUMBER AND START DATE OF THE NEW ONE.

LOT NUMBER	START DATE	STOP DATE

NIHem Noninvasive Hemodynamics Protocol Flowsheet

Phase	Time (min) Total	Phase	Instrumentation	Computer	Verbal	Misc.
Setup	0-5	5	• Place BP cuff on RA, microphone over brachial artery, pressure hose behind arm • Apply 4 ECG leads to chest; arm leads under L & R collarbones, leg leads on lower L & R ribcage	• Machine on, [Register] • Enter Pt initials • Enter Center ID & Pt ID • Study date (default) • Select Study Type • Select Operator(s) • Click [OK]	• 'Please lie down and make yourself comfortable' • 'I am going to place ECG electrodes on your chest and a BP cuff on your right arm'	• Patient should change into hospital gown (open in front), undershorts OK, remove bra or T-shirt • If gown is tight on arm, remove RA from sleeve before applying BP cuff
Acquire BP	5-14	9	• Check volume setting, put on headphones • Cuff will automatically inflate/deflate • Remove BP cuff and headphones and store after BP complete	• Click [Waveforms] on toolbar • Click [BP] • Set Max Cuff Pressure • Click [BP1] • Click [Sys] on first beat with K-sound and [Dia] on first beat without K-sound; repeat clicks OK • Program automatically saves data • Wait 2 min, then BP2, BP3. • Click [Review], should range ≤ 5/5 mmHg • Click [Close]	• 'Now I'm going to check your blood pressure several times' • 'The cuff will inflate and deflate automatically' • 'Lie and breathe quietly and try not to talk even between measurements'	• Make sure there is space between cuff and chest to avoid respiratory artifact • Watch for motion artifact on red and orange traces. • If major motion artifact or K-sounds as soon as pump stops [Abort], adjust Max P if needed and redo. • May replay and edit current BP, but only before moving on to next BP.
Acquire Tonometry	14-22	8	• Find maximal pulsation with fingertips first • Place tonometer over artery • Sweep across artery to find center, adjust pressure, maximize waveform amplitude and features	• Click [Bra] • Optimize brachial waveform • Click [Save] to freeze tracing • Repeat for radial [Rad], femoral [Fem] & carotid [Car] • Click site again to replace data, but complete each site before moving to next	• 'Now I'm going to check your pulses with the tonometer' • Before Femoral: 'I'm going to check the pulse at the top of your leg'	• Put on gloves • Place a small dot at each pulse site just after tonometry is acquired • Remove gloves
Acquire LVOT Imaging	22-26	4	• Optimize image • Minimize depth • Use 2:1 zoom	• Click [Aortic US] • Click [LVOT] to initiate acquisition into a 5 sec circular buffer • Click [Save] as soon as a continuous 5 sec loop of satisfactory images is obtained Click [Close]	• Sonographer should obtain parasternal long axis view through LVOT during systole, hinge points of aortic valve leaflets visible • Sonographer: 'I'm placing cold gel on your chest'	• Place patient in the left lateral decubitus position • Use pillows as props for patient comfort • Confirm that ECG tracing is intact after moving patient • Minimal depth setting:10-12 cm

NIHem Noninvasive Hemodynamics Protocol Flowsheet

Phase	Time (min) Total	Time (min) Phase	Instrumentation	Computer	Verbal	Misc.
Acquire Aortic Pressure-Flow	26-28	2	• HP Filter: 300Hz-400Hz • Prepare to use tonometer	• Click [Aortic PQ] • Click [LVOT PW] • Obtain 20 sec of good flow waveforms • Click [Car P] • Obtain 20 sec of good pressure waveforms • Click [Close]	• Verify 'Are you comfortable?' • 'The sonographer will take pictures of your heart. Then I will record the pulse in your neck'	• Pulsed Doppler from apical 5-chamber • Max. peak velocity in LVOT • Minimize wall filters • Adjust scale (not zero) if aliasing
Acquire Mitral Inflow	28-30	2	• HP Filter: 300Hz-400Hz	• Click [Diastole] on the menu toolbar • Click [Mitral] • Record 1 screen of mitral inflow Pulsed Doppler • Click [Save] • Click [Close]	• 'Breathe quietly while the sonographer takes more pictures of your heart. Please do not hold your breath'	• Pulsed Doppler from apical 4-chamber • SV at level of mitral leaflet tips during Diastole • AVOID getting leaflets in Doppler SV
Acquire Tissue Doppler Velocity	30-32	2	• Filter: 50Hz • Gain: 55% • Scale: 20 cm/sec • Sweep: 50	• Click [DTI] • Record 20 seconds of continuous Tissue Doppler signal • Click [Save] • Click [Close]	• 'Breathe quietly while the sonographer takes more pictures of your heart. Please do not hold your breath'	• Tissue Doppler from apical 4-chamber • SV at center of the lateral mitral annulus

Measure Transit Distances	32-34	2	• For SSN-F measurement, open calipers wider than SSN-F distance. Use right thumb as leverage to adjust calipers to size of measurement.	• Click [Distances]
				• Enter values in mm, e.g.,
				  • SSN-C = 65-110
				  • SSN-B = 380-490
				  • SSN-R = 600-770
				  • SSN-F = 480-650
				• Click [OK]
					• 'I'm going to take a few measurements'	• Measure Bra and Rad with arm out at 90^{o}
						• Each distance from SSN to site
						• Hold down tape at Bra when measuring Rad

Wrap Up & Write CD	34+	5+	• Disconnect ECG from patient	• Close NIHem program • See CD recording instructions • Shutdown computer from the NT [Start] menu • Power off and unplug main power cord after shutdown complete	• 'Thank you…'	• Make 2 copies (Data CD and Archive CD) • Append to the Archive CD until full

The Framingham Study's Noninvasive Cardiovascular Testing Station

In the cardiovascular testing station you will receive two tests that noninvasively examine your heart and blood vessels' structure and function. None of the tests involve radiation. You will receive the following tests:

1. Blood pressure

- The sonographers will carefully measure your blood pressure while listening with headphones.

2. Arterial tonometry

- The sonographer will hold a flat pressure-sensing device (the tonometer) against the superficial pulses in your elbow, wrist, top of your leg and neck for approximately a minute at each of these four sites. This approach allows us to assess blood vessel stiffness. At the very end of all vascular testing, the sonographers will measure the distances between the 4 sites where the pulse recordings were taken. **Details of the test are provided on the reverse side.**
- The sonographer will also acquire an ultrasound view of the aorta (the large artery carrying blood flow from the base of your heart) as part of the tonometry evaluation. This is not an echocardiogram and the results will be used for research only.
- The Arterial Tonometry Test results are solely used for research purposes. They are not used in clinical practice or to guide medical decisions. For this reason we will not be sending the results to your physician.

If at any point during the testing you are uncomfortable and would like to terminate the tests, please tell the sonographers.

Thank you for your support of the research at The Framingham Study.

The Arterial Pressure Waveform Test (Tonometry)

How is the test performed?

- Measurements are made by gently pressing the tip of flat pressure sensing device (the tonometer) against the superficial pulses in the arm, leg and neck for approximately a minute at each of four sites. This device records the pressure waveform that is associated with each pulse or heartbeat.
- Next, the distance from the base of the neck to each of the pulse sites is measured.
- You will be asked to lie quietly during this phase of the testing. There should be no discomfort. This test has been performed safely in thousands of patients.
- At a later date, using a computerized analysis, we will examine the shape of the pressure waveforms and calculate the speed at which pressure waves travel through the large arteries.

Why are we doing this test?

- The arterial pressure waveform test is a noninvasive method to evaluate the stiffness of the large arteries.
- This test will allow us to evaluate the relationship between cardiac risk factors, arterial stiffening and the development of cardiovascular disease.

If you have further questions about the noninvasive tests please contact us at [redacted].

Prueba Cardiovascular No-invasiva del Estudio del Corazón de Framingham

En esta parte del examen le haremos dos pruebas cardiovasculares para examinar las arterias, estructura y funciones vasculares.
Esto no requiere radiación de ningún tipo. Las pruebas serán:

1. **Presión arterial**
   El sonógrafo (o técnico) medirá cuidadosamente su presión arterial escuchándola con audífonos.

2. **Tonometría arterial**
   - **El sonógrafo medirán los pulsos superficiales de su codo, muñeca, parte superior de la pierna y cuello por cerca de un minuto en cada lugar, utilizando un sensor plano. Esto ayuda a verificar la dureza o elasticidad de las venas. Al terminar, los técnicos medirán la distancia entre cada uno de estos 4 lugares donde pusieron el sensor. AL REVERSO DE ESTA PAGINA ENCONTRARA MAS DETALLES SOBRE ESTA PRUEBA.**

   - **También se obtendrá una imagen por ultrasonido de la aorta (La gran arteria que lleva sangre a su corazón). Esto NO es un ecocardiograma. Los resultados serán usados solo para investigación médica.**

   - **Como los resultados de esta prueba de tonometría arterial son sólo usados para la investigación, no enviaremos estos resultados a su doctor. Ya que no se pueden usar para hacer diagnósticos o decisiones médicas.**

Si usted se siente incómodo durante esta prueba y quisiera terminarla antes, por favor dígaselo al técnico o técnica.

Muchas gracias por su participación a ayuda para las investigaciones del Estudio del Corazón de Framingham

04/07/11

Actical Protocol
(Use, Download and Creation of Data Sets)

CLINIC PROCEDURES

Identify Participants

1. The clinic schedule lists the participants for following week.
2. From the schedule determine number of clinic participants per day.
3. Organize Actical devices into the corresponding number of piles per day.
4. Assign an Actical device to each participant.
5. Enter device serial number and id into the log book (rm 114) in the order of the pile.
6. Label each pile with day of week
7. Place devices into the blue bin located in room 114.
8. DM gives clinic ID stickers on Friday, for the following week.
9. For each participant ID, place one ID sticker on the device case and another in the log book.

Return Envelopes

1. Envelopes are located across from the supply cabinet up stairs.
2. Prepare the return envelopes the week before they are needed and include:
    a. Bubble wrap pouch
    b. Feedback form (Appendix D – Feedback Form.doc)
3. Place envelope in room 112.

Initializing Device

1. Each morning, take out the pile for that day from the blue bin.
2. Initialize device during clinic (See Actical Software Protocol below).
3. Initialize by entering the participants ID, Age, Sex, Height, Weight, Step Box will be checked, Epoch length set to .50, Start Time will be set to 15:00, and Start Date will be the date of exam.

4. For participants who want a delay start, there is only a 4 day window at this time (Note the deviation on log sheet).

Mailing Device - Delayed Start

1. Clinic staff to initialize the device at 15:00, the day the device is mailed out.
2. Activation date is noted in the log book.
3. Participant is instructed to press the event button at the time that the device is first worn.

Actical Software Protocol- Initialization

1. Open the Actical software.
2. Turn on the ActiReader (power indicated by red flashing light).
3. From the main Actical window select 'File > Write'.
4. At this point, a new window will open.
5. Insert the 'Subject Identity'.
6. Insert a Subject Age (can be any number and then modified at a later time).
7. 'Check' the box for Step Counting as a data point (right side of the window).
8. 'Click' inside the box to select the Epoch Length. You will need to select 0.50 (which is 30 seconds) to allow for data collection to be possible for up to 11 days. Be sure the data collection time-frame indicates 11 days. If not, 'click through' the epoch choices until you are back to 0.50. (As a side note, I let our software engineering team know that this needs to be addressed).
9. If you would like to select a delayed start time, you can select that date and time by moving the date/time bars, clicking on the hours or clicking inside the bar area. That is your choice.
10. Review all of the information you have selected for accuracy.
11. Click the box 'Send' to send the data collection information to the Actical.

Distributing Device to Participant

1. Ask participant if they want to wear the device for 8 days.
2. If 'yes', explain the device using a formalized script (see Appendix A - Actical Script).
3. Demonstrate how to wear the device.
4. Provide feedback to the participant as they practices putting on the monitor.
5. **Log book checks and entries:** (Note: The technician in charge of the participant is responsible for the following):

a. Check the device number matches the ID.
b. Writes the ID number in column '*Tech ID ACC Hand Out*'.
c. If activation date is different from clinic date, enter the date in log book column '*Date Activated if differs from Clinic mm/dd/yy*', otherwise leave blank.
d. Ask if the participant will be wearing the device in their home community or outside their community and enter into column 'Home (Yes) or Non-home (No)'.
e. Write the log sheet observation number "OBS" on the return envelope and give it to the participant.

6. Give the participant written instructions to take home (Appendix B – Device Instructions and Appendix C – Device Position).
7. Explain instructions to them before they leave.

Return of Envelope – Device and Feedback Form

1. The participant returns the device in the envelope provided.
2. Front desk staff place return envelopes in black bin located in room 114.
3. Check the envelope for the feedback form (Appendix D – Feedback Form.doc)
4. Note in the comment section of the log book:
    a. No form – leave blank
    b. Negative comment – enter 0
    c. Positive comment – enter 1
    d. Other comments – enter 2
5. Place feedback forms in ID order in folder marked FEEDBACK.
6. Data Management will track this for the OSMB etc.

Download Data

1. Download data to the following directory:
\\Fhs-srv-array1\FHS_Common\Actical\OFF\off ACTICAL DATA\off AWC download Process Complete
2. Assigned technician will download the data.
3. Recheck ID, height, weight, age, and gender for accuracy.
4. After downloading:

a. Check off the participant in the margin of the log book with a highlighter
b. Enter the download date.
c. Enter your TECH ID number in logbook column '*Tech ID Downld Act*.'.

Actical Software Protocol - Downloading

1. Open the Actical software.
2. Turn on the ActiReader (power indicated by red flashing light).
3. From the main Actical window select 'Reader > Read'.
4. At this point, a new window will open.
5. Click 'OK' to start Reading.
6. The data download will be shown by the red progress bar at the bottom of the window.
7. A message is displayed to tell you when the download is complete.
8. Take the Actical off the reader then click 'Yes' to Save Data.

Save to: [redacted]

9. Saved file is automatic *idtype-id*.awc.

<u>Export Statistics for Energy Expenditure</u>

1. Open Actical software
2. Chose batch or individual download.
3. Choose type of statistics i.e. _A_Stats.csv , W_Stats.csv etc.

Save files to :

[redacted]

4. After imports into SAS move files to:
5. [redacted]

6. Move downloaded AWC files into the following directory:

From: [redacted]

To: [redacted]

After Downloading

1. Place device back in the box for reuse.
2. Place belts in the laundry bin for cleaning.

Output Files

Electronic Logsheet

1. The electronic log file is located in the following directory:

   [redacted]

   Designated clinic personnel, enter data from the log book into the electronic log i.e. ID sticker, serial number, date activated, and where they will be wearing the device.
2. Save electronic file ACTICALMMYY.xls'.
3. Each month, save the cumulative file as the new month and place the old file in previous_months' folder.

DATA MANAGEMENT PROCEDURES

Importing Data into SAS

1. KineSoft proprietary software imports data from
2. KineSoft outputs a 'Batch Report' i.e. an excel file with 7 worksheets .
3. 'Batch Report' file is saved in [redacted]
4. Run programs – see DIR above #3
5. Create data sets and manuals.

Data Checks

1. Check log date, clinic date and Actical date against exam dates file.
2. Check ht and wt against Offspring Exam 9 data.

Physical Activity Monitor Script:

We are asking everyone in your generation to wear this new device called an actical or physical activity monitor which will capture your movement. We would like you to wear this device for 8 days, **during waking hours**. It is very small and will be attached to a belt worn around your waist. You may wear the belt over or under your clothing which ever is more comfortable for you. Is this something you are willing to do for the Framingham Heart Study?

(If yes)
Great! I will show you how to wear the belt and then you can put it on for me. (Demonstrate and use the picture from the handout as a visual then watch them put it on.)

Here is an **information sheet** for you to take home. You will be wearing the device all day during awake hours. **You will be taking off the device when you go to bed at night, and will be wearing it immediately upon waking up in the morning.** For most people, this will mean '**wear device**' in the morning and '**take off device**' at night. (However, if you do shift work or have any other type of schedule, the same basic guidelines apply, ' **wear device**' during your waking hours, '**take off device**' during your sleeping hours).

Please keep the device close to your bedside so that you can wear it immediately upon getting up and do not forget to wear it. The only other time you will be taking the belt off is when you shower. The device is waterproof but we are not asking anyone to wear it while showering. You do not need to take off the device during daytime naps.

Please note that there is no 'on-off' switch on the device and you cannot turn it off.

Are you going to be going swimming or doing any water sports while wearing it? (If yes, give a second belt.)

Once you are done wearing the device place it with the belt into the return envelope and seal it in the bubble bag.

Please put the device in the mail immediately after 8 days. We need these devices for the next participants that are coming in. Because these devices are expensive, we cannot keep a lot in stock.

Please note that you will get a report of your physical activity in about 3 months. On a rare occasion, these devices can malfunction and then the activity recorded may be not valid. In such cases your report will acknowledge device malfunction.

Please read the instructions when you get home. There are some common questions on the back of the first page as well. If you have any questions or concerns just call [redacted] (point out on sheet). Thank you very much.

(If No or hesitant)
Okay, would you be willing to just try it?

If a definite no then write in the Comments box an explanation as to why.

SCRIPT FOR DOCUMENTING ACTICAL REFUSALS

PARTICIPANT CHOOSES NOT TO PARTICIPATE IN PA MONITORING

Your participation is, as always, completely voluntary. Knowing the reasons for refusal will help us improve the study in the future and evaluate the data we do collect.

Do you mind letting us know why you chose not to participate in this portion of the study?

This data is kept confidential.

If participant staes reason, then record.

If participant is unsure about stating reason, list/show the following and allow to choose:

1. **Illness or medical reasons**
2. **Family obligations**
3. **Travel or vacation plans**
4. **Not interested**
5. **Don't want to wear belt / device**
6. **Don't want to state reason**
7. **Other**
8. **Lives out of the country**

Actical Physical Activity Monitor Instructions

Please read carefully:

1. Wear the device for 8 days during waking hours.

2. Do **NOT** wear in the Shower (remember to put the device back on once you get out of the shower).**You will be taking off the device when you go to bed at night, and will be wearing it immediately upon waking up in the morning.**

   For most people, this will mean 'wear device' in the morning and 'take off device' at night. Please keep the device close to your bedside so that you can wear it immediately upon getting up and do not forget to wear it. (However, if you do shift work or have any other type of schedule, the same basic guidelines apply—'wear device' during your waking hours, 'take off' during your sleeping hours). You do not need to take off the device during daytime naps.

3. There is no 'on-off' switch on the device. You cannot turn it off by accident.

4. The device is worn over the right hip resting on the iliac crest (Do **NOT** change sides).

5. The device should be snug against the body but not tight. It can be worn underneath or on top of clothing.

6. You may engage in activities that you normally do.

7. Please take care that the device does not go into the washing machine/dryer. If it does, continue to wear as usual, but write a note letting us know.

8. Please return device and belt in the bubble pouch located inside the white return folder and write us any feedback you may have about your experience wearing the device.

You may take off the Actical physical activity monitor and send it back in the return envelope given to you at your exam on:

_____(Take off around 3 p.m.)

PLEASE RETURN THE DEVICE EVEN IF YOU ARE NOT ABLE TO WEAR IT FOR 8 DAYS. THE DEVICES ARE EXPENSIVE & ARE REUSED. SO, FAILURE TO RETURN THE DEVICE MAY LIMIT OUR ABILITY TO COMPLETE THIS IMPORTANT STUDY. IF DEVICE BECOMES DAMAGED, PLEASE DO NOT THROW AWAY! SEND BACK TO FHS WITH A NOTE.
AS ALWAYS, WE THANK YOU FOR YOUR PARTICIPATION.

FAQ

1. **What is the Actical physical activity monitor?**

   The Actical physical activity monitor is a small, waterproof device that measures activity. The Actical physical activity monitor can not tell exactly what you are doing, just whether you are moving or are still. The Actical physical activity monitor will also count the number of steps you take each day.

2. **Is there anything I can <u>not</u> do while wearing the Actical physical activity monitor?**

   The Actical physical activity monitor device is completely waterproof, so you can swim with the device. If you are planning a CT scan, MRI, or similar test, you may be instructed to remove the Actical physical activity monitor for the scan. If left on, it will not harm you. You have no limitation of activity with the Actical physical activity monitor that you would not otherwise have. The Actical physical activity monitor will pass through airport security undetected.

3. **Do I need to do anything to the Actical physical activity monitor while I am wearing it?**

   You do not need to do anything – just wear it and forget it. The Actical physical activity monitor can not 'turn off,' so there is no need to worry that it is not capturing your activity.

5. **Will I be getting any results from wearing the Actical physical activity monitor?**

   Yes, you will receive a report on the results of your activity in about 3 months after you return the device.

4. **Who do I contact if I have a question about the device I am wearing?**

For any questions you may contact:

[redacted]

Actical® Instruction Manual

The belt should be mounted on the body so that the Actical physical activity monitor rests on the iliac crest of the hip. The iliac crest is the uppermost and widest of the three bones constituting either of the lateral halves of the pelvis.

Proper hip mount

Instrucciones para usar el Monitor de Actividad Física

Por favor lea cuidadosamente:

1. Use el monitor por 8 días, 24 horas al día.

2. NO lo use mientras se baña (acuérdese de ponérselo de nuevo en cuanto salga de la ducha).

3. Uselo mientras duerme.

4. El monitor debe ponerse sobre la cadera derecha, alineándolo con la parte media de la clavícula.

5. El monitor debe sentirse ajustado en su cuerpo pero no demasiado apretado.

6. Puede usarse encima o debajo de la ropa.

7. Haga sus actividades como siempre lo hace.

8. Por favor devuelva el monitor por correo en el sobre de burbujas adentro del sobre blanco pre-pagado que le dimos, y escríbanos cualquier comentario que tenga respecto a su experiencia usando el monitor.

Por favor quítese el monitor alrededor de las 3 PM

el día:

_____

Y envíelo de vuelta por correo en el sobre pre-pagado que le dimos

***Lea al reverso las respuestas a las preguntas más frecuentes.**

Preguntas más frecuentes

1. **¿Qué es el monitor Actical de actividad física?**

   El monitor Actical es un pequeño aparato, resistente al agua que mide la actividad de una persona. Este aparato no puede decir exactamente lo que la persona está haciendo, solo si la persona se está moviendo o no.

2. **¿Hay algo que NO deba hacer mientras uso el Actical?**

   El monitor Actical es completamente resistente al agua, así que puede nadar con él, pero no lo use cuando se bañe. Si planea que le hagan un CT scan, un MRI o cualquier otra prueba similar, deberá quitarse el monitor antes de la prueba. Pero si de casualidad se le olvida quitárselo, esto no le hará daño a usted. mNo tiene ninguna limitación en cuanto a actividades que haga. El Actical podrá pasar por detectores de seguridad en el aeropuerto, sin ser detectado.

3. **¿Necesito hacerle algo al Actical mientras lo uso?**

   No tiene que hacer nada -sólo úselo y olvídese que lo tiene puesto. El Actical no se puede "apagar", así que no hay preocuparse de que no esté capturando su actividad.

4. **¿Voy a obtener resultados sobre el uso de este acelerómetro?**

   Sí, actualmente estamos trabajando en los procedimientos para generar un reporte.

5. **¿A quién debo contactar si tengo preguntas sobre el monitor que estoy usando?**

   Para cualquier pregunta, contacte en español a:

[redacted]

[redacted]

Manual de Instrucciones del monitor Actical

El cinturón debe estar ajustado a su cuerpo de forma que el aparato Actical descanse sobre la cresta del hueso iliaco de la cadera. El hueso iliaco de la cadera es la parta de más alta y ancha de los tres huesos que constituyen cualquiera de las dos mitades laterales de la pelvis

Forma apropiada de llevarlo:

Actical Physical Activity Monitor Instructions

Please read carefully:

1. As soon as you receive the Actical physical activity monitor, put it on.

2. Wear the device for 8 days during waking hours (Do **NOT** wear in the Shower). **You will be taking off the device when you go to bed at night and putting it on immediately upon waking up in the morning.**

   For most people, this will mean 'wear device' in the morning and 'take off device' at night. Please keep the device close to your bedside so that you can wear it immediately upon getting up and do not forget to wear it. (However, if you do shift work or have any other type of schedule, the same basic guidelines apply—'wear device' during your waking hours, 'take off' during your sleeping hours). You do not need to take off the device during daytime naps.

3. Please note that there is no 'on-off' switch on the device. You cannot turn it off by accident.

4. Remember to put the device back on once you get out of the shower.

5. The device will be worn over the right hip resting on the iliac crest (Do **NOT** change sides).

6. The device should be snug against the body but not tight. It can be worn underneath or on top of clothing.

7. You may engage in activities that you normally do.

8. Please return Actical physical activity monitor and belt in the bubble pouch.

9. **Please take care that the device does not go into the washing machine/dryer.** If it does, continue to wear as usual, but write a note letting us know.

PLEASE RETURN THE DEVICE EVEN IF YOU ARE NOT ABLE TO WEAR IT FOR 8 DAYS. THE DEVICES ARE EXPENSIVE & ARE REUSED. FAILURE TO RETURN THE DEVICE MAY LIMIT OUR ABILITY TO COMPLETE THIS IMPORTANT STUDY. IF DEVICE BECOMES DAMAGED, PLEASE DO NOT THROW AWAY! SEND BACK TO FHS WITH A NOTE. AS ALWAYS, WE THANK YOU FOR YOUR PARTICIPATION.

FAQ

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4. **Who do I contact if I have a question about the Actical physical activity monitor I am wearing?**

For any questions you may contact:

[redacted]

[redacted]

Actical® Instruction Manual

The belt should be mounted on the body so that the Actical physical activity monitor rests on the iliac crest of the hip. The iliac crest is the uppermost and widest of the three bones constituting either of the lateral halves of the pelvis.

Proper hip mount

TO INITIALIZE ACTICAL

- Turn on Reader (toggle switch in back)
    - Black actical goes on Reader labeled for black Actical
    - Gray actical goes on Reader labeled for gray Actical
- Put on Actical (green dot to green dot)
    - Green light on
    - Red light blinking

ON COMPUTER:

- Reader
- Write
    - Com Port: Com1 for black acticals; Com 3 for gray acticals
- Yes
- OK
- Dropdown: starting to read
    - Wait until loaded: click OK

PUT IN PARTICIPANT INFO:

- ID: under Identity
- Age
- Record Steps: click on
- HT (inches)
- WT (lbs)
- Start time: slide bar to 15:00 hours
- Epoch length: 0.50 (click on once to get to)
- Make sure days = 11 and epoch length = .50
- Send
- OK

Remove Actical First, then click OK

Put back in plastic case with participant label
Put case in Actical room
Put initials in Actical logbook under: Tech ID Initial

Battery Life:
If battery life = ≤12 days, get a new Actical from Rm 103 and write new serial number in logbook.

If you have any feedback about the accelerometer, please note it below and return it with your accelerometer.

Thank you again for your participation.

Office Use:	ID _____ - _____	
Initials:_____	Date Initialed: _____/_____/_____	*Version:061708*

If you have any feedback about the accelerometer, please note it below and return it with your accelerometer.

Thank you again for your participation.

Office Use:	ID _____ - _____	
Initials:_____	Date Initialed: _____/_____/_____	*Version:061708*

Si tiene cualquier comentario o sugerencia sobre el acelerómetro, por favor escríbalo abajo y regrese esta hoja con el acelerómetro.

Gracias de nuevo por su participación.

Office use: ID _____ - _____

Initials: _____ Date Initiated: _____ / _____ / _____ Version: 061708

The Framingham Heart Study

A Project of the National Heart, Lung, and Blood Institute and Boston University

October 26, 2011

Doe, Lilith
999 Belle View Hill Rd.
Framingham, MA 01541

Clinic Exam Date: 01/18/2011

PHYSICAL ACTIVITY MONITOR REPORT

Minutes of physical activity accumulated in each intensity category:

Day		Sedentary Minutes	Light Minutes	Moderate to Vigorous Minutes
1	826	157	14	
2	719	114	23	
3	535	46	0	
4	665	51	0	
5	360	13	0	
6	807	94	6	
7	905	51	1	

These are estimates based on data collected for research purposes only, assuming that the device was worn for 7 full days (the first day, a partial day, is not counted).

Current physical activity guidelines recommend that adults accumulate 150 minutes of moderate to vigorous physical activity per week (such as brisk walking, accumulated in bouts of 10 minutes or more).

If you have any questions, please contact [redacted] at the Framingham Heart Study: [redacted].

We greatly appreciate your participation in the Framingham Heart Study.

[redacted]
Professor of Medicine
Boston University School of Medicine

73 Mt. Wayte Avenue • Framingham, MA 01702 • 508.872.6562 tel • 508.626.1262 fax

The Framingham Heart Study

A Project of the National Heart, Lung, and Blood Institute and Boston University

October 26, 2011

Neville, Lilith
999 Belle View Hill Rd.
Framingham, MA 01541

Clinic Exam Date: 01/10/2011

PHYSICAL ACTIVITY MONITOR REPORT

Thank you for wearing the Actical physical activity monitor. Unfortunately, no data was obtained from the Actical device you returned. There are a number of reasons why there was no data including technical difficulties with the device. We apologize for the lack of data.

Current physical activity guidelines recommend that adults accumulate 150 minutes of moderate to vigorous physical activity per week (such as brisk walking, accumulated in bouts of 10 minutes or more).

If you have any questions, please contact [redacted] at the Framingham Heart Study: [redacted]

We greatly appreciate your participation in the Framingham Heart Study.

[redacted]
Professor of Medicine
Boston University School of Medicine

73 Mt. Wayte Avenue • Framingham, MA 01702 • 508.872.6562 tel • 508.626.1262 fax

Smith, Joa
9 Smith Road,
Ashland, MA 01721

Fecha del examen clínico: 09/09/09

REPORTE DE SU MONITOR DE ACTIVIDAD

Estos fueron sus minutos de actividad física acumulados y categorizados según la intensidad de actividad:

Día #	Actividad Sedentaria Minutos	Actividad Moderada Minutos	Moderada a Vigorosa Minutos
1	738	133	14
2	699	141	8
3	683	80	9
4	558	175	14
5	754	101	2
6	769	95	11
7	723	120	2

Estas estimaciones son basadas en la información de datos que ha sido colectada con propósitos de investigación médica, asumiendo que el aparato se usó por 7 días completos. (El primer día que es parcial, no se toma en cuenta).

Las guías generales para la actividad física recomiendan que los adultos acumulen 150 minutos de actividad moderada a vigorosa por semana (como caminar rápido, por períodos de 10 o más minutos cada vez).

Si tiene cualquier pregunta, por favor contacte a [redacted] al Estudio del Corazón de Framingham, al [redacted]
Agradecemos enormemente su participación en el Estudio del Corazón de Framingham.

Dr. [redacted]
[redacted]
Departamento de Medicina, Profesor de Medicina
Boston University School of Medicine

Fecha de su examen:

Reporte del Monitor de Actividad Física

Gracias por usar el monitor para medir su actividad física. Desafortunadamente no se pudo obtener información del monitor Actical que regresó. Hay varias razones por las que esto pudo haber sucedido, incluyendo problemas técnicos con el monitor. Le pedimos disculpas por la falta de resultados para usted.

Las guías generales para la actividad física recomiendan que los adultos acumulen 150 minutos de actividad física entre moderada y vigorosa por semana (como caminar rápido, por diez o más minutos cada vez).

Si tiene cualquier pregunta, por favor contacte a [redacted] al Estudio del Corazón de Framingham, [redacted].

Agradecemos enormemente su participación en el Estudio del Corazón de Framingham.

[redacted]

[redacted]

Departamento de Medicina, Profesor de Medicina

Boston University School of Medicine

EXIT INTERVIEW PROCEDURES

The float staff member's responsibility:

1. Put the chart in order & check the chart for completeness.
2. Using the Procedure Sheet on the back of the Numerical Data Sheet confirm that everything has been completed.
3. Complete the top portion of the Procedure Sheet by filling in the number 1 when something has been done.
4. If anything is missing flag the chart and make sure the procedure is completed prior to the participant having an exit interview.
5. Put the Numerical Data Sheet, Exit Interview, and Referral Tracking Form sticking sideways out of the chart in the correct order.
6. Ask a staff member to complete an exit interview.

During the exit interview (all staff):

1. Check the referral tracking sheet (complete with your ID number and any adverse events in clinic) and review with the participant any referral recommendations.
2. Confirm with the participant that they have completed their Food Frequency Questionnaire and have given it to a FHS staff member.
3. Ask for feedback from the participant on how they felt about their examination.
4. Write in any comments that are made.
5. Make sure the participant leaves the clinic area with all of their belongings; **ESPECIALLY THEIR MEDICATION BAG WITH MEDICATIONS**.
6. Read the disclaimer to the participant (on the Exit Interview Sheet):
   Your exam today was for research purposes only and is not designed to make a medical diagnosis. The exam cannot identify all serious heart and health issues. It is important that you continue regular follow-ups with your physician or health care provider.
7. Give participant the magnet gift.
8. Thank the participant for their time and willingness to participate.

NOTE: The chart does not have to be put in order to do an exit interview. If the clinic is busy and someone is unable to put it in order prior to the exit interview proceed as follows:

1. Take the Numerical Data Sheet, Exit Interview sheet & Referral tracking sheet in with you during the exit interview.
2. Review with the participant that each procedure has been completed.
3. Complete the top portion of the Procedure Sheet by filling in the number 1 when something has been done.
4. Check the referral tracking sheet (complete with your ID number and any adverse events in clinic) and review with the participant any referral recommendations.
5. Confirm with the participant that they have completed their Food Frequency Questionnaire and have given it to a FHS staff member.
6. Ask for feedback from the participant on how they felt about their examination.
7. Write in any comments that are made.

8. Read the disclaimer.
9. Give the participant the magnet gift.
10. Make sure the participant leaves the clinic area with all of their belongings; **ESPECIALLY THEIR MEDICATION BAG WITH MEDICATIONS.**
11. Thank the participant for their time and willingness to participate
12. Put the chart in order

COMMONLY ASKED QUESTIONS

Q. When will you call me back for my next exam?
A. *We can't say for sure right now. Investigators will begin planning for future exams as our current research contract with NHLBI is completed.*

Q. What will be in my report and when will I get it?
A. *You will receive your report in roughly 4-6 weeks. Your report will have results of your blood work, your blood pressures, a wallet-sized plastic copy of your ECG and a general statement from the physician who saw you.*

Q. How many participants are involved in the FHS?
A. *The original Cohort group had roughly 5200 in 1948. There are roughly about 100 of this group still living, of which we saw 91 for their Exam 31. We plan to see about 2800 Offspring during Exam 9 and we saw 4100 Generation 3 participants.*

24-hour urine

A 24-hour urine collection is a timed urine collection. The purpose of this research study is to investigate the role of electrolyte balance and muscle mass in your urine. 24-hour urine collections provide information regarding the balance of sodium and potassium. This will give us the insight into the development of kidney stones, cardiovascular disease, hypertension and kidney function.

Men and Women who are part of the Framingham Heart Study, living in the United States will be asked to participate. Participants with end-stage renal disease on dialysis are not eligible.

The 24-hour urine collection is done in the comfort of your home. The research lab will send a kit to your home following your clinic examination.

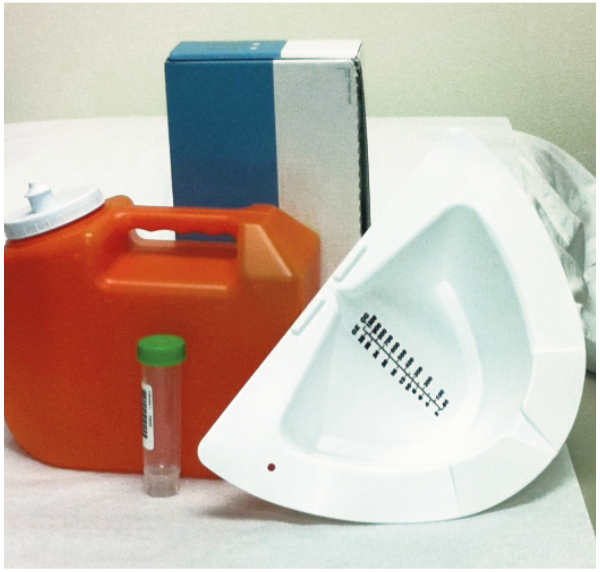
Contact:

[redacted]

Participant Coordinator

[redacted]

FRAMINGHAM HEART STUDY 24-HOUR URINE COLLECTION



FRAMINGHAM HEART STUDY

Three Generations of Dedication

1948 1971 2002

A Project of the National Heart, Lung, and Blood Institute and Boston University

What is a 24-hour urine?

A 24-hour urine collection is a timed urine collection. We will ask you to collect all of your urine in a 24-hour period.

Who is eligible to have a 24-hour urine?

Men and women who are part of the Framingham Heart Study. Participants must be living in the United States. Participants with end-stage renal disease on dialysis are not eligible.

What is the purpose of the 24-hour urine?

The purpose of this research study is to investigate the role of electrolyte balance and muscle mass in your urine. 24-hour urine collections provide information regarding the balance of sodium and potassium. This will give us insight into the development of kidney stones, cardiovascular disease, hypertension, and kidney function.

Is it safe?

The 24-hour urine procedure can be done safely in your home. To complete this test, you do not need to eat or drink anything different than usual.

Will my physician receive the results of my 24-hour urine?

Yes, your physician will receive a report from Litholink, the research lab that will analyze the 24-hour urines.

Incidental Findings

Similar to many of the tests that we do in the Framingham Heart Study, your results will be reviewed by a Framingham Heart Study physician. 24-hour urines are often done clinically in patients with recurrent kidney stones. The report that is generated from this will indicate your levels of several urinary minerals and electrolytes. The large majority of tests will not have any findings.

Where is the 24-hour urine done?

The 24-hour urine is done in the comfort of your own home. The research lab, Litholink, will send a kit to your home following your Framingham Heart Study examination. The kit will contain all the information that you need to complete the 24-hour urine, including instructions, the urine jug, a collection aid, and an envelope to mail part of the urine back to Litholink for analysis.

How long will it take?

The 24-hour urine takes 24 hours. You can select the day that you would like to collect your urine based on your own schedule and availability. The collection generally starts first thing in the morning, and will go until the next morning. The kit that we mail to your home contains instructions that explain how to do the collection.

How do I prepare for a 24-hour urine?

No preparation is necessary.

What happens after I have my 24-hour urine?

The 24-hour urine kit comes with a small tube and mailing envelope to return the urine sample to our research partners at Litholink. This small tube will be mailed back to Litholink following your test. Our kit will include a 1-800 number to call to schedule a FedEx pick-up of the collected urine from your home.

Intertech Quality Control Measurements

In order to maintain the quality of the data, each month every technician that performs anthropometric measures must complete quality control measurements.

This is done for:

1) Neck
2) Waist
3) Hip
4) Thigh
5) Height
6) Weight
7) Ankle-Brachial Blood Pressure Measurements

1) Neck Measurement

Each technician, paired with another technician and out of each other's view, performs the neck measurement.

Measurement with a difference of > .25 in. is repeated by the second tech with first tech observing.

2) Waist, Hip, Thigh

Each technician, paired with another technician and out of each other's view, performs the Waist, Hip and Thigh measurements.

Each measurement with a difference of > .50 inches is repeated by the second tech with first tech observing.

3) Ankle-Brachial Blood Pressure Measurements

Each technician, paired with a second technician and out of each other's view, performs the ABI measurements on the same participant. The first tech obtains the primary data including original and repeat blood pressure measurements in both arms and both ankles. The second tech obtains one set of blood pressure measurements and compares those readings to the *average* of the first technician's readings. If the difference between technician readings is greater than 10 mmHg for any one measurement, then that measurement is repeated.

3) Height and Weight

Each technician, paired with another technician and out of each other's view, performs each height and weight measurement.

Height: Record in inches rounded down to the nearest ¼ inch
Weight: Record in whole pounds recorded to nearest pound. Round up if ≥ 0.5, round down if < 0.5

If the difference in height is more than .25 inches, the measurement is repeated.
If the difference in weight is more than 1 pound, or the average of .5 pound, the measurement is repeated.

_____ / _____ (tech1/tech2) Framingham Heart Study

Intertech Quality Control Measurements
Height and Weight

QC Measurement for 6 Week Period: to

Participant ID # _____ Clinic/Measurement Date _____

Tech ID # _____ circle one 1=1st measurer (tech1) 2=2nd measurer (tech2)

Measurements:
Each tech paired with another tech and out of each other's view, performs each height and weight measurement.
If the difference in height is more than **.25 inches**, the measurement is repeated.
If the difference in weight is more than **1 pound**, or the average of **.50 pound**, the measurement is repeated.

Height Measurement
(Record in inches rounded down to the nearest ¼ inch)

_____in. **Repeated Height Measurement _____in.**

Weight Measurement
(Record in whole pounds recorded to nearest pound. Round up if ≥ 0.5, round down if < 0.5)

_____lbs. **Repeated Weight Measurement _____lbs.**

Comments (Optional):

Keyer1:___
Keyer2:___

_____ / _____ (tech1/tech2) Framingham Heart Study

Intertech Quality Control (Anthropometrics) Measurements Neck, Waist @ Umbilicus, Hip Circumference, Thigh

QC Measurement for 6 Week Period: to

Participant ID # _____ Clinic/Measurement Date _____

Tech ID # _____ circle one 1=1st measurer (tech1) 2=2nd measurer (tech2)

Each tech paired with another tech and out of each other's view performs each measurement.
Measurements with a difference of > **.25 in.** on the neck circumference are repeated.
Measurements with a difference of **> .50 in**. on the umbilicus waist measurement are repeated.
Measurements with a difference of **> .50 in**. on the hip (Buttocks) Circumference are repeated.
Measurements with a difference of > **.50 in.** on the thigh measurement are repeated.

Neck Circumference

_____in. **Repeated Neck Circumference _____in.**

Umbilicus Waist Measurement

_____in. **Repeated Umbilicus Measurement _____in.**

Hip Circumference

_____in. **Repeated Hip Circumference _____in.**

Thigh Measurement

_____in. **Repeated Thigh Measurement _____in.**

Comments (Optional):

_____

_____

_____

Keyer1:____
Keyer2:____

_____ / _____ (tech1/tech2) Framingham Heart Study

Intertech Quality Control Measurements Ankle Arm Doppler

QC Measurement 6 Week Period: _to

Participant ID # _____ Clinic/Measurement Date _____

Tech ID # _____ circle one **1=1st measurer (tech1)** **2=2nd measurer (tech2)**

Each technician, paired with another technician and out of each other's view, performs the AAD measurements on the same participant. The first tech does the regular test including 2 rounds of measurements. The second tech does only one round of measurements and compares those reading to the **average** of the first tech's readings. If the difference between technician's readings is greater than 10 mmHg on any one measurement, then that measurement is repeated by the second tech. Each tech will record his/her own Maximum Inflation Level.

***If three readings were taken by the first technician then the two closest readings are averaged. For each limb, 1st reading + 2nd reading = Total divided by 2 = Average.**

Cuff Size Arm: _____ Cuff Size Ankle: _____ (0=pedi, 1=regular, 2=lg, 3=thigh)

Max Inflation Level Right Arm: _____ Max Inflation Level Right Ankle: _____

R Ankle BP Site: _____ L Ankle BP Site: _____ (0=ankle 1=top of foot)

Initial Measurements:	Repeat Measurements (tech 2 only) (If tech 1 and tech 2 differ >10mmHg)
Right Arm: _____	Right Arm: _____
Right Ankle: _____	Right Ankle: _____
Left Ankle: _____	Left Ankle: _____
Left Arm: _____	Left Arm: _____

Comments (Optional):

_____

_____

_____

_____

Keyer1:___
Keyer2:___

Intertech Quality Control – Date – Date

Measurement	Tech	Tech 1 Initial Measurement	Tech 2 Measurement	Retake	Retake	Resolution/Comment

Tech #[redacted] Tech #[redacted] Tech #[redacted] Tech #[redacted]

INTERTECH / QC
Six Week Report
Date

Number of technicians participating: 4

	Number of Sets Completed	Sets not within Guidelines	QC Guidelines (Acceptable Difference)
Height			No greater than .25 Inches
Weight			No greater than 1 lb
Neck			No greater than .25 in
Umbilicus Waist			No greater than .5 in
Hip			No greater than .5 in
Thigh			No greater than .5 in
AAD			No greater than 10 mm Hg

SIX WEEK CYCLE QUALITY CONTROL TRACKING FORM

_____

	HEIGHT/WEIGHT	ANTHRO	AAD
19/788			
19/794			
19/797			

	HEIGHT/WEIGHT	ANTHRO	AAD
788/19			
788/794			
788/797			

	HEIGHT/WEIGHT	ANTHRO	AAD
794/19			
794/788			
794/797			

	HEIGHT/WEIGHT	ANTHRO	AAD
797/19			
797/788			
797/794			

TECH ID #'s

[redacted] 19

[redacted] 788

[redacted] 794

[redacted] 797

Certifications

Clinic staff will be trained and certified in the following components upon hire and then according to the schedule below:

Annually

- OSHA / Lab Safety
- Blood Pressure

Bi-Annually

- CPR Re-certification

Monthly

- Human Subjects Protection Training / CR Times

All Certifications of staff will be kept and tracked in the Clinic Certification Records Logbook (black binder in room 237).

TECHNICIAN CERTIFICATION/RECERTIFICATION

Certification	Tech 788	Tech 797	Tech 19	Tech 794
AAD				
Anthropometrics				
Blood Pressure				
ECG				
Observed Performance				
PFT				
Questionnaires				
Actical				
MARCH 2012				
AAD				
Anthropometrics				
Blood Pressure				
ECG				
Observed Performance				
PFT				
Questionnaires				
Actical				

Problems/Corrective Action Log

Problem Area	Retrain/Review	Date

MONTHLY/ANNUALLY CALIBRATIONS-2014

	JAN.	FEB.	MARCH	APRIL	MAY	JUNE
Room 100 (ECG)						
Manometer V88290						
Stadiometer Level						
Scale Detecto						
Measuring Tape						
Hand Grip 31209634						
Room 102 (ECG)						
Manometer CE3201						
Stadiometer Level						
Scale Seca 700						
Measuring Tape						
Hand Grip 30208097						
Room 101 (PFT)						
Manometer T30928						
Stadiometer Level						
Scale Detecto						
Syringe						
Room 109 (MD)						
Manometer T30906						
Room 107 (MD)						
Manometer T30927						
Offsite						
Hand Grip 10593388						
Scale Health O Meter						
Scale Health O Meter						
Measuring Tape						

MONTHLY/ANUALLY CALIBRATIONS-2014

	JULY	AUG.	SEPT.	OCT.	NOV.	DEC.
Room 100 (ECG)						
Manometer V88290						
Stadiometer Level						
Scale Detecto						
Measuring Tape						
Hand Grip 31209634						
Room 102 (ECG)						
Manometer CE3201						
Stadiometer Level						
Scale Seca 700						
Measuring Tape						
Hand Grip 30208097						
Room 101 (PFT)						
Manometer T30928						
Stadiometer Level						
Scale Detecto						
Syringe						
Room 109 (MD)						
Manometer T30906						
Room 107 (MD)						
Manometer T30927						
Offsite						
Hand Grip 10593388						
Scale Health O Meter						
Scale Health O Meter						

Date:_____ Tech ID#_____ Quarter: I, II, III, IV (circle one)
Supervisor: [redacted] Participant label:_____

Height & Weight Supervisor Checklist

Check that each procedure is carried out correctly. Check yes if correct or no if incorrect. Provide an explanation of the incorrect item. Items are presented in the sequence of the examination procedure, but may require confirmation before or after the exam.

Yes	No	Weight Measurement
		Ask participant to wear FHS gown for measurement if he/she brought a heavy gown from home. The participant should remove slippers or shoes.
		Prior to asking the participant to step onto the scale, lift the counter poise and position it at zero.
		Ask the participant to step onto the scale, facing measurement beam.
		Instruct the participant to stand in the middle of the scale platform with head erect and eyes looking straight ahead. Weight should be equally distributed on both feet, and participant should not touch or support him/herself.
		With the participant standing still in the proper position, lift the counterweight (larger weight), and slide it to the right until the beam approaches balance.
		Adjust the top poise until the beam is evenly balanced.
		Have the participant step off the scale. The technician should stand directly in front of the scale and read the weight with eyes level to the point of measurement.
		Record the weight to the nearest pound; **round up if ≥ 0.5, round down if < 0.5**.

Yes	No	Standing Height Measurement
		The participant should be barefoot or wearing thin socks so positioning of the body can be seen. Ask participant to stand erect with his/her back to vertical mounted stadiometer.
		Heels should be together and against the vertical ruler, both feet flat on the floor, with weight distributed evenly across both feet. Check to make sure both feet are back against the wall.
		Participant faces straight ahead with his/her head positioned in the Frankfort horizontal plane. The lower margin of the bony orbit (the socket containing the eye) should be on the same horizontal plane as the most forward point in the supratragal notch (the notch just above the anterior cartilaginous projections of the external ear).
		Ask participant to let arms hang freely by the sides of the trunk, palms facing the thighs. Ask participant to inhale deeply and maintain a fully erect position.
		Bring the level down snugly (but not tightly) on top of participant's head. Use an extension board for proper measurement of severely kyphotic subjects.

Date:_____ Tech ID#_____ Quarter: I, II, III, IV (circle one)
Supervisor: [redacted] Participant label:_____

Yes	No	Deviations
		Did the tech perform any minor deviations?
		Did the tech perform any major deviations?
Comments/Corrections/Deviations:		
Supervisor Initials:		
Date:		

Date: _____ Tech ID#_____ Quarter: I, II, III, IV (circle one)
Supervisor: [redacted] Participant Label_____

Anthropometrics

Check that each procedure is carried out correctly. Check yes if correct or no if incorrect. Provide an explanation of the incorrect item. Items are presented in the sequence of the examination procedure, but may require confirmation before or after the exam.

Yes	No	Neck Circumference
		Participant stands erect, arms hanging loosely at sides, weight equally distributed on both feet, head positioned in the Frankfort horizontal plane
		Standing to face the left side of the participant, identify the thyroid cartilage by gentle palpation of the neck. Gently place your left index and second fingers on the front of the neck and ask the subject to swallow to help find the correct spot. You should feel a slight depression.
		Place the superior border of the anthropometric tape just inferior to the laryngeal prominence
		Apply the tape snugly, but not tightly, perpendicular to the long axis of the neck, which is not necessarily in the horizontal plane at approximately a 90 degree angle.
		Record the neck circumference to the nearest 1/4 inch, rounding down.
		The pressure on the tape should be the minimum required to maintain skin contact

Yes	No	Waist Girth Measurement
		Participant is asked to stand erect with head facing straight ahead. The examiner tells the participant that she is going to open the robe and place it over the ppt left shoulder. The examiner then asks the ppt to cross arms over chest to hold the robe, standing up straight but shoulders relaxed.
		The examiner places the anthropometric tape at the level of the umbilicus, underneath the gown. If underwear is covering the umbilicus, the examiner rolls down the under below the umbilicus.
		Tape is applied snugly but not tightly.
		The examiner checks the tape that it is placed horizontal and not twisted. It is checked from both the front and back using 2 mirrors mounted to the wall.
		Measurement is recorded to the nearest ¼ inch, rounding down.

Date: _____ Tech ID#_____ Quarter: I, II, III, IV (circle one)
Supervisor: [redacted] Participant Label_____

Yes	No	Hip Circumference
		Participant is asked to stand erect with head facing straight ahead. The examiner tells the participant that she is going to open the robe and place it over the ppt left shoulder. The examiner then asks the ppt to cross arms over chest to hold the robe, standing up straight but shoulders relaxed, weight equally distributed on both feet, facing straight ahead
		The examiner stands on the participants left side and applies the measuring tape around the largest part of the buttocks.
		The examiner then adjusts the sides of the tape and checks the front and sides of the tape measure is horizontal
		The zero end of the tape is held under the measurement value
		Apply tape snugly but not tightly
		Record measurement **to the nearest ¼ inch, rounding down**

Yes	No	Thigh Circumference
		Measurement of the thigh is taken on the right side. If left side is used a protocol modification is marked on the numerical data sheet.
		The participant is asked to sit on a chair, with the knees flexed to about 90 degrees and the thighs horizontal.
		Script is read: "I am going to measure your right thigh circumference. In order to do that I first have to mark your thigh with a cosmetic pencil to determine where to do the measurement."
		The proximal border of the patella (knee cap) is marked. To help locate the landmark, the participant is asked to straighten their leg to about a 120 degree angle while keeping their heel on the floor with the thigh muscles relaxed.
		The midpoint of the inguinal crease is marked. This is located if the hips are flexed as they will be with the participant seated. To help locate the landmark, the participant is asked to lift the thigh about 1 cm. The point where the muscle and tendon contract is the midpoint of the crease.
		With the participant seated and the thigh muscles relaxed, measure the distance between the inguinal crease and the proximal border of the patella and divide by two to get the midpoint. Mark the location with a grease pencil.
		The participant is asked to stand up and place the heels about 20 cm apart.
		The weight should be evenly distributed over both feet, both feet flat on the floor. If balance is a problem, the participant may hold

		onto a chair or wall. The examiner should be squatting so that their eyes are at the level of the mid thigh.
		The circumference is measured at the marked midpoint with the measuring tape placed horizontally (that is, perpendicular to the long axis of the thigh) around the thigh.
		The thigh is viewed from the front and both sides to check this.
		The tape should be in complete contact with the skin, without compressing the soft tissue.
		The midpoint mark should be visible in the gap made by the upper and lower wrap of the tape.
		Make sure that the lower edge of the tape at the zero mark sits directly at the top of the midpoint mark. Make sure that the top edge of the lower wrap of the tape sits directly below the midpoint mark. Read the value directly below the zero mark.
		Record the circumference to the nearest 0.1 cm and mark which thigh was measured.
		Remove and reposition the tape. Repeat the measurement. If the difference between the measurements is > 1 cm, a third and fourth measurement should be obtained. Record all the measurements on the inter-tech forms. The computed value will be the mean of the two or four recorded values.

Yes	**No**	**Deviations**
		Did the tech perform any minor deviations?
		Did the tech perform any major deviations?

Comments/Corrections/Deviations:

Supervisor Initials:

Date: _____ Tech ID#_____ Quarter: I, II, III, IV (circle one)
Supervisor: [redacted] Participant Label_____

Date:

Date: _____ Tech ID#_____ Quarter: I, II, III, IV (circle one)
Supervisor: [redacted] Participant Label_____

Ankle-Brachial Doppler Blood Pressure Measurement

Supervisor Checklist

Check that each procedure is carried out correctly. Check yes if correct or no if incorrect. Provide an explanation of the incorrect item. Items are presented in the sequence of the examination procedure, but may require confirmation before or after the exam.

Yes	No	Screening
		Tech asks if h/o blood clots. If yes and being treated now, do not do that extremity.

Yes	No	Lower Extremity Exclusions
		Persons with venous stasis ulceration or other pathology that precludes placing a BP cuff around the ankle (e.g. open wounds). Code as 1
		Persons with bilateral amputations of legs. Code as 2
		Persons with rigid arteries such that an occlusion pressure cannot be reached. Code as 3= Other

Yes	No	Upper Extremity Exclusions
		If a subject has undergone a mastectomy, blood pressure measurement will be excluded in that extremity only, and recorded as 1= mastectomy. **Note**: If a subject refuses or does not complete the exam, code as a 3 (Other) and write in the reason.

Yes	No	Set-Up Procedure
		Ask participant to remove shoes and stockings so that the ankles are bare to mid-calf.
		Lay participant supine on the examining table.
		Keep participant supine for at least five minutes before measuring BP.
		Place four BP cuffs on the participant (be sure to check for appropriate cuff size). The cuffs are placed on the right arm & leg, & left arm & leg.
		Apply ankle cuffs with midpoint of bladder over posterior tibial artery, with lower end of bladder approximately 3 cm above medial malleolus.

Date: _____ Tech ID#_____ Quarter: I, II, III, IV (circle one)
Supervisor: [redacted] Participant Label_____

Yes	No	General Guide to Blood Pressure Readings
		For each participant, determine the maximal inflation level, or the pressure to which the cuff is to be inflated for blood pressure measurement. This assures that the cuff pressure at the start of the reading exceeds the systolic blood pressure and thus allows the first Kortokoff sound to be heard.
		Attach the cuff tubing to the sphygmomanometer.
		Palpate the brachial artery pulse for the right arm
		Inflate the cuff rapidly until the brachial artery pulse is no longer heard by inflating rapidly to 70 mmHg, then inflating by 10mmHg increments.
		The examiner's eyes should be level with the mid-range of the manometer scale and focused at the level to which the pressure will be raised.
		Deflate the cuff quickly and completely.
		The maximal inflation level is 30 mmHg **above** where the systolic pressure was last heard.
		Repeat procedure for right posterior tibial artery in the ankle.
		Following any previous inflation, wait at least 30 seconds after cuff has completely deflated.

Yes	No	Ankle-Arm Blood Pressure Measurement
		Blood pressure readings are taken in the following order: 1. Right arm 2. Right ankle 3. Left ankle 4. Left arm
		Attach right arm cuff tubing to manometer.
		Apply ultrasound jelly over brachial artery
		Locate brachial artery using Doppler pen probe.
		Hold the Doppler probe *absolutely* still. It can easily slip off the artery.
		Inflate cuff quickly to maximal inflation level (30 mmHg above systolic pressure).
		Deflate at 2 mmHg/second, to appearance of systolic pressure.
		Follow down for 10 mmHg. Two subsequent beats should be heard for any valid systolic blood pressure reading.
		Remove Doppler pen probe.
		Deflate cuff quickly and completely.
		Neatly record systolic blood pressure.

Date: _____ Tech ID#_____ Quarter: I, II, III, IV (circle one)
Supervisor: [redacted] Participant Label_____

Yes	No	Repeat of Ankle and Arm Blood Pressure Measurements
		Repeat the sequence of measures in reverse order: a. Left arm b. Left ankle c. Right ankle d. Right arm
		If initial and repeat blood pressures measured at any one site (Right arm, Left arm, Right ankle or Left ankle) differ by more than 10 mmHg, please take a third measurement at that site.
		For Ankle Measurements record which sites the measurement was taken from. 0= posterior tibial (ankle) 1=dorsalis pedis (foot)
		Record any lower or upper extremity exclusions on data form.

Yes	No	Completion
		Review form for completeness and legibility.
		Remove cuffs and conducting jelly.

Note: If posterior tibial pulse cannot be found with palpation or Doppler pen probe, the dorsalis pedis artery is used. Another technician has verified the absence of the tibial pulse.

Yes	No	Deviations
		Did the tech perform any minor deviations?
		Did the tech perform any major deviations?
Comments/Corrections/Deviations:		
Supervisor Initials:		
Date:		

Date: _____ Tech ID#_____ Quarter: I, II, III, IV (circle one)
Supervisor: [redacted] Participant Label_____

ECG P Hi-Res Supervisor Checklist

Check that each procedure is carried out correctly. Check yes if correct or no if incorrect. Provide an explanation of the incorrect item. Items are presented in the sequence of the examination procedure, but may require confirmation before or after the exam.

Yes	No	Procedures
		The technician informs the participant they will be performing an ECG and following script is read: *An ECG is made up of waves showing the electrical activity in different parts of the heart. This new research test is an ECG that looks at a specific wave, the P wave, which shows activity in the top part of the heart. In order to get an accurate test please try to lie still. The test takes approximately 10 minutes.*
		Tech establishes a rapport with participant so participant is at ease with procedure and answers any questions participant may have.
		The participant is told that electrodes will be placed on their arms, legs, chest and back. They are informed the areas will be cleaned with alcohol wipes and that marks will be made on their chest with a cosmetic pencil.
		If they are allergic to alcohol (tech would be notified after blood draw) areas V1, E, V2-V6, RL, RA, LL, LA, and I are prepared by rubbing with water and drying with a washcloth. If allergies are denied, the areas are prepared by wiping with a Tens Cote Cleaner. Let dry.
		V2: The first intercostal space is palpated just below the clavicle. The tech counts down and identify the 4th intercostal space just below the fourth rib. Point V2 is just to the left of the sternum in the fourth intercostal space. A small line is made with a marking pencil here to show where the ECG lead should be placed.
		V1: Is at the same level as Point V2 and immediately to the right of the sternum. A small line is made with a marking pencil to show where the ECG lead should be placed.
		E: To locate the horizontal reference level for electrodes (Point E), starting from V2, fifth intercostal space is located. The tech moves their finger in the 5th intercostal space laterally to where the midclavicular (center of the chest where you feel a bend in the clavicle) line intersects the fifth intercostal space. A horizontal line is made at this point. The exact transverse (horizontal) level at this spot with the midsternal line is made. It should be about one inch (1") below V1 and V2 placements. This is point E.
		V6: The participant's left elbow is moved laterally away from the body. The midaxillary line is made in the exact vertical

Date: _____ Tech ID#_____ Quarter: I, II, III, IV (circle one)
Supervisor: [redacted] Participant Label_____

Yes	No	Procedures
		center plane of the thorax down to the intersection of the horizontal plane marked by the location of E. This is the exact location of V6. (NOTE: It is a common mistake to locate the midaxillary line too far anteriorly, toward the V5 location).
		V4: The # arm of the Heart Square is placed firmly across the lower sternum at the level of Point E (as you face the participant, the writing on the Heart Square will appear upside down and backwards). The E and V6 arms of the Heart Square are adjusted so they are both perpendicular to the long axis of the thoracic spine at the level of the E position. The E arm should be exactly horizontal. If the participant is lying flat, the V6 arm should be exactly vertical. The V6 arm is adjusted so the 0 point (the arrow labeled V6) is at the marked location for V6. The tech double checks that the E arm is still in the correct spot. On the V6 arm (the slide) the number corresponding to the E measurement is found. Following the corresponding 45 degree line to the surface (e.g. 16) and mark the location following the inside of the square. This is point V4. The mark is made on TOP of the breast. Note: For women with smaller breasts the measurements may land directly below the breast tissue. The participant may now place their left arm in a more comfortable position next to their body.
		V3: Exactly halfway between V2 and V4.
		V5: Exactly halfway between V4 and V6.
		Electrodes are placed on the participant in the following order: LA, LL, RA, RL, V1, E, V2-V6, I, H, M with tabs facing toward the heart (except H & M that face down). Arm leads should be placed midway between the elbow and the wrist. Leg electrodes should be placed midway between the knee and ankle. If the participant has an amputation, the electrode should be placed above this.
		I: While standing on the participant's right side the tech moves the participant's right elbow laterally away from the body. The midaxillary line is made in the exact vertical center plane of the thorax down to the intersection of the horizontal plane marked by the location of E. This is the exact location of I. The participant may now place their right arm in a more comfortable position next to their body.
		The Acquisition Module is placed on the participants lap and the tech asks the participant to hold it. The leadwires are

Date: _____ Tech ID#_____ Quarter: I, II, III, IV (circle one)
Supervisor: [redacted] Participant Label_____

Yes	No	Procedures
		separated. While holding wires 1 and 4 (the two longest wires) the tech asks the participant to sit up. The tech moves robe to expose the participant's back.
		The tech asks the participant to sit up straight and prepares the skin by cleaning areas H and M with a Tens Cote Cleaner.
		Electrode H is placed at the Back of neck tab facing downward, on the bony prominence.
		Electrode M is placed at the center of spine tab facing downward, on the same horizontal level as lead E.
		Leads H and M are connected
		The wires are placed over the participants left shoulder and the participant is asked to lie down. Making sure the lead connections are not disrupted.
		The leads should be connected in the following order: LA, LL, RA, RL, V1-V6, E, I
		The participant is asked to lie still and relax. In the computer, enter the participants Name, ID, Age, Height (clinic only), Weight, and Gender. Enter the Exam Cycle, Location (1=clinic 2=offsite) and your Technician ID Number. Note: When entering Height and Weight round up if the weight is ≥.5 or ≥ .50 for height.
		Tech double check that all leads are connected properly
		The tech offers to cover the participant with a blanket or their robe. Note: If the participant is cold this could interfere with the quality of the ECG.
		When a quality ECG is displayed on the computer screen hit ECG to store. Hit Continue to print. Two ECGs are printed out: one for the physician/chart and one for the ECG card.
		The ECG is reviewed and printed for errors
		The tech verifies the ECG Data Storage to Mac 5000
		After the completion of the standard ECG the tech again asks the participant to lie quietly and still during the acquisition of signal to decrease noise. Turn off the lights
		Begin the ECG P Hi Res/ The tech verifies the PHiRes Data Storage to Mac 5000.
		Leads are checked again for proper placement and disconnected after all leads are checked. Electrodes are carefully removed.
		The tech clears out the participant data.
		Both standard ECG and P Hi-Res ECG are stamped with #9 (Offspring) or # 4 (Omni)
		The standard ECG is placed in participant's file for MD to review during exam
		The paper copy of P Hi-Res ECG is placed in folder in hall.

Date: _____ Tech ID#_____ Quarter: I, II, III, IV (circle one)
Supervisor: [redacted] Participant Label_____

Yes	No	Deviations
		Did the tech perform any minor deviations?
		Did the tech perform any major deviations?
Comments/Corrections/Deviations:		
Supervisor Signature:		
Date:		

Date: _____ Tech ID#_____ Quarter: I, II, III, IV (circle one)
Supervisor: [redacted] Participant Label_____

PFT
Supervisor Checklist

Check that each procedure is carried out correctly. Check yes if correct or no if incorrect. Provide an explanation of the incorrect item. Items are presented in the sequence of the examination procedure, but may require confirmation before or after the exam.

Yes	No	PFT Instructions
		Exclusion criteria is reviewed
		Blood Pressure is taken per FHS protocol
		If the participant is found to be ineligible due to the exclusion criteria the test is aborted and only the respiratory questions are completed & the reason is documented.

Yes	No	Spirometry/Forced Vital Capacity
		The participant is positioned properly (chair, mouthpiece, nose clip)
		The maneuver is accurately explained
		The maneuver is demonstrated by the technician
		The participant is asked to connect to the machine and the instructions are given to the participant accurately.
		While the participant is inspiring, the space bar is pressed
		Once s/he has blown out for at least 12 seconds **and** the graph of his breathing has become flat and you see the **"Good Effort"** message, push the spacebar to end the test.
		If the participant fails to perform the maneuver correctly, the technician demonstrates the maneuver again.
		The tech does not ask the participant to do more than **eight** FVC maneuvers
		Once the participant has 3 acceptable tests, the tests are saved.
		The technician correctly assesses reproducibility of the 3 acceptable tests.
		Staff accurately accesses if the participant qualifies for albuterol.

Yes	No	Diffusion Capacity
		Explain the instructions to the participant as the machine is setting up
		The spacebar is pressed once prior to the participant is asked to hook up to the machine.
		The participant is asked to connect to the machine and the instructions are given to the participant accurately.
		The technician waits 4 minutes between each maneuver

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Supervisor: [redacted] Participant Label_____

		The test is repeated after 4 minutes.
		Grading the test: The technician confirms that both tests are acceptable, they will be displayed in green. For DLCO, two acceptable (all green effort marks) maneuvers must be within 10% of each other (i.e. 10% of the higher value).
		The technician does not ask the participant to do more than 3 maneuvers.
		Once the participant has 2 acceptable test click save.
		If there is a comment regarding a participant that is beneficial and should be saved, enter the comment under "Technician Notes" and then click on "Save and Exit" after the participant leaves the room.

Yes	**No**	**Albuterol Participants/Spirometry/FVC**
		Any participants that have EITHER a FEV1-to-FVC ratio less than 90 % of the predicted value **OR** a FEV1 less than 85 % of the predicted value is asked to undergo post-bronchodilator testing.
		The administration of the albuterol is given after all of the other exam components have been completed.
		Getting ready 1. Shake the inhaler. 2. Take the cap off the inhaler. 3. Attach the spacer to the inhaler
		Using the MDI 1. Have the participant breathe all the way out. 2. Insert just the tip of the spacer into the participant's mouth. 3. Have the participant start to take a deep breath. 4. As the participant starts breathing in **slowly** through their mouth, actuate the inhaler (press down on the inhaler) **one** time. 5. Have the participant keep breathing in **slowly,** as deeply as they can. 6. Have the participant hold their breath as you count to 10 slowly, if they can. 7. Wait about 1 minute between puffs. 8. Allow at least 15 minutes and no more than 30 minutes before doing post-bronchodilator spirometry
		The spirometry/FVC protocol is performed according to the same protocol above.

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Supervisor: [redacted] Participant Label_____

Yes	No	PFT Completion
		Respiratory questionnaire is administered. Questions are asked exactly as they are listed on the page.
		The tech fills in their ID number in "PFT Daily Log, Comment, and Calibration" binder verifying they completed the PFT. If the participant qualified for albuterol "ALB" is marked in the comments. If they refused or if there are notes in the computer regarding the participant this is noted as well.

Yes	No	Technician Review
		Did the technician introduce the set of questions with clear explanation?
		Did the technician ask the questions exactly as written on the form?
		Did the technician correctly clarify any questions the participant had?
		Did the technician correctly use the answer key?
		Did the technician score the participant's responses correctly?
		Did the technician review the form for completeness?

Yes	No	Deviations
		Did the tech perform any minor deviations?
		Did the tech perform any major deviations?
Comments/Corrections/Deviations:		
Supervisor Signature:		
Date:		

Date: _____ Tech ID#_____ Quarter: I, II, III, IV (circle one)
Supervisor: [redacted] Participant Label_____

Questionnaire Supervisor Checklist

Check that each procedure is carried out correctly. Check yes if correct or no if incorrect. Provide an explanation of the incorrect item. Items are presented in the sequence of the examination procedure, but may require confirmation before or after the exam.

MMSE Supervisor Checklist

Yes	No	MMSE
		Introductory Script: I'm going to start by asking questions that require concentration and memory. Some questions are more difficult than others and some will be asked more than one time
		What is the date today? (3 = correct score for month (1 pt), day (1 pt) and year (1 pt))
		What is the season? Since distinctions between seasons can be difficult during certain months, one week leeway is allowed on either side of the actual date.
		What day of the week is it? What Town, County and State Are We in? For offsite visits, refer to the section of the manual titled "New England Counties" for a complete list of all counties.
		What is the name of this place? Ask the participant where they are. Any appropriate answer is okay. On home visits, the examiner can ask, What is the address of this place?
		What floor of the building are we on?
		I am going to name 3 objects. After I have said them I want you to repeat them back to me. Remember what they are because I will ask you to name them again in a few minutes: Apple, Table, Penny.
		Now I am going to spell a word forward and I want you to spell it backwards. The word is WORLD. W-O-R-L-D. Please spell it in reverse order.
		What are the 3 objects I asked you to remember a few moments ago? Items may be repeated in any order
		What is this called? (Watch) Show the wristwatch to the participant
		What is this called? (Pencil) a. Show the pencil to the participant. NOTE: the pencil should be a standard sharpened wooden pencil with eraser.
		Please repeat the following: No ifs, ands or buts. a. Enunciate clearly -- include the "S" at the end of ifs, ands, or buts, (if you think the participant heard you but repeated it incorrectly, make a note of what was missed and score 0). b. Allow only one attempt.
		Please read the following and do what it says. a. Hand participant the "Please Close Your Eyes" card. b. The participant may read the sentence out loud. The task to be coded is the participant's ability to follow instructions by closing his/her eyes. It is not necessary for the sentence to be read out loud if the participant performs the function properly.

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Supervisor: [redacted] Participant Label_____

		Please write a sentence.
		Please copy this drawing.
		Take this piece of paper in your right hand, fold it in half with both hands, and put it in your lap. (If participant is unable to use right hand because of physical disability, you can alter instructions to read "Take this piece of paper in your left hand, fold it in half with your left hand, and put it in your lap". The goal is to see whether the subject is able to follow a 3-step command, so this variation to the directions to accommodate subject's physical limitations is allowable.) a. Read the full statement BEFORE handing the paper to the participant. b. DO NOT direct the paper to participant's right side. Hold the paper in front and have the participant reach out to take it. Observe which hand is used. c. DO NOT repeat instructions or coach participant. Only repeat if the examiner felt it was not heard or if instructions were not given clearly (just repeat the directions in full as they were the first time).

Sociodemographics

Yes	No	Sociodemographics
		Where do you live? Coding 0 = Private residence 1 = Nursing home 2 = Other institution, such as: assisted living, retirement community 9 = Unknown
		Does anyone live with you? (NOTE: Code nursing home resident as NO to these questions.) Coding 0 = No 1 = Yes 9 = Unknown
		If the answer to the above question was 0 or 9 you may skip the following section. If the answer was yes, the examiner needs to determine who lives in the same household. Spouse, Children, Other Relative

Rosow-Breslau

Yes	No	Rosow-Breslau Questions
		Are you able to do heavy work around the house, like shovel snow or wash windows, walls, or floors without help?
		Are you able to walk half a mile without help?
		Are you able to walk up and down one flight of stairs without help?

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Supervisor: [redacted] Participant Label_____

Fractures

Yes	No	Fractures
		Since your last clinic visit have you broken any bones? **If yes, code the location of the 1st 3 fractures**

Physical Activities

Yes	No	Physical Activity – Part One
		Participant is handed a copy of the Physical Activity Questionnaire.
		The tech explains that the first section is Rest and Activity for a Typical Day over the past year (24 hours).
		The tech explains that it has to be a whole number and it has to equal 24 hours.
		The tech reads through each activity. ▪ Sleep ▪ Sedentary ▪ Slight Activity ▪ Moderate Activity ▪ Heavy Activity
		Examples are given as needed
		Adjustments are made according to the participant until the total number of hours equals 24
		The tech does not coach them or help them fill in the numbers.

Yes	No	Time Spent Doing Sitting Activities
		The tech explains she will be asking 2 questions about sitting activities.
		The tech reads the first questions and responses
		The tech reads second questions and responses

Date: _____ Tech ID#_____ Quarter: I, II, III, IV (circle one)
Supervisor: [redacted] Participant Label_____

Yes	No	Physical Activity – Part Two
		SCRIPT: *During the past year, how often did you participate in each of the following recreational activities?* ▪ In a typical 2 week period of time, how often do you (name activity) ▪ Average time/session ▪ Number of months/year
		Tech goes through each activity & codes correctly

Use of Nursing and Community Services		
|__|	**Have you been admitted to a nursing home (or skilled facility) in the past year?**	0=No 1=Yes 9=Unk.
|__|	**In the past year, have you been visited by a nursing service, or used home, community, or adult day care programs?** (examples: home health aide, visiting nurses, etc)	

Date: _____ Tech ID#_____ Quarter: I, II, III, IV (circle one)
Supervisor: [redacted] Participant Label_____

CES-D

Yes	No	CES-D
		SCRIPT: *The questions below ask about your feelings. For each of the following statements, please say how often you felt that way <u>during the past week</u>.*
		Hand the response sheet to the participant and explain the response options. The following definitions should be given: <u>Code</u> Rarely or none of the time (< one full day) Some or a little of the time (1-2 days) Occasionally or moderate amount of time (3-4 days) Most of the time (5-7 days)
		Read each item as it is written on the form. Preface statements 1, 6 & 11 with the statement *During the past week*, then continuing with the response categories. **Question 1: During the past week I was bothered by things that usually don't bother me. Question 6: During the past week I felt depressed. Question 11: During the past week my sleep was restless**
		Circle the response on the form
		When the participant asks about the meaning of any item or tries to qualify a statement, simply repeat the statement.
		If the participant is unable to read the response sheets, the interviewer should read each response as well as the question referring to their feelings in the past week.

Nagi Questions

Yes	No	Nagi Questions
		Show and explain the answer key *before* administering the questionnaire ▪ No difficulty ▪ A little difficulty ▪ Some difficulty ▪ A lot of difficulty ▪ Unable to do ▪ Don't do on physician or health care provider orders ▪ Don't know ▪ Unknown
		Tech goes through each activity & codes correctly

Date: _____ Tech ID#_____ Quarter: I, II, III, IV (circle one)
Supervisor: [redacted] Participant Label_____

Katz ADLs

Yes	No	Katz ADLs
		SCRIPT: *During the Course of a Normal Day, can you do the following activities independently or do you need help from another person or use special equipment or a device?*
		Tech goes through each activity: ▪ Dressing (undressing and redressing) *Devices such as: Velcro, elastic laces* ▪ Bathing (including getting in and out of a tub or shower) *Devices such as: bath chair, long handled sponge, hand held shower, safety bars* ▪ Eating *Devices sucha as: rocking knife, spork, long straw, plate guard* ▪ Transferring (getting in and out of a chair) *Devices such as: sliding board, grab bars, special seat* ▪ Toileting Activities (usuing bathroom facilities and handle clothing) *Devices such as: special toilet seat, commode*
		Tech codes responses correctly: ▪ 0=No help needed, independent ▪ 1=Uses device, independent ▪ 2=Human assistance needed, minimally dependent ▪ 3=Dependent ▪ 4=Does not do during a normal day ▪ 9=Unknown

Yes	***No***	***Technician Review***
		Did the technician introduce the set of questions with clear explanation?
		Did the technician ask the questions exactly as written on the form?
		Did the technician correctly use the answer key?
		Did the technician correctly clarify any questions the participant had?
		Did the technician score the participant's responses correctly?
		Did the technician review the form for completeness?

Yes	No	Deviations
		Did the tech perform any minor deviations?
		Did the tech perform any major deviations?
Comments/Corrections/Deviations:		
Supervisor Initials:		
Date:		

Date: _____ Tech ID#_____ Quarter: I, II, III, IV (circle one)
Supervisor: [redacted] Participant Label_____

Observed Physical Performance Measures
Supervisor Checklist

Check that each procedure is carried out correctly. Check yes if correct or no if incorrect. Provide an explanation of the incorrect item. Items are presented in the sequence of the examination procedure, but may require confirmation before or after the exam.

Yes	No	JAMAR Hand Grip Strength Test
		Introductory script: ***This instrument will measure your grip strength. The instrument is a little heavy, so be careful. When I tell you, I want you to squeeze the instrument as hard as you can. Do not expect the handle to move very much.***
		Participant is seated in chair with arms, forearm resting on chair arm, elbow at about a 90 degree angle.
		Participant should hold JAMAR in upright position, wrist in neutral position, JAMAR facing the technician.
		Make sure that red peak-hold needle is set to zero.
		Tell participant to squeeze as hard as s/he can, and squeeze until you tell s/he to stop. Say "Ready, Squeeze" once. Have participant hold squeeze for a 3 to 5-1000 second count.
		Take back JAMAR, hold at eye level at about a foot from your eyes and record reading on the kilogram scale. If directly in the middle of the scale then the reading is the odd number between the two even hash marks; otherwise record as the closest hash mark.
		Repeat steps until three measurements are recorded with the right hand.
		Repeat steps for three trials with the left hand.

Date: _____ Tech ID#_____ Quarter: I, II, III, IV (circle one)
Supervisor: [redacted] Participant Label_____

Repeated Chair Stands

Yes	No	Repeated Chair Stands
		Repeated Chair Stands is explained to participant
		A demonstration of the Chair Stands is provided to participant.
		Participant is asked if s/he would feel safe doing a Chair Stand. (If no, test is over. If yes, continue)
		Participant is asked to demonstrate the Chair Stand once, without using arms. (arms are folded across chest)
		The safety and ability of participant is assessed
		The Participant is asked if s/he thinks it would be safe to try and stand up from a chair five times without using his arms
		It is explained to Participant that s/he will be timed for the five Chair Stands
		The command "Ready, Begin" and timing begin simultaneously
		The stopwatch is started on the word "Stand" and stopped on "5."
		Once participant completes each stand, tester counts out loud.
		Data sheet is completely and accurately filled out, question are answered and pulse rate is recorded.

Timed Walk(s)

Yes	No	Instructions for Technician: Walk One
		Now I am going to observe how you normally walk, if you use a cane or other walking aid and would be more comfortable with it, you may use it.
		This is our walking course. I want you to walk to the other end of the course at your usual speed, just as if you were walking down the street. Walk all the way past the other end of the tape before you stop. Do you think this would be safe?
		If participant says that it would not be safe indicate this on the data sheet and abort walks.
		Please watch while I demonstrate. When I want you to start, I will say "Ready, begin."
		Have the participant line up his or her toes behind the line on the floor. Start timing when you say, "begin" and stop timing when the participant breaks the plane of the line at the end of the course. Record the time on data sheet.

Date: _____ Tech ID#_____ Quarter: I, II, III, IV (circle one)
Supervisor: [redacted] Participant Label_____

Yes	No	Instructions for Technician: Walk Two
		Now I want you to repeat the walk. Remember to walk at your usual pace, and all the way past the other end of the course. *Ready? Begin.*

Yes	No	Instructions for Technician: Walk Three
		Now I want you to repeat the walk again, but this time, I would like you to walk at a rapid pace, as fast as you can. Make sure you go all the way past the other end of the course. *Please watch while I demonstrate.* *Ready? Begin.*
		For each walk, the following questions will be answered: *Was this test completed?* **Coding** **0** = No **1** = Yes **8** = Not attempted **9** = Unknown *If the test was not attempted or completed, why not?* **Coding** **1** = Physical limitation **2** = Refused **3** = Other (write in) ***9*** = Unknown
		Walk time for each walk is recorded.

Yes	No	Deviations
		Did the tech perform any minor deviations?
		Did the tech perform any major deviations?
Comments/Corrections/Deviations:		
Supervisor Initials:		
Date:		

Date: _____ Tech ID#_____ Quarter: I, II, III, IV (circle one)
Supervisor: [redacted] Participant Label_____

Actical Supervisor Checklist

Check that each procedure is carried out correctly. Check yes if correct or no if incorrect. Provide an explanation of the incorrect item. Items are presented in the sequence of the examination procedure, but may require confirmation before or after the exam.

Yes	No	Actical
		Intro script: *We are asking everyone in your generation to wear this new device called an accelerometer which will capture your movement. We would like you to wear this device for 8 days during your waking hours. It is very small and will be attached to a belt worn around your waist. You may wear the belt over or under your clothing which ever is more comfortable for you. Is this something you are willing to do for the Framingham Heart Study?*
		If yes, tech states: *Great! I will show you how to wear the belt and then you can put it on for me.*
		If no or if the participant hesitates, the tech states: "*Okay, would you be willing to just try it?*" If participant gives a definite no, then the tech should write in the Comment box in the log book an explanation as to why.
		Tech asks the participant "Are you going to be wearing the device in your home community?" If not, ask if/when they would like it mailed to them. Answer is marked in the log book.
		Tech demonstrates and uses the picture from the handout as a visual and then watches them put it on
		Tech reads through each instruction: 1. Wear the device for 8 days during waking hours. 2. Do NOT wear in the shower (remember to put the device back on once you get out of the shower) (please note: the device is waterproof) or while sleeping (except for naps) 3. The device will be worn over the right hip resting on the iliac crest. Do not change sides 4. The device should be snug against the body but not tight 5. It can be worn underneath or on top of clothing 6. You may engage in activities that you normally do 7. Please return device and belt in the bubble pouch located inside the white return folder and write us any feedback you may have about your experience wearing the device.
		Tech writes the date the participant can take off the monitor and tells the participant to take it off around 3 pm.
		Tech gives the participant the information sheet to take home and points out Maureen's contact information for questions.
		Tech asks the participant if they are going to be swimming or doing water sports. If yes, a second belt is given.
		Tech fits the participant with the belt and checks for proper placement of the actical.
		Tech confirms the actical device number matches the log book

Date: _____ Tech ID#_____ Quarter: I, II, III, IV (circle one)
Supervisor: [redacted] Participant Label_____

Yes	No	Deviations
		Did the tech perform any minor deviations?
		Did the tech perform any major deviations?
Comments/Corrections/Deviations:		
Supervisor Initials:		
Date:		

Exit Interview Supervisor Checklist

Yes	No	
		Check Numerical Data Sheet that everything has been done. Check referral tracking sheet and review with ppt any referral recommendations
		Confirm that ppt has completed FFQ or is taking it home
		Ask for any feedback from ppt on how they felt about their exam; write in comments
		Read disclaimer: *Your exam today was for research purposes only and is not designed to make a medical diagnosis. The exam cannot identify all serious heart and health issues. It is important that you continue regular follow-ups with your physician or health care provider.*
		Make sure ppt leaves with all belongings, especially medications.
		Give ppt gift
		Thank them for their time and willingness to participate
		Escort them out

Supervisor Observation Report
Individual Performance
Observation Date(s):_____
Meeting date: _____

|__||__||__|	**Supervisor ID #**
|__||__||__|	**Tech ID #**
|__|	**Quarter**
|__| **if yes fill in below**	Did the tech perform any minor deviations? 0=No, 1=Yes, 9=Unknown
RESULT	
|__|	Number of minor deviations
AREA OF MINOR DEVIATION	
Check all the apply	□ Anthropometry □ ECG □ AAD □ Questionnaires □ PFT □ Observed Perf.
DEVIATION & CORRECTIVE ACTION	
	_____ _____ _____ _____ _____ _____
|__|	Did the supervisor review minor deviations with tech? 0=No, 1=Yes, 9= Unknown

Definition:
Minor deviation: A non-serious departure from the standard protocol. A minor deviation does not affect data outcome. Examples: Handouts not being used, instructions not being given word for word

|__| **if yes fill in below**	Did the tech perform any major deviations? 0=No, 1=Yes, 9=Unknown
RESULT	
|__|	Number of major deviations
AREA OF MAJOR DEVIATION	
Check all the apply	□ Anthropometry □ ECG □ AAD □ Questionnaires □ PFT □ Observed Perf.
DEVIATION & CORRECTIVE ACTION	
	_____ _____ _____ _____ _____ _____ _____
|__|	Did the supervisor review major deviations with tech? 0=No, 1=Yes, 9= Unknown
___/___/____	Follow-up date to ensure major deviation is no longer performed. 0=No, 1=Yes, 9= Unknown

Definition:
Major deviation: A serious departure from the standard protocol. A major deviation does affect the outcome of data. Therefore requires supervisor follow-up. Examples: Leads crossed during ECG, leading question, improper placement of equipment.

COMMENTS	
	Protocol areas not reviewed above: Other Notes: Overall Impression: Supervisor follow-up: Tech Feedback from Meeting:

|__|	Was a copy of this report given to technician? 0=No, 1=Yes, 9=Unknown
|__|	Was a copy of this report given to the clinic director? 0=No, 1=Yes, 9=Unknown

Supervisor Signature: **Date:**

Tech Signature: **Date:**

Supervisor Observation Report
Quarter Final Report -
Meeting Date:

Cumulative Deviations Quarter
Total Number of Minor Deviations:
Total Number of Major Deviations:

MINOR DEVIATIONS	
Area of Deviation	

MAJOR DEVIATIONS	
Area of Deviation	

DEVIATION & CORRECTIVE ACTION
_____ _____ _____ _____

Offspring Exam 9: Short Examination/Split Exam

A short exam is completed when a participant requests an abbreviated exam (usually up to 2 hours of testing). A split exam is completed when a participant requests to do an examination in 2 visits.

The priority of exam procedures is listed below:

I. Informed Consent & Tracking Procedures

1) Informed Consent
2) HIPPA-Release of Health Information for Research Purposes
3) Tracking Information Form

II. Clinical Measurements & Procedures

1) Lab
   a. Blood
   b. Urine
2) Anthropometrics
   a. Weight
   b. Height
   c. Neck
   d. Waist at Umbilicus
   e. Hip
   f. Thigh
3) ECG

III. Physician-Administered Medical History and Physical Exam

1) Medical History
2) Resting Blood Pressure
3) Physical Exam

IV. PFT

If time permits for a short exam, the participant will undergo Tonometry, other measurement of vascular function (Ankle-Arm Doppler) and tech administered questionnaires.

If the participant chooses to have a split exam a second date will be arranged to complete all of the remaining testing for the exam cycle.

Call Backs/ Split Exams
Offspring Exam 9

Participants Name / I.D : **Second Appointment Date:**

Clinic Exam Date: **Recruiter's Initials:_____**

***Check Box to indicate which test(s) will be completed on the second visit.**

	TEST:	APPROXIMATE TIME:
___	MD Questionnaire/ Physical Exam	30 Min.
___	Anthropometry (Ht, Wt, Waist/Hip/Thigh girth, Neck)	10 Min.
___	Self-Administered Questionnaires	15 Min.
___	Tech Administered Questions	15 Min.
___	Mini-Mental	10 Min.
___	Urine	5 Min.
___	Lab	10 Min
___	ECG (with PHiRes)	20 Min.
___	Observed Performances	10 Min.
___	Ankle/Arm Doppler	15 Min.
___	Tonometry	20 Min
___	PFT	20-50* Min.
___	Accelerometer	10 Min.

* Maximum Time is with Albuterol Testing Only.

- Why did this participant leave early?

- Which Technician did this participant work with most?

Offspring Exam 9 Components-Offsite

Section I: Informed Consent & Tracking Procedures

1) Information Sheet
2) HIPPA - Release of Health Information for Research Purposes
3) Admitting Form
4) Research Proxy

Section II: Clinical Measurements & Procedures

1) **Anthropometrics**
    a. Weight
2) **ECG**
    a. ECG
3) **Observed Physical Performance**
    a. Hand Grip Test
    b. Measured Walks
    c. Chair Stands

Section III: Tech-Administered Questionnaires

1) **Cognitive Function**
    a. MMSE
2) **Physical Function**
    a. KATZ-ADL Scale
    b. Rosow-Breslau
    c. NAGI
3) **Depressive Symptoms**
    a. CES-D
4) **Physical Activity Questionnaire**
    a. Exercise
5) **Other**
    a. Fractures
    b. Proxy Form

Section IV: Technician-Administered Medical History and Physical Exam

1) Medical History
2) Resting Blood Pressure

Section V: Self-Administered Questionnaires

1) Socio-demographics
2) SF12 Health Survey
3) Sleep Questionnaire

Section VI: Exam Completeness

1) Physical Activity Monitor (optional)
2) Referral Tracking & Adverse Events
3) Exit Interview

ID: «Idtype» - «Id» OFFSITE EXAM

Numerical Data/Anthropometry

☐ Check here if whole page is blank. Reason why_____

|__|__|__| **Technician Number** (for basic information)

Basic Information

|__|	**Sex of Participant** 1=Male, 2=Female
|__|	**Site of Exam** (0=Heart Study, 1=Nursing home, 2=Residence, 3=Other)
|__|__|	**Age of Participant** (number of years)
|__|__|	**What state do you reside in?** *(If reside outside the USA, code ZZ, if plans to wear accelerometer while visiting USA code state of visit)* Code: AL, AK, AS, etc.

Anthropometry

Check Protocol Modification *ONLY if there was one and document it in Comment section*

88*88=Refused, 99*99=Not done or Unk.

|9_|9_|*|9_|9_| **Height** *(inches, to next lower 1/4 inch)*

☐ **Protocol modification**

|__|__|__| **Weight** *(to nearest pound)* (400=400 or more 888=refused, 999=Unk.)

☐ **Protocol modification**

|__| **In the past year, have you lost more than 10 pounds?**
0=No, 1= Yes, unintentionally, NOT due to dieting or exercise
2= Yes, intentionally, due to dieting or exercise

|9_|9_|9_| **Technician Number** (for anthropometry)

|9_|9_|*|9_|9_| **Neck Circumference** *(inches, to next lower1/4 inch)*

☐ **Protocol modification**

|9_|9_|*|9_|9_| **Waist Girth at umbilicus** *(inches, to next lower 1/4 inch).*

☐ **Protocol modification**

|9_|9_|*|9_|9_| **Hip Girth** *(inches, to next lower 1/4 inch)*

☐ **Protocol modification**

|9_|9_|*|9_|9_| **Thigh Girth** *(inches, to next lower 1/4 inch)*

☐ **Protocol modification**

Comments for ALL Protocol Modification *(specify measurement)*

_____

_____

TECH01

☐ Check here if whole page is blank. Reason why_____

Procedures Sheet

0=No, 1=Yes, 8=Offsite visit

|_**8**_|	**Type of Exam**	1=Complete exam, 2=Split exam(exam completed in 2 visits), 3=short exam (incomplete exam), 8=offsite
|__|	**Informed Consent Signed**	0=No, 1=Yes, 2= offspring waiver of consent, LAR, or next-of-kin
|_**8**_|	**Urine Specimen**	
|_**8**_|	**Blood Draw**	
|__|	**Mini-Mental Status Exam**	
|__|	**Anthropometry**	
|__|	**Sociodemographic Questions** (self administered)	
|__|	**SF-12 Health Survey**	
|__|	**CES-D Scale**	
|__|	**NAGI, Rosow-Breslau, Katz**	
|__|	**Exercise Questionnaire**	
|__|	**ECG**	
|_**8**_|	**P Wave Signal Averaged ECG**	
|__|	**If not performed why:** 1=AF, 2=Pacemaker, 3=Pat. ran out of time, 4=Pat. couldn't lie flat, 5=equipment malfunction, 6=other	
|__|	**Observed performance (**Timed walk, hand grip, chair stands)	
|_**8**_|	**Tonometry**	
|_**8**_|	**Ankle-brachial blood pressure by Doppler.** *(Participants ≥ 40 years)*	
|_**8**_|	**Spirometry 8=offsite**	0=Not Done, 1=Done, 2=Attempted, not finished, 3= Attempted, tech aborted ,4=Other
|__|	**Reason Spirometry not done**	1=Medical exclusion, 2=Refused, 3=equipment problems 4=Other
|_**8**_|	**Post Albuterol Spirometry 8=offsite**	0=Not Done, 1=Done, 2=Attempted, not finished, 3= Attempted, tech aborted ,4=Other
|__|	**Reason Post Alb. Spir. not done**	1=Medical exclusion, 2=Refused, 3=equipment problems 4=Other 5=Do not qualify
|_**8**_|	**Diffusion Capacity 8=offsit**	0=Not Done, 1=Done, 2=Attempted, not finished, 3= Attempted, tech aborted ,4=Other
|__|	**Reason Diffusion not done**	1=Medical exclusion, 2=Refused, 3=equipment problems 4=Other
|__|	**Accelerometer**	

TECH02

For Participants Who Wish to Complete Their Exam on a Second Visit (Split Exam)

(Leave blank for OFFSITE visits)

|__|__|*|__|__|*|__|__|__|__|	**Second Exam Date** *(If participant returns to finish their clinic exam on a date other than the original exam date, then fill in the date they return here. Otherwise leave entire page completely blank)*

Keyers: if Second Exam Date is not filled and page is blank' then leave the page all blank.

*Fill in with 1=yes if procedure **was done** on the **Second** Exam Date and 0=no if procedure **was not done** on the **Second** Exam Date. Note that informed consent from first visit will cover the second visit.*

Procedures Sheet

0=No, 1=Yes, 8=Offsite visit

|__|	**Type of Exam**	1=Complete exam, 2=Split exam(exam completed in 2 visits), 3=short exam (incomplete exam), 8=offsite
|__|	**Urine Specimen**	
|__|	**Blood Draw**	
|__|	**Mini-Mental Status Exam**	
|__|	**Anthropometry**	
|__|	**Sociodemographic Questions** (self administered)	
|__|	**SF-12 Health Survey**	
|__|	**CES-D Scale**	
|__|	**NAGI, Rosow-Breslau, Katz**	
|__|	**Exercise Questionnaire**	
|__|	**ECG**	
|__|	**P Wave Signal Averaged ECG**	
|__|	**If not performed why:** 1=AF, 2=Pacemaker, 3=Pat. ran out of time, 4=Pat. couldn't lie flat, 5=equipment malfunction, 6=other	
|__|	**Observed performance (**Timed walk, hand grip, chair stands)	
|__|	**Tonometry**	
|__|	**Ankle-brachial blood pressure by Doppler.** *(Participants ≥ 40 years)*	
|__|	**Spirometry**	0=Not Done, 1=Done, 2=Attempted, not finished, 3= Attempted, tech aborted ,4=Other
|__|	**Reason Spirometry not done**	1=Medical exclusion, 2=Refused, 3=equipment problems 4=Other
|__|	**Post Albuterol Spirometry**	0=Not Done, 1=Done, 2=Attempted, not finished, 3= Attempted, tech aborted ,4=Other
|__|	**Reason Post Alb. Spir. not done**	1=Medical exclusion, 2=Refused, 3=equipment problems 4=Other 5=Do not qualify
|__|	**Diffusion Capacity**	0=Not Done, 1=Done, 2=Attempted, not finished, 3= Attempted, tech aborted ,4=Other
|__|	**Reason Diffusion not done**	1=Medical exclusion, 2=Refused, 3=equipment problems 4=Other
|__|	**Accelerometer**	

TECH03

☐ Check here if whole page is blank. Reason why_____

Exit Interview

|__|__|__| **Technician Number**

|__| **Procedure sheet reviewed**

|__| **Referral sheet reviewed**

|_8_| **Left clinic w/ belongings**

0=No
1=Yes
8=Offsite
9=Unk.

|_8_| **Dietary questionnaire provided** 1=Brought to exam completed or filled out in clinic, 2=Given in clinic to complete at home and send back, 3=Other, 8=Offsite, 9=Unk.

|__| **Left clinic with accelerometer** 0=No, refused, 1=Yes, 2=it will be mailed to them, 8=Offsite, 9=Unk.

|__| **Feedback** 0=No feedback, 1=Positive feedback, 2=Negative feedback, 3=Other, 9=Unk.

Comments_____

_____

_____

CLINIC visit only

|__|__|__| **Technician Number**

|__| **Was there an adverse event in clinic that does not require further medical evaluation?** (0=No, 1=Yes, 9=Unk.)
Comments:_____
_____

OFFSITE visit only

|__|__|__| **Technician Number**

|__| **Was a FHS physician contacted during the examination due to adverse exam finding?** (0=No, 1=Yes, 9=Unk.)
Comments:_____
_____

|__|__|__| **Technician who reviewed TECH portion of exam**

Your exam today was for research purposes only and is not designed to make a medical diagnosis. The exam cannot identify all serious heart and health issues. It is important that you continue regular follow-up with your physician or health care provider.

TECH04

MMSE-Cognitive Function-Part I

☐ Check here if whole page is blank. Reason why_____

I'm going to start by asking questions that require concentration and memory. Some questions are more difficult than others and some will be asked more than one time.

|__|__|__| **Technician Number**

SCORE	*Write all responses on exam form* 0=incorrect, 1-3=score 1 point for each correct response, 6=item administered, Participant doesn't answer, 9=Unk.
0 1 2 3 6 9	**What Is the Date Today?** *(Month, day, year, correct score=3)*
0 1 6 9	**What Is the Season?**
0 1 6 9	**What Day of the Week Is it?**
0 1 2 3 6 9	**What Town, County and State Are We in?** *(Town, county, state, correct score=3)*
0 1 6 9	**What Is the Name of this Place?** *(any appropriate answer all right, for instance my home, street address, heart study..max score=1)*
0 1 6 9	**What Floor of the Building Are We on?**
0 1 2 3 6 9	**I am going to name 3 objects. After I have said them I want you to repeat them back to me. Are you ready? Apple, Table, Penny. Could you repeat the three items for me** **Remember what they are because I will ask you to name them again in a few minutes.**
|__|__|__|__|__|	**Now I am going to spell a word forward and I want you to spell it backwards. The word is world. W-O-R-L-D.** **Please Spell it in Reverse Order.** *(Letters Are Entered and Scored Later)*
	Score as 66666=Not administered for reason unrelated to cognitive status 00000=Administered, but couldn't do 99999=Unk.
0 1 2 3 6 9	**What are the 3 objects I asked you to remember a few moments ago?**

TECH05

MMSE-Cognitive Function -Part II

☐ Check here if whole page is blank. Reason why_____

SCORE	*Write all responses on exam form* 0=incorrect, 1-3=score 1 point for each correct response, 6=item administered, Participant doesn't answer, 9=Unk.
0 1 6 9	**What Is this Called?** (Watch)
0 1 6 9	**What Is this Called?** (Pencil)
0 1 6 9	**Please Repeat the Following: "No Ifs, Ands, or Buts."** (Perfect=1)
0 1 6 9	**Please Read the Following & Do What it Says** *(performed=1, code 6 if low vision)*
0 1 6 9	**Please Write a Sentence** (*code 6 if low vision)*
0 1 6 9	**Please Copy this Drawing** *(code 6 if low vision)*
0 1 2 3 6 9	**Take this piece of paper in your right hand, fold it in half with both hands, and put in your lap** *(score 1 for each correctly performed act, code 6 if low vision)*

No	Yes	Maybe	Unk. (*coding for below*)	Factor Potentially Affecting Mental Status Testing
0	1	2	9	**Not fluent in English**
0	1	2	9	**Poor eyesight**
0	1	2	9	**Poor hearing**
0	1	2	9	**Other, write in** _____

TECH06

Sentence and Design Handout for Participant

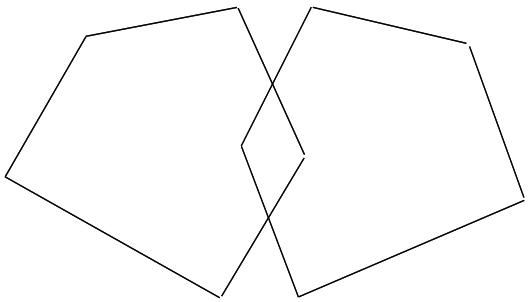
PLEASE WRITE A SENTENCE

_____

_____

_____

PLEASE COPY THIS DESIGN



Socio-demographic Questionnaire
(Tech-administered)

☐ Check here if whole page is blank. Reason why_____

|__|__|__| **Technician Number**

Socio-demographics

|__| **Where do you live?** (0=Private residence, 1=Nursing home, 2=Other, setting (no longer able to live independently) such as assisted living, 9=Unk.)

|__| **Does anyone live with you?** (0=No, 1=Yes, 9=Unk.)
Code Nursing Home Residents as NO

If Yes, fill ☞

If 0 or 9, skip to next table

|__|	Spouse	0=No
|__|	Significant Other	1=Yes, more than 3 months per year
|__|	Children	2=Yes, less than 3 months per year
|__|	Friends	9=Unk.
|__|	Relatives	

Use of Nursing and Community Services

|__| **Have you been admitted to a nursing home (or skilled facility) in the past year?**

|__| **In the past year, have you been visited by a nursing service, or used home, community, or adult day care programs?** (examples: home health aide, visiting nurses, etc)

0=No
1=Yes
9=Unk.

TECH07

Nagi Questions

(Tech-administered)

☐ Check here if whole page is blank. Reason why_____

|__|__|__| **Technician Number**

Nagi Questions

For each activity tell me whether you have:

(0) No Difficulty
(1) A Little Difficulty
(2) Some Difficulty
(3) A Lot Of Difficulty
(4) Unable To Do
(5) Don't Do On Physician or Health Care Provider Orders
(6) Don't Know
(9) Unk.

|__|	**Pulling or pushing large objects like a living room chair**
|__|	**Either stooping, crouching, or kneeling**
|__|	**Reaching or extending arms below shoulder level**
|__|	**Reaching or extending arms above shoulder level**
|__|	**Either writing, or handling, or fingering small objects**
|__|	**Standing in one place for long periods, say 15 minutes**
|__|	**Sitting for long periods, say 1 hour**
|__|	**Lifting or carrying weights under 10 pounds** *(like a bag of potatoes)*
|__|	**Lifting or carrying weights over 10 pounds** *(like a very heavy bag of groceries)*

TECH08

Rosow-Breslau Scale and Katz Activities of Daily Living
(Tech-administered)

☐ Check here if whole page is blank. Reason why_____

|__|__|__| **Technician Number**

Rosow-Breslau Questions

|__|	**Are you able to do heavy work around the house, like shoveling snow or washing windows, walls, or floors without help?**	0=No 1=Yes 9=Unk.
|__|	**Are you able to walk half a mile without help? (About 4-6 blocks)**	
|__|	**Are you able to walk up and down one flight of stairs without help?**	

Katz ADLs

During the Course of a Normal Day, can you do the following activities independently or do you need help from another person or use special equipment or a device?
0=No help needed, independent,
1=Uses device, independent,
2=Human assistance needed, minimally dependent,
3=Dependent,
4=Does not do during a normal day,
9=Unk.

|__|	**Dressing** (undressing and redressing) *Devices such as: velcro, elastic laces*
|__|	**Bathing** (including getting in and out of tub or shower) *Devices such as: bath chair, long handled sponge, hand held shower, safety bars*
|__|	**Eating** *Devices such as: rocking knife, spork, long straw, plate guard.*
|__|	**Transferring**(getting in and out of a chair) *Devices such as: sliding board, grab bars, special seat*
|__|	**Toileting Activities** (using bathroom facilities and handle clothing) *Devices such as: special toilet seat, commode*

TECH09

Fractures

☐ Check here if whole page is blank. Reason why_____

|__|__|__| **Technician Number**

Fractures

|__| **Since Your Last Clinic Visit Have You Broken Any Bones?**
(0=No, 1=Yes, 2=Maybe, 9=Unk.)

If Yes, fill ☞

|__|__| **Location of fracture:**

|__|__| **Location of second fracture** (if more than one)**:**

|__|__| **Location of third fracture** (if more than two)**:**

Code for Location (*code Unk. as 99***)**
1= Clavicle (collar bone)
2=Upper arm (humerus) or elbow
3=Forearm or wrist
4=Hand
5=Back *(If disc disease only, code as no)*
6=Pelvis
7=Hip
8=Leg
9=Foot
10=Other, specify_____

TECH10

Physical Activity Questionnaire Part 1--Framingham Heart Study
Tech-administered

☐ Check here if whole page is blank. Reason why_____

|__|__|__| **Technician Number**

Rest and Activity for a Typical Day over the past year (A typical day = most days of the week) (*Activities must equal 24 hours*)	**Number of hours**
Sleep - Number of hours that you typically sleep?	_____
Sedentary - Number of hours typically sitting? Such as reading, watching TV, using the computer, doing handcrafts	_____
Slight Activity - Number of hours with activities such as standing, walking?	_____
Moderate Activity - Number of hours with activities such as housework (vacuum, dust, yard chores, climbing stairs; light sports such as bowling, golf)?	_____
Heavy Activity - Number of hours with activities such as heavy household work, heavy yard work such as stacking or chopping wood, exercise such as intensive sports--jogging, swimming etc.?	_____
Total number of hours *(should be the total of above items)*	**24**

|__|	**Over the past 7 days, how often did you participate in SITTING ACTIVITIES such as reading, watching TV, using the computer, or doing handcrafts?**
	0 = Never 1 = Seldom/1-2 days 2 = Sometimes/3-4 days 3 = Often/5-7 days 8 = refused 9 = Don't know/Unknown
|__|	**Over the past 7 days, how many hours per day did you engage in these sitting activities?**
	1 = less than 1 hour 2 = 1 hour but less than 2 hours 3 = 2-4 hours 4 = more than 4 hours 8 = refused 9 = Don't know/Unknown

TECH11

Physical Activity Questionnaire Part 2--Framingham Heart Study

Tech-administered

☐ Check here if whole page is blank. Reason why_____

|__|__|__| **Technician Number**

I am going to read a list of activities. Please tell me which activities you have done in the past year.

	During the past year did you (do)? 0=No, 1=Yes, 8=Refused, 9=Unk.	**In a typical 2 week period of time, how often do you** *(name of activity)*	**Average time/session** hours	minutes	**Number months/year** 0-12
|__|	**Walk** *(walking to work, walking the dog, walking in the mall)*	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Calisthenics/general exercise** (yoga, pilates)	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Exercise cycle, ski or stair machine** (*treadmill, elliptical, stair master, etc.)*	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Exercises to increase muscle strength or endurance -Weight training** *(free weights, machines)*	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Moderate/strenuous household chores** *(vacuuming, scrubbing floors, washing windows, carrying wood)*	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Jog**	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Bike**	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Dance**	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Aerobics**	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Swim**	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Tennis**	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Golf (no cart)**	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Lawn work or yard care*** *(Mowing the lawn, snow or leaf removal)*	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Outdoor Gardening**	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Hike**	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Light sport or recreational activities** *(bowling, golf with a cart, shuffleboard, fishing, ping-pong)*	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Other*, write in**_____ _____	|__|__|	|__|__|	|__|__|	|__|__|

TECH12

CES-D Scale

Tech-administered

☐ Check here if whole page is blank. Reason why_____

|__|__|__| **Technician Number**

The questions below ask about your feelings. For each statement, please say how often you felt that way during the past week.

	Circle best answer for each question			
DURING THE PAST WEEK	**Rarely or none of the time (less than 1 day)**	**Some or a little of the time (1-2 days)**	**Occasionally or moderate amount of time (3-4 days)**	**Most or all of the time (5-7 days)**
***I was bothered by things that usually don't bother me.**	0	1	2	3
I did not feel like eating; my appetite was poor.	0	1	2	3
I felt that I could not shake off the blues, even with help from my family and friends.	0	1	2	3
I felt that I was just as good as other people.	0	1	2	3
I had trouble keeping my mind on what I was doing.	0	1	2	3
***I felt depressed.**	0	1	2	3
I felt that everything I did was an effort.	0	1	2	3
I felt hopeful about the future.	0	1	2	3
I thought my life had been a failure.	0	1	2	3
I felt fearful.	0	1	2	3
***My sleep was restless.**	0	1	2	3
I was happy.	0	1	2	3
I talked less than usual.	0	1	2	3
I felt lonely.	0	1	2	3
People were unfriendly.	0	1	2	3
I enjoyed life.	0	1	2	3
I had crying spells.	0	1	2	3
I felt sad.	0	1	2	3
I felt that people disliked me	0	1	2	3
I could not "get going"	0	1	2	3

** Indicates that the technician should preface the statement with "During the past week"*

TECH13

Proxy form

☐ Check here if whole page is blank. Reason why_____

|__| **Proxy used to complete this exam (**0=No, 1=Yes, 1 proxy, 2=Yes, more than 1 proxy, 9=Unk.)

if yes, fill ☞

Proxy Name _____

|__| **Relationship** (1=1st Degree Relative(spouse, child), 2=Other Relative, 3=Friend, 4=Health Care Professional, 5=Other, 9=Unk.

|__|__|*|__|__| **How long have you known the participant?** (Years, months; 99.99=Unk.) example: 3m=00*03

|__| **Are you currently living in the same household with the participant?** (0=No, 1=Yes, 9=Unk.)

|__| **How often did you talk with the participant during the prior 11 months?** (1=Almost every day, 2=Several times a week, 3=Once a week, 4=1 to 3 times per month, 5=Less than once a month, 9=Unk.)

Proxy Name _____

|__| **Relationship** (1=1st Degree Relative(spouse, child), 2=Other Relative, 3=Friend, 4=Health Care Professional, 5=Other, 9=Unk.

|__|__|*|__|__| **How long have you known the participant?** (Years, months; 99.99=Unk.) example: 3 m=00*03

|__| **Are you currently living in the same household with the participant?** (0=No, 1=Yes, 9=Unk.)

|__| **How often did you talk with the participant during the prior 11 months?** (1=Almost every day, 2=Several times a week, 3=Once a week, 4=1 to 3 times per month, 5=Less than once a month, 9=Unk.)

TECH014

Observed performance Part 1
Technician Administered

☐ Check here if whole page is blank. Reason why_____	

|__|__|__|	**Technician Number**

HAND GRIP TEST *Measured to the nearest kilogram*		
Right hand		
Trial 1	99=Unk.	|__|__|
Trial 2	99=Unk.	|__|__|
Trial 3	99=Unk.	|__|__|
Left hand		
Trial 1	99=Unk.	|__|__|
Trial 2	99=Unk.	|__|__|
Trial 3	99=Unk.	|__|__|

☐	**Check if this test not completed or not attempted.**
|__|	**If not attempted or completed, why not?** 1=Physical limitation, 2=Refused, 3=Other _____write in, 9=Unk.

Protocol modification for Hand Grip , Chair stands and Walk testing
☐ **Check for Protocol modification**

Comments: _____

_____

_____

_____

TECH15

Observed performance Part 2
Technician Administered

☐ Check here if whole page is blank. Reason why_____	
|__|__|__|	**Technician Number**

Repeated Chair Stands (5)

Time to complete five stands in seconds (99.99=Unk.)	|__|__|*|__|__|
If less than five stands, enter the number (9=Unk.)	|__|
IF OFFSITE visit, Chair height (in inches, 99*99=Unk.)	|__|__|*|__|__|
☐ **Check if this test not completed or not attempted.**	
|__| **If not attempted or completed, why not?** (1=Physical limitation, 2=Refused, 3=Other _____write in, 9=Unk.)	

Measured Walks

Walking aid used: 0=No aid, 1=Cane, 2=Walker, 3=Wheelchair, 4=Other, 9=Unk.	|__|
Course in meters. *OFFSITE ONLY* *(check one)*	|__| **3m** |__| **4m**

First Walk

Walk time (in seconds, 99.99=Unk.)	|__|__|*|__|__|
Laser walk time (in seconds, 99.99=Unk.)	**|9 |9 |*|9 |9 |**
☐ **Check if this test not completed or not attempted.**	
|__| **If not attempted or completed, why not?** (1=Physical limitation, 2=Refused, 3=Other _____write in, 9=Unk.)	

Second Walk

Walk time (in seconds, 99.99=Unk.)	|__|__|*|__|__|
Laser walk time (in seconds, 99.99=Unk.)	**|9 |9 |*|9 |9 |**
☐ **Check if this test not completed or not attempted.**	
|__| **If not attempted or completed, why not?** (1=Physical limitation, 2=Refused, 3=Other _____write in, 9=Unk.)	

Quick Walk

Walk time (in seconds, 99.99=Unk.)	|__|__|*|__|__|
Laser walk time (in seconds, 99.99=Unk.)	**|9 |9 |*|9 |9 |**
☐ **Check if this test not completed or not attempted.**	
|__| **If not attempted or completed, why not?** (1=Physical limitation, 2=Refused, 3=Other _____write in, 9=Unk.)	

Ankle Brachial Blood Pressure Measurements. Participants ≥40 years

☒ Check here if whole page is blank Reason why_____

.|__|__|__| **Technician Number** for Doppler Ankle Brachial Blood Pressure.

|__| **Have you had any problems with blood clots in your legs?**

If yes, fill ☞ ***do NOT proceed with testing in the extremity with the blood clot***

|__| **Are you being treated for this problem now?**

0=No
1=Yes

|__| **Cuff size, arm**
|__| **Cuff size, ankle**

0= pediatric, 1= regular adult
2= large adult, 3= thigh

|__|__|__| **Right arm**
|__|__|__| **Right ankle**
|__|__|__| **Left ankle**
|__|__|__| **Left arm**

300=≥300 mmHg
888= Not Done
999= Unk.

REPEAT SYSTOLIC BLOOD PRESSURE MEASUREMENTS (reverse order)

|__|__|__| **Left arm**
|__|__|__| **Left ankle**
|__|__|__| **Right ankle**
|__|__|__| **Right arm**

300=≥300 mmHg
888= Not Done
999= Unk.

THIRD SYSTOLIC BLOOD PRESSURE MEASUREMENT (order as in repeat SBP). To be obtained if initial and repeat SBP at any site differ by more than 10 mmHg. For site that differs.

|__|__|__| **Right arm**
|__|__|__| **Right ankle**
|__|__|__| **Left ankle**
|__|__|__| **Left arm**

300=≥300 mmHg
888= Not Done
999= Unk.

|__| **Right Ankle blood pressure site**
|__| **Left Ankle blood pressure site**

0= posterior tibial (ankle)
1= dorsalis pedis (foot), 8=Not Done

EXCLUSIONS:

*Enter exclusion **ONLY** if there is an 888 above*

Right	Left	
|__|	|__|	**Lower Extremity Exclusions** 1= venous stasis ulceration, or DVT 2= amputation, 3= other_____
|__|	|__|	**Upper Extremity Exclusions** 1=Mastectomy, 3= Other_____

☐ **Check if Protocol modification,** write in_____

Comments _____

_____

TECH17

Respiratory Disease Questionnaire Part 1
Technician Administered

DATE of last exam *«Lexam»*

DATE of last medical history update *«Lupdate»*

☐ Check here if whole page is blank. Reason why_____

|__|__|__| **Technician Number**

Respiratory Diagnoses

|__| **Have you ever had asthma?** (0=No, 1=Yes, 9=Unk.)

If yes, fill ☞

- |__| **Do you still have it?**
- |__| **Was it diagnosed by a doctor or other health care professional?**
- |__|__| **At what age did it start?** *(Age in years 88=N/A, 99=Unk.*
- |__|__| **If you no longer have it, at what age did it stop?** *(Age in years) 88=still have it, 99=Unk.*
- |__| **Have you received medical treatment for this in the past 12 months?**

|__| **Have you ever had hay fever** (allergy involving the nose and/or eyes)**?** (0=No, 1=Yes, 9=Unk.)

If yes, fill ☞

- |__| **Do you still have it?** (0=No, 1=Yes, 9=Unk.)

Have you ever had any of the following conditions diagnosed by a doctor or other health care professional? (0=No, 1=Yes, 9=Unk.)

- |__| **Chronic Bronchitis**
- |__| **Emphysema**
- |__| **COPD** (Chronic obstructive pulmonary disease)
- |__| **Sleep Apnea**
- |__| **Pulmonary Fibrosis**

Inhaler Use (0=No, 1=Yes)

|__| **Do you take inhalers or bronchodilators?**

If yes, fill ☞

- |__| **Do you take any of the inhaled medications**?- albuterol, ProAir, Proventil, Ventolin, pirbuterol, Maxair, levalbuterol, Xopenex, metaproterenol, Alupent, or ipratropium, Atrovent, Combivent

  If yes, fill ☞ |__|__| How many hours ago did you last use the medication, either by inhaler or nebulizer? *if last used >48 hrs ago code 88, 99= Unk.* **Time in hours 1-48**

- |__| **Do you take any of the following inhaled medications?** salmeterol, Serevent, Advair, formoterol, Foradil, Symbicort, arformoterol, Brovana, tiotropium, or Spiriva,

  If yes, fill ☞ |__|__| How many hours ago did you last use the medication, either by inhaler or nebulizer? *if last used >48 hrs ago code 88, 99=Unk.* **Time in hours 1-48**

TECH18

Respiratory Disease Questionnaire Part 2
Technician Administered

☐ Check here if whole page is blank. Reason why_____

Acute Respiratory Illnesses Since Last Exam

Since your last exam or medical history update

|__| **Have you been hospitalized because of breathing trouble or wheezing?** (0=No, 1=Yes, 9=Unk.)

If yes, fill ☞

|__|__| **How many times has this occurred?**

|__| **Were any of these hospitalizations due to a lung or bronchial problem, for example COPD, asthma, bronchitis, emphysema, or pneumonia?** (0=No, 1=Yes, 9=Unk.)

|__| **Have you required an emergency room visit or an unscheduled visit to a doctor's office or clinic because of breathing trouble or wheezing?** (0=No, 1=Yes, 9=Unk.)

If yes, fill ☞

|__|__| **How many times has this occurred?**

|__| **Were any of these emergency room or unscheduled visits due to a lung or bronchial problem, for example COPD, asthma, bronchitis, emphysema, or pneumonia?** (0=No, 1=Yes, 9=Unk.)

|__| **Have you had pneumonia (including bronchopneumonia)?** (0=No, 1=Yes, 9=Unk.)

If yes, fill ☞

|__|__| **How many times have you had pneumonia?**

The following questions are about problems which occur when you **DO NOT** have a cold or the flu. Please list problems that occurred IN THE PAST 12 MONTHS only

|__| **Have you had a problem with sneezing or a runny or blocked nose when you DID NOT have a cold or the flu?** (0=No, 1=Yes, 9=Unk.)

If yes, fill ☞

|__| **Has this nose problem been accompanied by itchy-watery eyes?** (0=No, 1=Yes, 9=Unk.)

In which of the months did this nose problem occur? (0=No, 1=Yes) *Fill in ALL months.*

|__| January	|__| July
|__| February	|__| August
|__| March	|__| September
|__| April	|__| October
|__| May	|__| November
|__| June	|__| December

TECH19

Sociodemographic questions.
Self-administered (Offsite - tech-administered)

|__|__|__| **Technician Number** for OFFSITE visit ONLY

What is your current marital status? *(check ONE)*	
☐ 1	single/never married
☐ 2	married/living as married/living with partner
☐ 3	separated
☐ 4	divorced
☐ 5	widowed
☐ 9	prefer not to answer

Please choose which of the following best describes your current employment status? *(check ONE)*	
☐ 0	homemaker, not working outside the home
☐ 1	employed (or self-employed) full time
☐ 2	employed (or self-employed) part time
☐ 3	employed, but on leave for health reasons
☐ 4	employed, but temporarily away from my job
☐ 5	unemployed or laid off
☐ 6	retired from my usual occupation and not working
☐ 7	retired from my usual occupation but working for pay
☐ 8	retired from my usual occupation but volunteering
☐ 9	prefer not to answer
☐ 10	unemployed due to disability

What is your current occupation?

Write in _____

|__|__| **Using the occupation coding sheet choose the code that best describes your occupation.**

☐ **YES**	☐ **NO**	**Do you have some form of health insurance?**
☐ **YES**	☐ **NO**	**Do you have prescription drug coverage?**

TECH20

Medication Questionnaire

Self-administered (Offsite - tech-administered)

☐	**Check if NO medication taken and leave the page BLANK**

This questionnaire refers to medication recommended to you by your doctor or health care provider. For the question below, please check YES or NO

☐ **YES**	☐ **NO**	**Did you ever forget to take your medicine?**
☐ **YES**	☐ **NO**	**Are you careless at times about taking your medicine?**
☐ **YES**	☐ **NO**	**When you feel better do you stop taking your medicine?**
☐ **YES**	☐ **NO**	**Sometimes if you feel worse when you take the medicine, do you stop taking it?**

How often do you forget to take your medicine? *(Circle only ONE)*	
1.	Never
2.	More than once per week
3	Once per week
4.	More than once per month
5.	Once per month
6.	Less than once per month.

TECH21

SF-12® Health Survey (Standard)
Self-administered

This questionnaire asks for your views about your health. This information will help you keep track of how you feel and how well you are able to do your usual activities.

Please answer every question by marking one box. If you are unsure about how to answer a question, please give the best answer you can.

---

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐	☐	☐	☐	☐

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
2. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐	☐	☐
3. Climbing **several** flights of stairs	☐	☐	☐

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Yes	No
4. Accomplished less than you would like	☐	☐
5. Were limited in the **kind** of work or other activities	☐	☐

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	Yes	No
6. Accomplished less than you would like	☐	☐
7. Didn't do work or other activities as **carefully** as usual	☐	☐

TECH22

SF-12® Health Survey (Standard)
Self-administered

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐	☐	☐	☐	☐

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks...

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
9. Have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
10. Did you have a lot of energy?	☐	☐	☐	☐	☐	☐
11. Have you felt downhearted and blue?	☐	☐	☐	☐	☐	☐

12. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

TECH23

Sleep Questionnaire. Part 1
Self-administered

What is the chance that you would doze off or fall asleep (not just "feel tired") in each of the following situations? (Circle one response for each situation. If you are never or rarely in the situation, please give your best guess for that situation)

	None	Slight	Moderate	High
Sitting and reading	**0**	**1**	**2**	**3**
Watching TV	**0**	**1**	**2**	**3**
Sitting inactive in a public place (such as theater or a meeting)	**0**	**1**	**2**	**3**
Riding as a passenger in a car for an hour without a break	**0**	**1**	**2**	**3**
Lying down to rest in the afternoon when circumstances permit	**0**	**1**	**2**	**3**
Sitting and talking to someone	**0**	**1**	**2**	**3**
Sitting quietly after a lunch without alcohol	**0**	**1**	**2**	**3**
In a car, while stopped in traffic for a few minutes	**0**	**1**	**2**	**3**

TECH24

Sleep Questionnaire Part 2
Self-administered

During the past month...	
when have you usually gone to bed at night?	|__|__|:|__|__| |__| |__| hours : min AM PM
how long has it usually taken you to fall asleep each night?	|__|__|:|__|__| hours : min
when have you usually gotten up in the morning?	|__|__|:|__|__| |__| |__| hours : min AM PM
how much *actual sleep* did you get at night?	|__|__|:|__|__| hours : min

When you experience the following situations, how likely is it for you to have difficulty sleeping?
Circle an answer even if you have not experienced these situations recently.

	Not likely	Somewhat likely	Moderately likely	Very likely
Before an important meeting the next day	**0**	**1**	**2**	**3**
After a stressful experience during the day	**0**	**1**	**2**	**3**
After a stressful experience in the evening	**0**	**1**	**2**	**3**
After getting bad news during the day	**0**	**1**	**2**	**3**
After watching a frightening movie or TV show	**0**	**1**	**2**	**3**
After having a bad day at work	**0**	**1**	**2**	**3**
After an argument	**0**	**1**	**2**	**3**
Before having to speak in public	**0**	**1**	**2**	**3**
Before going on vacation the next day	**0**	**1**	**2**	**3**

|__|	**On average over the past year, how often do you snore?**	0= Never 1= Less than 1 night per week 2= 1-2 nights per week 3= 3-5 nights per week 4= 6-7 nights per week 9= Don't know
|__|	**On average over the past year, how often do you have times when you stop breathing while you are asleep?**	

TECH25

Sleep Questionnaire Part 3
Self-administered

One hears about "morning" and "evening" types of people. Which ONE of these types do you consider yourself to be? Please **check ONE box** below

☐ 1	**Definitely a "morning" type**
☐ 2	**Rather more a "morning" than an "evening" type**
☐ 3	**Neither a "morning" nor an "evening" type**
☐ 4	**Rather more an "evening" than a "morning" type**
☐ 5	**Definitely an "evening" type**

|__|__| hour **|__|__| min** **☐ AM** **☐ PM**	**Considering only your "feeling best" rhythm, at what time would you get up if you were entirely free to plan your day?**
|__|__| hour **|__|__| min** **☐ AM** **☐ PM**	**Considering only your "feeling best" rhythm, at what time would you go to bed if you were entirely free to plan your evening?**

Have you ever been told by a doctor or other health professional that you have any of the following?

(Circle one response for each item)	No	Yes	Don't know
Sleep apnea or obstructive sleep apnea	**0**	**1**	**9**
if yes, fill ☞ Do you wear a mask ("CPAP") or other device at night to treat sleep apnea?	**0**	**1**	**9**
Insomnia	**0**	**1**	**9**
Restless legs	**0**	**1**	**9**

TECH26

Framingham Study Vascular Function Participant Worksheet

(circle on)e			**Keyer 1:** _____	**Keyer 2:** _____
0	**1**	**9**	**Have you had any caffeinated drinks in the last 6 hours?** (0=No, 1=Yes, 9=Unk.)	
		if yes fill ☞	|__|__| **How many cups?** (99=Unk.)	
0	**1**	**9**	**Have you eaten anything else including a fat free cereal bar this morning?** (0=No, 1=Yes, 9=Unknown)	
0	**1**	**9**	**Have you smoked cigarettes in the last 6 hours?** (0=No, 1=Yes, 9=Unk.)	
		if yes fill ☞	|__|__|:|__|__| **If yes, how many hours and minutes since your last cigarette?** (99:99=Unk.)	

Tonometry

|__|__|/|__|__|/|__|__|__|__|		**Date of Tonometry scan?** (99/99/9999=Unk.)
|__|__|__|		**Tonometry Sonographer ID**
|__|__|__|-|__|__|__|		**Tonometry CD number**
0	**1**	**Was Tonometry done?** 0= No, test was not attempted or done 1= Yes, test was done, even if all 4 pulses could not be acquired and recorded.
	If no fill ☞	**Reason why: (***Check all that apply)*
		☐ Subject refusal
		☐ Subject discomfort
		☐ Time constraint
		☐ Equipment problem, specify _____
		☐ Other, specify _____

Not for Data Entry. (below)

Distances:

_____Carotid(mm) _____Brachial(mm) _____Radial(mm) _____Femoral(mm)

Date of exam

_____/_____/_____

Framingham Heart Study

Summary Sheet to Personal Physician

Blood Pressure	First Reading	Second Reading
Systolic		
Diastolic		

ECG Diagnosis _____

_____

Summary of Findings_____

☐ 1. **No history or physical exam findings to suggest cardiovascular disease**
(check box if applicable)

_____

_____

_____

_____

_____

_____

_____

_____
Examining Physician

The Heart Study Clinic examination is not comprehensive and does not take the place of a routine physical examination.

Referral Tracking

☐ Check here if whole page is blank. Reason why_____

|__| **Was further medical evaluation recommended for this participant?** 0=No, 1=Yes, 9=Unk.

if yes fill below

RESULT	Reason for further evaluation: *(Check ALL that apply)*.	
☐	**Blood Pressure** **result** _____/_____ mmHg **result** _____/_____ mmHg	SBP or DBP Phone call ≥ 200 or ≥110 Expedite ≥ 180 or ≥100 Elevated ≥ 140 or ≥90
	Write in abnormality	
☐	**Abnormal laboratory result**_____	
☐	**ECG abnormality** _____	
☐	**Clinic Physician** *identified medical problem*_____	
☐	**Other** _____	

Method used to inform participant of need for further medical evaluation
(Check ALL that apply)

☐	**Face-to-face in clinic**
☐	**Phone call**
☐	**Result letter**
☐	**Other**

Method used to inform participant's personal physician of need for further medical evaluation *(check ALL that apply)*

☐	**Phone call**
☐	**Result letter mailed**
☐	**Result letter FAX'd** *(inform staff if Fax needed)*
☐	**Other**

Date referral made: _____/____/_____

ID number of person completing the referral: _____

Notes documenting conversation with participant or participant's personal physician:_____

Medical History—Hospitalizations, ER Visits, MD Visits

OFFSITE EXAM **DATE** _____

DATE of last exam *«Lexam»*

DATE of last medical history update *«Lupdate»*

Health Care	
Since your last exam or medical history update	
|__|__|__|	**1st Examiner ID** _____ 1st Examiner Name
|_1_|	**1st Examiner Prefix** (0=MD, 1=Tech. for OFFSITE visit)
|__|	**Hospitalizations** (*not just E.R.*) (0=No; 1=yes, hospitalization, 2=yes, more than 1 hospitalization, 9=Unk.)
|__|	**E.R. Visits** (0=No, 1=Yes, 1 visit, 2=Yes, more than 1 visit, 9=Unk.)
|__|	**Day Surgery** (0=No, 1=Yes, 9=Unk.)
|__|	**Major illness with visit to doctor** (0=No, 1=Yes, 1 visit, 2=Yes, more than 1 visit; 9=Unk.)
|__|	**Check up by doctor or other health care provider?** (0=No, 1=Yes, 9=Unk.)
|__|	**Have you had a fever or infection in <u>past two weeks</u>?** (0=No, 1=Yes, 9=Unk.)
|__|__| |__|__| |__|__|__|__| MM DD YYYY	**Date of this FHS exam** *(Today's date - See above)*

Medical Encounter	Month/Year (of last visit)	Name & Address of Hospital or Office	Doctor

MD01

Medical History—Medications

|__|	**Do you take aspirin regularly?** (0=No, 1=Yes, 9=Unk.)	
If yes, fill☞	|__|__|	**Number of aspirins taken regularly** (99=Unk.)	
	|__|	**Frequency per** (1=Day, 2=Week 3=Month, 4=Year, 9=Unk.)	
	|__|__|__|	**Usual dose** (write in mgs, 999=Unk.)	Examples: 081=baby,160=half dose, 250= like in Excedrin, 325=usual dose, 500=extra strength

Since your last exam

(0=No, 1=Yes, 9=Unk.)

|__| **Have you been told by doctor you have high blood pressure or hypertension?**
|__| **Have you taken medication for high blood pressure or hypertension?**
|__| **Have you been told by doctor you have high blood cholesterol or high triglycerides?**
|__| **Have you taken medication for high blood cholesterol or high triglycerides?**
|__| **Have you been told by doctor you have high blood sugar or diabetes?**
|__| **Have you taken medication for high blood sugar or diabetes?**
|__| **Have you taken medication for cardiovascular disease? (for example angina/chest pain, heart failure, atrial fibrillation/heart rhythm abnormality, stroke, leg pain when walking, peripheral artery disease)**

MD02

Medical History – Prescription and Non-Prescription Medications

Copy the name of medicine, the strength including units, and the total number of doses per day/week/month/year. Include vitamins and minerals.

|__| **Medication bag with medications or bottles/packs brought to exam?** (0=No 1=Yes)

*****List medications taken regularly in past month/ongoing medications*****
Code ASPIRIN ONLY on screen MD02.

☐ **Check if NO medication taken**

Medication Name (Print first 20 letters)	**Strength** (include mg, IU, etc)	**Route** 1= oral, 2=topical, 3=injection, 4=inhaled, 5=drops,6=nasal 88=other	**Number per** (circle one) #	**Number per** (circle one) day/week/month/year 1 / 2 / 3 / 4	**PRN** 0=no, 1=yes,9=Unk.	**Check if OTC med**
EXAMPLE: SAMPLE DRUG NAME	100 mg	1	1	D W M Y	0	☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐

Continue on the next page→

Medical History – Prescription and Non-Prescription Medications

Medication Name (Print first 20 letters)	Strength (include mg, IU, etc)	Route 1= oral, 2=topical, 3=injection, 4=inhaled, 5=drops,6=nasal 88=other	Number per (circle one) #	Number per (circle one) day/week/month/year 1 / 2 / 3 / 4	PRN 0=no, 1=yes, 9-Unk	Check if OTC med.
EXAMPLE: SAMPLE DRUG NAME	100 mg	1	1	D W M Y	0	☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
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				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐

MD04

Medical History–Female Reproductive History Part 1

☐ **Check here if Male Participant (and skip to Smoking Questions page 48/MD08)**

«Meno» **Check here if definitely menopausal (and skip to Female History Part 3 page 47) (*preloaded from previous exam)***

|__| **Since your last exam have you taken or used birth control pills, shots, or hormone implants for birth control or medical indications (not post menopausal hormone replacement)?** (0=no, 1=yes, now, 2=yes, not now, 9=Unk.)

|__| **Have you been pregnant since last exam?** (0=No, 1=Yes, 9=Unk.)

If yes, fill☞

|__|__| **Number of pregnancies?**

|__|__| **Number of live births?**

fill in number

|__| **During any of these pregnancies, were you told you had high blood pressure or hypertension?**

|__| **During any of these pregnancies, were you told you had eclampsia, pre-eclampsia (toxemia)?**

|__| **During any of these pregnancies, were you told you had high blood sugar or diabetes?**

0=No
1=Yes
9=Unk.

MD05

Medical History–Female Reproductive History Part 2

What is the best way to describe your periods? *Check the BEST answer* – ***only one***

☐	**Not stopped**
☐	**Periods stopped due to pregnancy, breastfeeding, or hormonal contraceptive** (for example: depo-provera, progestin releasing IUD, extended release birth control pill)
☐	**Periods stopped due to low body weight, heavy exercise, or due to medication or health condition such as thyroid disease, pituitary tumor, hormone imbalance, stress,**
	Write in cause _____
☐	**Periods stopped for less than 1 year (perimenopausal)**
	|__|__| **Number of months since last period** 99=Unk.
☐	**Periods stopped for 1 year or more**
☐	**Periods stopped, but now have periods induced by hormones.**
	|__|__| **Number months stopped before hormones started.** 99=Unk.

|__|__|*|__|__|*|__|__|__|__| month day year	**When was the first day of your last menstrual period?** 99/99/9999=Unk. **88/88/8888**= periods stopped for more than 1 year or using postmenopausal hormones *If periods stopped due to pregnancy, breastfeeding, hormonal contraception or health condition code date of last menstrual period*
|__|__|	**Age when periods stopped** (00=not stopped, 99=Unk.) *If periods now induced by hormones, code age when periods naturally stopped.* *If periods stopped due to pregnancy, breastfeeding, or hormonal contraception code as 0=not stopped*
|__|	**Was your menopause natural or the result of surgery, chemotherapy, or radiation?** (0=still menstruating, 1=natural, 2=surgical, 3=chemo/radiation, 4=other, 9=Unk.) *If periods stopped due to pregnancy, breast feeding, or hormonal contraception code as 0=still menstruating*

MD06

Medical History–Female Reproductive History Part 3

Surgery History

|__| **Since your last exam have you had a hysterectomy (uterus/womb removed)?** (0=No, 1=Yes, 9=Unk.)

If yes, fill☞

|__|__| **Age at hysterectomy?** 99=Unk.

|__|__|*|__|__|__|__| **Date of surgery** (mo/yr) 99/9999=Unk.

|__| **Since last exam have you had an operation to remove one or both of your ovaries?** (0=No, 1=Yes, 9=Unk.)

If yes, fill☞

|__|__| **Age when ovaries removed?** *If more than one surgery, use age <u>at last surgery</u>* 99=Unk.

Number of ovaries removed? (check one)

☐	☐	☐	☐
1=one ovary	2=two ovaries	3= unknown number of ovaries	4= part of an ovary

|__| **Have you since your last exam taken hormone replacement therapy (estrogen/progesterone) or a selective estrogen receptor modulator (such as evista or raloxifene)?** (0=No, 1=Yes, now, 2=Yes, not now, 9=Unk.)

Comments_____

_____

_____

_____

_____

MD07

Medical History--Smoking

Cigarettes

|__| **Since your last exam have you smoked cigarettes regularly?** (0=No, 1=Yes, 9=Unk.)

If yes, fill☞

|__| **Have you smoked cigarettes regularly in the last year?** *(No means less than 1 cigarette a day for 1 year.)* (0=No, 1=Yes, 9=Unk.)

|__| **Do you now smoke cigarettes (as of 1 month ago)?** (0=No, 1=Yes, 9=Unk.)

|__|__| **How many cigarettes do you smoke per day now?** (99=Unk.)

Questions below refer to "since your last exam"

|__|__| **During the time you were smoking, on average how many cigarettes per day did you smoke** (99=Unk.)

|__|__| **If you have stopped smoking cigarettes completely, how old were you when you stopped?** (Age stopped, 00=Not stopped, 99=Unk.)

|__| **When you were smoking, did you ever stop smoking for >6 months?** (0=No, 1=Yes, 9=Unk.)

If yes, fill☞ |__|__| **For how many years in total did you stop smoking cigarettes** (01=6 months – 1 year, 99=Unk.)

Pipes or Cigars

|__| **Since your last exam, have you regularly smoked a pipe or cigar?**

If yes, fill☞ |__| Do you smoke a pipe or cigar now

0=No
1=Yes
9=Unk.

Comments:_____

_____

_____

MD08

Medical History –Alcohol Consumption

Now I will ask you questions regarding your alcohol use.

Do you drink any of the following beverages at least once a month? (0=No, 1=Yes, 9=Unk.)	
|__|	Beer
|__|	Wine
|__|	Liquor/spirits

If yes, what is your average number of servings in a typical week or month over past year? (999=Unk.)

Code alcohol intake as EITHER weekly OR monthly as appropriate.

Beverage	Per week	Per month
Beer (12oz bottle, glass, can)	|__|__|__|	|__|__|__|
Wine (red or white, 4oz glass)	|__|__|__|	|__|__|__|
Liquor/spirits (1oz cocktail/highball)	|__|__|__|	|__|__|__|

|__|__|__| **At what age did you stop drinking alcohol?** (0= Not stopped, 888=Never drank, 999=Unk.)

|__|	**Over the past year, on average on how many days per week did you drink an alcoholic beverage of any type?** (0=No drinks, 1=1or less, 9=Unk.)
|__|__|	**Over the past year, on a typical day when you drink, how many drinks do you have?** (0=No drinks, 1=1or less, 99=Unk.)
|__|__|	**What was the maximum number of drinks you had in 24 hr. period during the past month?** (0=No drinks, 1=1or less, 99=Unk.)
|__|	**Since last exam has there been a time when you drank 5 or more alcoholic drinks of any kind almost daily?** (0=No, 1=Yes, 9=Unk.)

☐ **Check if over past year participant drinks less than one alcoholic drink of any type per month.**

Comments:_____

_____

_____

MD09

Medical History—Respiratory Symptoms Part I

Cough (0=No, 1=Yes, 9=Unk.)

|__| **Do you usually have a cough?** *(Exclude clearing of the throat)*

|__| **Do you usually have a cough at all on getting up or first thing in the morning?**

If **YES** to **either** question above **answer** the following:

|__| **Do you cough like this on most days for three consecutive months or more during the past year?**

|__|__| **How many years have you had this cough?** *(# of years)* 1=1 year or less 99=Unk.

Phlegm (0=No, 1=Yes, 9=Unk.)

|__| **Do you usually bring up phlegm from your chest?**

|__| **Do you usually bring up phlegm at all on getting up or first thing in the morning?**

If **YES** to **either** question above **answer** the following:

|__| **Do you bring up phlegm from your chest on most days for three consecutive months or more during the year?**

|__|__| **How many years have you had trouble with phlegm?** *(# of years)* 1=1 year or less 99=Unk.

Wheeze (0=No, 1=Yes, 9=Unk.)

In the past 12 months…

|__| **Have you had wheezing or whistling in your chest at any time?**

if yes, fill all☞

|__| **How often have you had this wheezing or whistling?**
0=Not at all 1=MOST days or nights 2=A few days or nights a WEEK
3=A few days or nights a MONTH 4=A few days or nights a YEAR 9=Unk.

|__| **Have you had this wheezing or whistling in the chest when you had a cold?**

|__| **Have you had this wheezing or whistling in the chest apart from colds?**

|__| **Have you had an attack of wheezing or whistling in the chest that had made you feel short of breath?**

MD10

Medical History—Respiratory Symptoms Part II

Nocturnal chest symptoms (0=No, 1=Yes, 9=Unk.)

In the past 12 months…

|__| **Have you been awakened by shortness of breath?**

|__| **Have you been awakened by a wheezing/whistling in your chest?**

|__| **Have you been awakened by coughing?**

if yes, fill all☞

|__| **How often have you been awakened by coughing?**
0=Not at all 1=MOST days or nights 2=A few days or nights a WEEK
3=A few days or nights a MONTH 4=A few days or nights a YEAR 9=Unk.

Shortness of breath (0=No, 1=Yes, 9=Unk.)

Since your last exam…

|__| **Are you troubled by shortness of breath when hurrying on level ground or walking up a slight hill?**

if yes, fill all☞

|__| **Do you have to walk slower than people of your age on level ground because of shortness of breath?**

|__| **Do you have to stop for breath when walking at your own pace on level ground?**

|__| **Do you have to stop for breath after walking 100 yards (or after a few minutes) on level ground?**

|__| **Do you/have you needed to sleep on two or more pillows to help you breathe (Orthopnea)?**

|__| **Have you since last exam had swelling in both your ankles (ankle edema)?**

|__| **Have you been told by your doctor you had heart failure or congestive heart failure?**

if yes, fill☞

Name of doctor _____

Date of visit |__|__|*|__|__|*|__|__|__|__| 99/99/9999=Unk.

|__| **Have you been hospitalized for heart failure?** *(Provide details on MD01-Health Care page 41)*

CHF First Examiner Opinion

|__| **First examiner believes CHF** 0=No,1=Yes 2=Maybe, 9=Unk.

Comments_____

_____

_____

MD11

Physical Exam—Blood Pressure

Physician Blood Pressure First reading	
Systolic	**BP cuff size**
|__|__|__| to nearest 2 mm Hg	|__| 0=pedi,1=reg.adult, 2=large adult, 3= thigh, 9=Unk.
Diastolic	**Protocol modification**
|__|__|__| to nearest 2 mm Hg	|__| 0=No, 1=Yes, 9=Unk.

Comments for Protocol modification_____

_____

_____

_____

MD12

Medical History—Chest pain

|__| **Since your last exam have you experienced any chest discomfort?** *(please provide narrative comments in addition to completing the appropriate boxes)*

0=No, 1=Yes, 2=Maybe, 9=Unk.

if yes, fill ☞ and below

|__| **Chest discomfort with exertion or excitement**

|__| **Chest discomfort when quiet or resting**

Chest Discomfort Characteristics

|__|__|*|__|__|__|__|	**Date of onset** *(mo/yr)*	99/9999=Unk.
|__|__|__|	**Usual duration** *(minutes)*	1=1 min or less, 900=15 hrs or more, 999=Unk.
|__|__|__|	**Longest duration** *(minutes)*	1=1 min or less, 900=15 hrs or more, 999=Unk.
|__|	**Location**	0=No, 1=Central sternum and upper chest, 2=L Up Quadrant, 3=L Lower ribcage, 4=R Chest, 5=Other, 6=Combination, 9=Unk.
|__|	**Radiation**	0=No, 1=Left shoulder or L arm, 2=Neck, 3=R shoulder or arm, 4=Back, 5=Abdomen, 6=Other, 7=Combination, 9=Unk.
|__|__|__|	**Number of episodes of chest pain in past month**	999=Unk.
|__|__|__|	**Number of episodes of chest pain in past year.**	999=Unk.
|__|	**Type**	1=Pressure, heavy, vise, 2=Sharp, 3=Dull, 4=Other, 9=Unk.

|__|	**Relief by Nitroglycerin in <15 minutes**	0=No,
|__|	**Relief by Rest in <15 minutes**	1=Yes,
|__|	**Relief Spontaneously in <15 minutes**	*8=Not tried*
|__|	**Relief by Other cause in <15 minutes**	9=Unk.

|__| **Since your last exam have you been told by a doctor you had a heart attack or myocardial infarction?** 0=No, 1=Yes, 2=Maybe, 9=Unk.

if yes, fill l ☞

Name of doctor _____

Date of visit |__|__|*|__|__|*|__|__|__|__| 99/99/9999=Unk.

CHD First Examiner Opinions

0=No, 1=Yes, 2=Maybe, 8=No revasculation 9=Unk.

|__| **Angina pectoris**

if yes,fill ☞ |__| **Angina pectoris since revascularization procedure**

|__| **Coronary insufficiency**

|__| **Myocardial infarct**

Comments_____

_____

_____

MD13

Medical History—Atrial Fibrillation/Syncope

Since your last exam or medical history update…

|__| **Have you been told you have/had atrial fibrillation?** 0=No, 1=Yes, 2=Maybe, 9=Unk.

if yes,fill☞ |__|__|*|__|__|*|__|__|__|__| **Date of first episode** 99/99/9999=Unk.

|__| **ER/hospitalized or saw M.D.** 0=No, 1=Hosp/ER, 2=Saw M.D., 9=Unk.

if yes, fill☞ _____ **Name of the Hospital** (write Unk. if unknown)

_____ **Name of M.D.** (write Unk. if unknown)

|__| **Do you have a family history of a heart rhythm problem called atrial fibrillation?** 0=No, 1=Yes, 9=Unk

if yes,fill☞	**Mother**	**Father**	**Siblings**	**Children**	0=No, 1=Yes, 9=Unk.
	|__|	|__|	|__|	|__|	

|__| **Have you fainted or lost consciousness?** 0=No, 1=Yes, 2=Maybe, 9=Unk..
(If event immediately preceded by head injury or accident code 0=No)

if yes, fill all☞

|__|__|__| **Number of episodes in the past two years** 999=Unk.

|__|__|*|__|__|__|__| **Date of first episode** *(mo/yr)* 99/9999=Unk.

|__|__|__| **Usual duration of loss of consciousness** *(minutes)* 999=Unk.,1=1 min or less

|__| **Did you have any injury caused by the event?** 0=No, 1=Yes, 2=Maybe, 9=Unk.

|__| **ER/hospitalized or saw M.D.** 0=No, 1=Hosp/ER, 2=Saw M.D., 9=Unk.

if yes, fill☞ _____ **Name of the Hospital** (write Unk.. if unknown)

_____ **Name of M.D.** (write Unk. if unknown)

|__| **Have you had a head injury with loss of consciousness?** 0=No, 1=Yes, 2=Maybe, 9=Unk.

if yes, fill☞ |__|__| * |__|__| * |__|__|__|__| **Date of serious head injury with loss of consciousness** 99/99/9999=Unk.

|__| **Have you had a seizure**? 0=No, 1=Yes, 2=Maybe, 9=Unk.

if yes,fill☞ |__|__| * |__|__| * |__|__|__|__| **Date of most recent seizure** 99/99/9999=Unk.

|__| **Are you being treated for a seizure disorder?** 0=No, 1=Yes, 2=Maybe, 9=Unk.

Syncope First Examiner Opinion

|__| **Syncope** (0=No, 1=Yes, 2=Maybe, 3=Presyncope, 9=Unk.) *needs second opinion*

if yes, fill☞

|__| **Cardiac syncope**

|__| **Vasovagal syncope**

|__| **Other-Specify:** _____

0=No, 1=Yes, 2=Maybe, 9=Unk.

Comments:_____

_____**MD14**

Medical History—Cerebrovascular Diseases

Since your last exam or medical history update have you had…

|__|	**Sudden muscular weakness**	0=No,
|__|	**Sudden speech difficulty**	
|__|	**Sudden visual defect**	1=Yes,
|__|	**Sudden double vision**	
|__|	**Sudden loss of vision in one eye**	2=Maybe,
|__|	**Sudden numbness, tingling**	9=Unk.
if yes, fill ☞	|__|	**Numbness and tingling is positional**	
|__|	**Head CT scan *OTHER THAN FOR THE FHS***	0=No,1=Yes, 2= Maybe,9=Unk.
if yes, fill ☞	|__|__| * |__|__| * |__|__|__|__|	**Date**	99/99/9999=Unk.
	_____	**Place**	
|__|	**Head MRI scan *OTHER THAN FOR THE FHS***	0=No,1=Yes, 2= Maybe,9=Unk.
if yes, fill ☞	|__|__| * |__|__| * |__|__|__|__|	**Date**	99/99/9999=Unk.
	_____	**Place**	
|__|	**Seen by neurologist** *(write in who and when below)* _____	
|__|	**Have you been told by a doctor you had a stroke or TIA** (transient ischemic attack, mini-stroke)**?**	0=No,
|__|	**Have you been told by a doctor you have Parkinson Disease?**	1=Yes,
|__|	**Have you been told by a doctor you have memory problems, dementia or Alzheimer's disease?**	2=Maybe,
|__|	**Do you feel or do other people think that you have memory problems that prevent you from doing things you've done in the past?**	9=Unk.
|__|	**Do you feel like your memory is becoming worse?**	

Cerebrovascular Disease First Examiner Opinion

|__|	**TIA or stroke took place**	0=No, 1=Yes,2=Maybe, 9=Unk.
if yes or maybe fill ☞	|__|__|*|__|__|__|__|	**Date** (*mo/yr*, 99/9999=Unk.) **Observed by**_____
	|__|__|*|__|__|*|__|__|	**Duration** (*use format days/hours/mins*, 99/99/99=Unk.)
	|__|	**Hospitalized or saw M.D.** (0=No, 1=Hosp.,2=Saw M.D, 9=Unk.) Name_____ Address_____

Comments_____

Medical History--Venous and Peripheral Arterial Disease

Venous Disease

Since your last exam or medical history update have you had…

|__| **Deep Vein Thrombosis - DVT** (blood clots in legs or arms)

|__| **Pulmonary Embolus – PE** (blood clot in lungs)

0=No,1=Yes, 2=Maybe, 9=Unk.

Peripheral Arterial Disease

Since your last exam have you had…

|__| **Do you get discomfort in either leg on walking?** (0=No, 1=Yes, 9=Unk.)

if yes, fill ☞

|__| **Does this discomfort ever begin when you are standing still or sitting?** (0=no, 1=yes, 9=Unk.)

|__|__| **When walking at an ordinary pace on level ground, how many city blocks until symptoms develop** (1=1 block or less, 99=Unk.) *where 10 blocks=1 mile, code as no if more than 98 blocks required to develop symptoms*

Left	Right	Claudication symptoms	0=No, 1=Yes, 9=Unk.
|__|	|__|	**Discomfort in calf while walking**
|__|	|__|	**Discomfort in lower extremity (not calf) while walking** Write in site of discomfort_____
	|__|	**Occurs with first steps (code worse leg)**
	|__|	**Do you get the discomfort when you walk up hill or hurry?**
	|__|	**Does the discomfort ever disappear while you are still walking?**
	|__|	**What do you do if you get discomfort when you are walking?** (1=stop, 2=slow down, 3=continue at same pace, 9=Ukn.)
	|__|__|__|	**Time for discomfort to be relieved by stopping (minutes)** (000=No relief with stopping, 999=Unk.)
	|__|__|	**Number of days/month of lower limb discomfort** (1=1 day/month or less, 99=Unk.)

|__| **Since your last exam have you been told by a doctor you have intermittent claudication or peripheral artery disease?** (0=No, 1=Yes, 9=Unk.)

if yes, fill ☞

Name of doctor _____

Date of visit |__|__|*|__|__|*|__|__|__|__| 99/99/9999=Unk.

|__| **Since your last exam have you been told by a doctor you have spinal stenosis?** (0=No, 1=Yes, 9=Unk.)

Intermittent Claudication First Examiner Opinion

|__| **Intermittent Claudication** 0=No, 1=Yes, 2=Maybe, 9=Unk.

Comments

_____

_____

MD16

Medical History-- CVD Procedures

Since your last exam or medical history update did you have any of the following cardiovascular procedures?

0=No, 1=Yes 2=Maybe, 9=Unk.	Cardiovascular Procedures *(if procedure was repeated code only first and provide narrative)*
|__|	**Heart Valvular Surgery**
if yes fill☞	|__|__|__|__| Year done (9999=Unk.)
|__|	**Exercise Tolerance Test**
if yes fill☞	|__|__|__|__| Year done (9999=Unk.)
|__|	**Coronary arteriogram**
if yes fill ☞	|__|__|__|__| Year done (9999=Unk.)
|__|	**Coronary artery angioplasty or stent**
if yes fill☞	|__|__|__|__| Year done (9999=Unk.)
|__|	**Coronary bypass surgery**
if yes fill☞	|__|__|__|__| Year done (9999=Unk.)
|__|	**Permanent pacemaker insertion**
if yes fill ☞	|__|__|__|__| Year done (9999=Unk.)
|__|	**AICD**
if yes fill ☞	|__|__|__|__| Year done (9999=Unk.)
|__|	**Carotid artery surgery or stent**
if yes fill ☞	|__|__|__|__| Year done (9999=Unk.)
|__|	**Thoracic aorta surgery**
if yes fill ☞	|__|__|__|__| Year done (9999=Unk.)
|__|	**Abdominal aorta surgery**
if yes fill ☞	|__|__|__|__| Year done (9999=Unk.)
|__|	**Femoral or lower extremity surgery**
if yes fill ☞	|__|__|__|__| Year done (9999=Unk.)
|__|	**Lower extremity amputation**
if yes fill ☞	|__|__|__|__| Year done (9999=Unk.)
|__|	**Other Cardiovascular Procedure (write in below)**
if yes fill ☞	|__|__|__|__| Year done (9999=Unk.) Description_____

Write in *other procedures, year done, and location if more than one.*

Comments:_____

Physical Exam—Blood Pressure

Physician Blood Pressure Second reading	
Systolic	**BP cuff size**
|__|__|__| to nearest 2 mm Hg	|__| 0=pedi,1=reg.adult, 2=large adult, 3= thigh, 9=Unk.
Diastolic	**Protocol modification**
|__|__|__| to nearest 2 mm Hg	|__| 0=No, 1=Yes, 9=Unk.

Comments for Protocol modification_____

_____

_____

_____

_____

History of Kidney Disease		
|__|	**Have you had a kidney stone in the past 10 years?** (0=No, 1=Yes, 9=Unk.)	
if yes, fill☞ |__|	**ER/hospitalized or saw M.D.** **(**0=No, 1=Hosp/ER, 2=Saw M.D., 9=Unk.)	
if yes, fill☞	_____	**Name of the Hospital** (write Unk.. if unknown)
	_____	**Name of M.D.** (write Unk. if unknown)

MD18

Cancer Site or Type

|__| **Since your last exam or medical history update have you had a cancer or a tumor?**
(0=No and skip to next page MD20; If 1=Yes, 2=Maybe, 9=Unk. please continue)

Check ALL that apply	Site of Cancer or Tumor	Year First Diagnosed	Cancer	Maybe cancer	Benign	Name Diagnosing M.D.	City/State of M.D.
			Check ONE				
			1	2	3		
☐	**Esophagus**		☐	☐	☐		
☐	**Stomach**		☐	☐	☐		
☐	**Colon**		☐	☐	☐		
☐	**Rectum**		☐	☐	☐		
☐	**Pancreas**		☐	☐	☐		
☐	**Larynx**		☐	☐	☐		
☐	**Trachea/Bronchus/ Lung**		☐	☐	☐		
☐	**Leukemia**		☐	☐	☐		
☐	**Skin**		☐	☐	☐		
☐	**Breast**		☐	☐	☐		
☐	**Cervix/Uterus**		☐	☐	☐		
☐	**Ovary**		☐	☐	☐		
☐	**Prostate**		☐	☐	☐		
☐	**Bladder**		☐	☐	☐		
☐	**Kidney**		☐	☐	☐		
☐	**Brain**		☐	☐	☐		
☐	**Lymphoma**		☐	☐	☐		
☐	**Other/Unk.** _____		☐	☐	☐		

|__| **Diagnostic biopsy done**? (0=No, 1=Yes, 9=Unk.)

if yes fill ☞ ___ - ___ -_____ **Date** **Location of biopsy**_____

Hosp./office name_____ **Address (city/state)**_____

Comment *(If participant has more details concerning tissue diagnosis, other hospitalization, procedures, and treatments)*

_____

_____

MD19

Physical Exam—Respiratory, Heart, Abdomen

OFFSITE VISIT – leave page BLANK

Respiratory		
|__|	**Wheezing on auscultation**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**Rales**	
|__|	**Abnormal breath sounds**	

Heart		
|__|	**S3 Gallop**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**S4 Gallop**	
|__|	**Systolic Click**	
|__|	**Neck vein distention at 90 degrees** (sitting upright)	

|__| if yes, fill below	**Systolic murmur(s)**			0=No, 1=Yes, 2=Maybe, 9=Unk.
Murmur Location	**Grade** 0=No sound 1 to 6 for grade of sound heard 9=Unk.	**Type** 0=None 1=Ejection 2=Regurgitant 3=Other 9=Unk.	**Radiation** 0=None 1=Axilla 2=Neck 3=Back 4=Rt. chest 9=Unk.	**Origin** 0=None, indet. 1=Mitral 2=Aortic 3=Tricuspid 4=Pulm 9=Ukn.
Apex	|__|	|__|	|__|	|__|
Left Sternum	|__|	|__|	|__|	|__|
Base	|__|	|__|	|__|	|__|

|__| if yes, fill ☞	**Diastolic murmur(s)**	0=No, 1=Yes, 2=Maybe, 9=Unk.
	|__|	**Valve of origin for diastolic murmur(s)** (1=Mitral, 2=Aortic, 3=Both, 4=Other, 8=N/A, 9=Unk)

Abdominal Abnormalities		
|__|	**Liver enlarged**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**Surgical scar**	
|__|	**Abdominal aneurysm**	
|__|	**Abdominal bruit**	

Comments _____

_____

_____

MD20

Physical Exam--Peripheral Vessels—Veins and Arterial pulses

OFFSITE VISIT – leave page BLANK

Left	Right	Lower Extremity Abnormalities
|__|	|__|	**Stem varicose veins** *(Do not code reticular or spider varicosities)* (0=No abnormality 1=Yes 9=Unk.)
|__|	|__|	**Ankle edema** (0=No, 1=Yes, 2=Maybe, 8=absent due to amputation 9=Unk.)
|__|	|__|	**Amputation level** (0=No, 1=Toes only, 2=Foot, 3=below Knee, 4=above Knee, 5= Other, write in_____, 9=Unk.)

Artery	Pulse (0=Normal, 1=Abnormal, 9=Unk.)		Bruit (0=Normal, 1=Abnormal, 9=Unk.)	
	Left	Right	Left	Right
Femoral	|__|	|__|	|__|	|__|
Popliteal			|__|	|__|
Post Tibial	|__|	|__|		
Dorsalis Pedis	|__|	|__|		

Comments_____

_____

_____

MD21

Physical Exam--Neurological Exam

OFFSITE VISIT – leave page BLANK

Neurological Exam			
Left	**Right**		
|__|	|__|	**Carotid Bruit**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|		**Speech disturbance**	
|__|		**Disturbance in gait**	
|__|		**Other neurological abnormalities on exam** Specify_____	

Comments _____

_____

_____

_____

MD22

Electrocardiograph--Part I

OFFSITE ONLY		
|__|__|__|	**MD Id#**	_____ **MD Name**

	Rates and Intervals	
|__|__|__|	**Ventricular rate per minute**	(999=Unk.)
|__|__|__|	**P-R Interval** (milliseconds)	(999=Fully Paced, Atrial Fib, or Unk.)
|__|__|__|	**QRS interval** (milliseconds)	(999=Fully Paced, Unk.)
|__|__|__|	**Q-T interval** (milliseconds)	(999=Fully Paced, Unk.)
|__|__|__|__|__|	**QRS angle** (put plus or minus as needed)	(e.g. -045 for minus 45 degrees, +090 for plus 90, 9999=Fully paced or Unk.)

	Rhythm-predominant
|__|	**0 or 1 = Normal sinus,** (including s.tach, s.brady, s arrhy, 1 degree AV block) **3 = 2nd degree AV block, Mobitz I (Wenckebach)** **4 = 2nd degree AV block, Mobitz II** **5 = 3rd degree AV block / AV dissociation** **6 = Atrial fibrillation / atrial flutter** **7 = Nodal** **8 = Paced** **9 = Other or combination of above (list)**

	Ventricular conduction abnormalities	
|__|	**IV Block**	(0=No, 1=Yes, 9=Fully paced or Unk.)
if yes, fill ☞	|__| **Pattern**	(1=Left, 2=Right, 3=Indeterminate, 9=Unk.)
	|__| **Complete (QRS interval=.12 sec or greater)**	(0=No, 1=Yes, 9=Unk.)
	|__| **Incomplete (QRS interval = .10 or .11 sec)**	(0=No, 1=Yes, 9=Unk.)
|__|	**Hemiblock**	(0=No, 1=Left Ant, 2=Left Post, 9=Fully paced or Unk.)
|__|	**WPW Syndrome**	(0=No, 1=Yes, 2=Maybe, 9=Fully paced or Unk.)

	Arrhythmias	
|__|	**Atrial premature beats**	(0=No, 1=Atr, 2=Atr Aber, 9=Unk.)
|__|	**Ventricular premature beats** (0=No, 1=Simple, 2=Multifoc, 3=Pairs, 4=Run, 5=R on T, 9=Unk.)	
|__|__|	**Number of ventricular premature beats in 10 seconds** (see 10 second rhythm strip)	

MD23

Electrocardiograph-Part II

Myocardial Infarction Location		
|__|	**Anterior**	0=No, 1=Yes, 2=Maybe, 9=Fully paced or Unk.
|__|	**Inferior**	
|__|	**True Posterior**	

Left Ventricular Hypertrophy Criteria		
|__|	**R > 20mm in any limb lead**	0=No, 1=Yes, 9=Fully paced, Complete LBBB or Unk.
|__|	**R > 11mm in AVL**	
|__|	**R in lead I plus S in lead III ≥ 25mm**	
	Measured Voltage	
*|__|__|	**R AVL in mm** (at 1 mv = 10 mm standard) **Be sure to code these voltages**	
*|__|__|	**S V3 in mm** (at 1 mv = 10 mm standard) **Be sure to code these voltages**	
	R in V5 or V6-----S in V1 or V2	
|__|	**R≥ 25mm**	0=No, 1=Yes, 9=Fully paced, Complete LBBB or Unk.
|__|	**S≥ 25mm**	
|__|	**R or S ≥ 30mm**	
|__|	**R + S ≥ 35mm**	
|__|	**Intrinsicoid deflection ≥.05 sec**	
|__|	**S-T depression (strain pattern)**	

Hypertrophy, enlargement, and other ECG Diagnoses	
|__|	**Nonspecific S-T segment abnormality** (0=No, 1=S-T depression, 2=S-T flattening, 3=Other, 9=Fully paced or Unk.)
|__|	**Nonspecific T-wave abnormality** (0=No, 1=T inversion, 2=T flattening, 3=Other, 9=Fully paced or Unk.)
|__|	**U-wave present** (0=No, 1=Yes, 2=Maybe, 9=Paced or Unk.)
|__|	
|__|	**RVH** (0=No, 1=Yes, 2=Maybe, 9=Fully paced or Unk.; **If complete RBBB OR LBBB present, RVH=9**)
|__|	**LVH** (0=No, 1=LVH with strain, 2=LVH with mild S-T Segment Abn, 3=LVH by voltage only, 9=Fully paced or Unk., **If complete LBBB present, LVH=9)**

Comments_____

_____

_____

MD24

Clinical Diagnostic Impression--Part I

Heart Diagnoses		
|__|	**Rheumatic Heart Disease**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**Aortic Valve Disease**	
|__|	**Mitral Valve Disease**	
|__|	**Arrhythmia**	
|__|	**Other Heart Disease (includes congenital)**	
	(Specify)_____	

Peripheral Vascular Disease		
|__|	**Other Peripheral Vascular Disease**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**Other Vascular Diagnosis**	
	(Specify)_____	

Neurological Disease		
|__|	**Stroke/ TIA**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**Dementia**	
|__|	**Parkinson's Disease**	
|__|	**Adult Seizure Disorder**	
|__|	**Migraine**	
|__|	**Other Neurological Disease**	
	(Specify)_____	

Comments _____

_____

_____

_____

MD25

Clinical Diagnostic Impression--Part II. Non Cardiovascular Diagnoses

Endocrine		
|__|	**Thyroid Disease**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**Diabetes Mellitus**	
|__|	**Other endocrine disorders,** specify_____	
GU/GYN		
|__|	**Renal disease,** specify_____	0=No, 1=Yes, 2=Maybe, 8=male/female 9=Unk.
|__|	**Prostate disease**	
|__|	**Gynecologic problems,** specify_____	
Pulmonary		
|__|	**Emphysema**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**Pneumonia**	
|__|	**Asthma**	
|__|	**Other pulmonary disease,** specify_____	
Rheumatologic Disorders		
|__|	**Gout**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**Degenerative joint disease**	
|__|	**Rheumatoid arthritis**	
|__|	**Other musculoskeletal or connective tissue disease,** specify_____	
GI		
|__|	**Gallbladder disease**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**GERD/ulcer disease**	
|__|	**Liver disease**	
|__|	**Other GI disease,** specify_____	
Blood		
|__|	**Hematologic disorder**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**Bleeding disorder**	
Infectious Disease		
|__|	**Infectious Disease**	0=No, 1=Yes, 2=Maybe, 9=Unk.
if yes ☞	specify_____	
Mental Health		
|__|	**Depression**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**Anxiety**	
|__|	**Psychosis**	
|__|	**Other Mental health,** specify_____	
Other		
|__|	**Eye**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**ENT**	
|__|	**Skin**	
|__|	**Other,** specify_____	

Comments

_____

_____

Second Examiner Opinions

OFFSITE VISIT – leave page BLANK

|__|__|__| **2nd Examiner ID number** _____ **2nd Examiner Last Name**

Coronary Heart Disease

(Provide initiators, qualities, radiation, severity, timing, presence after procedures done)

Item requires 2nd opinion *Check ALL that apply.*	**2nd opinion**		
☐	|__|	**Congestive Heart Failure**	0=No, 1=Yes, 2=Maybe, 9=Unk.
☐	|__|	**Cardiac Syncope**	
☐	|__|	**Angina Pectoris**	
☐	|__|	**Coronary Insufficiency**	
☐	|__|	**Myocardial Infarct**	

Comments about heart disease _____

_____

_____

Intermittent Claudication

(Provide initiators, qualities, radiation, severity, timing, presence after procedures done)

Item requires 2nd opinion *Check ALL that apply.*	**2nd opinion**		
☐	|__|	**Intermittent Claudication**	0=No, 1=Yes, 2=Maybe, 9=Unk.

Comments about peripheral artery disease _____

_____

Cerebrovascular Disease

(Provide initiators, qualities, severity, timing, presence after procedures done)

Item requires 2nd opinion *Check ALL that apply.*	**2nd opinion**		
☐	|__|	**Stroke**	0=No, 1=Yes, 2=Maybe, 9=Unk.
☐	|__|	**TIA**	

Comments about possible cerebrovascular disease_____

_____

_____

MD27

Any Additional Comments for Second Examiner Opinions.

FRAMINGHAM HEART STUDY RESEARCH INFORMATION FORM

BACKGROUND

This information sheet is for the Framingham Heart Study research exam. This exam is a continuation of the Framingham Heart Study (FHS). You have consented on numerous occasions to continue in the FHS. This information sheet will explain what will happen as part of your FHS Exam

If you have any questions about the FHS or your Exam, please let the study staff know. The investigator and/or his/her designee will try to answer all of your questions. If you have questions or concerns at any time, you may contact [redacted]

Although you have consented in the past to be in the FHS, you have a right to refuse to participate at this time. Also, if you decide now to take part you may stop at any time if you wish.

This exam is limited to RESEARCH and does not take the place of a routine physical examination by your physician.

PURPOSE

The Framingham Heart Study (FHS) is an observational research study of risk factors for cardiovascular disease and other health conditions. The purpose of this research study is to 1) investigate factors related to the development of heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, cancer, and other diseases and health conditions; and 2) examine DNA and its relationship to the risks of developing these diseases and other health conditions.

WHAT WILL HAPPEN DURING YOUR FHS EXAM

Your exam will take place at the Framingham Heart Study at 73 Mt. Wayte Avenue in Framingham, MA, or may take place in your home or other residence for your convenience. The examination will take 2 to 2.5 hours. The exam will include the following:

1) History
An interview about your medical status including: heart and lung illnesses, hospitalizations, emergency room visits, surgeries, physician visits, and health habits (including prescription and non-prescription drug use, smoking and alcohol use).

2) Measurements and Procedures
The examination includes measurements of height, weight, blood pressure, and an electrocardiogram. You will be asked questions about activities of daily living, your memory, mood and social support. You will be asked to perform tasks of walking, balance, and hand grip strength. If you have had a stroke, you will be examined during your hospitalization at 3, 6, 12, and 24 months. With your permission, a summary letter of routine test results from this exam will be sent to you and your physician.

3) Medical Records
You will be asked to sign a medical release form (called a HIPAA Authorization form) allowing the Framingham Heart Study staff to obtain and review copies of your hospital, physician, cancer registry, and clinic records for the Framingham Heart Study investigators to review.

FRAMINGHAM HEART STUDY RESEARCH INFORMATION FORM

Future contact
You may be contacted by phone every 1-2 years to obtain additional health information. You may also be invited to participate in other Framingham Heart Study health-related studies. Another FHS exam may be offered every 1-2 years. At that time you will be given a new exam information sheet.

RISKS & BENEFITS
We do not expect any unusual risk or injury to occur as a result of participation.
If you think that you have been injured by being in this study, please contact [redacted] right away.

SUBJECT COSTS & PAYMENTS
You will not be charged or paid for the examination. In the event that your physician decides that follow up clinical tests or treatments are necessary, you or your third party payer will be charged for these, if applicable (for example, health insurance or Medicare). No special arrangements will be made by the Framingham Heart Study for compensation or for payment of treatment solely because of your participation in this study.

CONFIDENTIALITY
Information we obtain about you during this study will be treated in a confidential manner. Laboratory and DNA samples will be stored securely, separated from files which link your name to the code numbers. The risk in providing this sample is minimal. Your sample will be kept until it is no longer of scientific value.

You may choose to withdraw your blood samples. Your samples would be destroyed after your request is received. If you choose to withdraw your samples, you should call the Framingham Heart Study at [redacted] and ask for the lab manager.

When study results are published, your name and any other personally identifying information will not be revealed. You will be kept informed through periodic publications from the Framingham Heart Study of any new findings about genetics, cardiovascular disease or other health conditions generated from the DNA analyses.

The Framingham Heart Study investigates selected factors contributing to heart and blood vessel diseases, lung and blood diseases, stroke, memory loss and other diseases and health conditions. Your DNA and genetic data may be used to develop new lab tests or medications that could benefit many people. (You and/or your heirs will not benefit financially from this, nor will your DNA be sold to anyone.)

If a genetic condition happens to be identified with important health implications, the Framingham Heart Study may notify you, and then with your permission, may notify your physician.

Protocol for Scheduling Offsite Visits

Before making a call, check the roster.

- On the main screen, check the comment line and Consent Status and date.
- Check the Referral screen (F14 or shift F4) for additional comments.
- Check the Booking screen (F12 or shift F2) for scheduled exams, exam history, and the participant's age.

The core exam takes priority over ancillary study appointments and should be scheduled first. If, however, a participant has been seen recently or is scheduled for another appointment, wait several months before trying to schedule the appointment

After an appointment has been scheduled, the Coordinator will update the roster, email the schedule to the offsite email list and provide a hard copy to the Senior Secretary with the appropriate letter (either the nursing home letter or home visit letter with medical information form attached)

Staff may call a participant directly to schedule an offsite appointment if:

(1) There is no notation of cognitive impairment (*COG IMP* on the comment line or the F4/F14 screen),
(2) Consent Status is less than 3,
(3) and there are no comments regarding severe hearing loss or speech difficulties.

A. Home Visits

If the Coordinator calls the participant directly because these conditions do not apply, but then has questions about the participant's cognitive status, the Coordinator should call the designated proxy or family member before scheduling. If the contact person denies any problems and says the participant is capable of answering questions and signing consent forms, ask the contact if he or she would be willing to provide additional information if necessary after the exam.

If any of the above cognitive issues are noted, call the participant's designated FHS Proxy or family member first to determine if a Home Visit is feasible. If unable to reach any contacts, (telephones disconnected, etc.), check the participant's Personal and Family

History Data sheet (the salmon sheet) and/or any recent medical records in the chart to see who is listed as the responsible party or next of kin.

B. Nursing Home Visits

If there is no cognitive impairment noted in the roster, the Coordinator may call the nursing home, identifying herself as a Framingham Heart Study staff member, and ask to speak to the nurse in charge of the care of the participant, When speaking with the nurse, explain why you are calling, what the visit will entail, determine what the best time to visit would be and then schedule an appointment. As a courtesy, call the participant's proxy or a listed contact, starting with the spouse (unless there are instructions to the contrary on the roster) to inform her/him that we will be going to the nursing home; this person or another family member may wish to be present at the exam.

If the nursing home staff member says the participant is too ill for a visit and/or has had serious medical events since our last visit or health update, the Coordinator may call a family member for details concerning the participant's condition and ask again about visiting. If the contact also refuses, ask if he/she will complete a telephone health update, using the Medical History Update form.

If a recruiter is told by the nursing home that the participant has died since the Heart Study's last visit or health update, she/he will complete a Death Information Form for the Participant Coordinator, who will immediately update the Roster, and give copies to the relevant staff members. If the nursing home can't or won't provide the information needed and the death occurred at least several months ago, the Coordinator may call the proxy or family member for information.

Scheduling a PPT in PTS

1. Schedule appointment with PPT.
2. Put appointment into 1. Roster, 2. Referral, 3. Booking screens.
3. IN ROSTER SCREEN … change date (survival date) to date you spoke with PPT.
4. IN ROSTER SCREEN…put what was done, i.e. booking (this is the 1st line that is looked at).

REFERRAL SCREEN

It has to be noted what it was scheduled at i.e. a 6 code like 61 = home visit.

BOOKING SCREEN

1. Click on new record at the end of booking screen.
2. Put in Full Date 12/20/2013 space then time (military time) 13.30 (1.30pm).
3. Put in # for exam .e.g. 9.
4. Exam type. E.g. Nursing home visit or home visit.
5. Exam stat… is either current or canceled.
6. Exam location e.g. home or nursing home.
7. Confidential comment can be removed if not pertaining to exam. These comments are carried over from previous exams.
8. Rescheduled… put in if it is a rescheduled or not.
9. Alternate address… This area is where you can put comments that are important to person doing the home visit. Such as speech issues, wheel chair, etc. Be careful these comments will print on the apt schedule, and roll over from previous exams.
10. PUT IN INITIALS (ST) AND THEN HIT UPDATE. If the initials are not entered it will not save, and you will not be able to print appointment letter.

CRYSTAL REPORTS

This is where the schedule is printed from

1. Go to Recruiting / Admitting
2. Click on book_off report.
3. Put in Date.. click OK
4. Print from printer icon on side.
5. Be sure to **log off** when finished.

Crystal Report to print CALL BACK LIST

1. Click on call back reports.
2. Enter ID type e.g. 1 for Off spring and also Referral Code you are requesting, i.e. 39 or 31.
3. Then hit ok and print.
4. Again **log off** when finished.

To copy and paste info in the screen , highlight ,HIT Ctrl and c move curser to where you need and hit Ctrl and v.

5.

Preparation for an Off-site Examination

A. Supplies

The following supplies should be brought with you on an offsite visit:

1 Portable EKG machine
1 Portable EKG acquisition module
1-2 Packs of EKG electrodes
1 Heart square
Alcohol wipes
Gauze
Adhesive remover pads
3 Blood pressure cuffs; large adult, adult and pediatric (Latex Free)
1 Pocket Aneroid Sphygmomanometer
1 Littman Classic II Stethoscope
1 Pencil
1 Wristwatch
1 Portable scale
Response sheets for participant
1 JAMAR dynamometer
1 Stopwatch
1 Tape measure
1 Pocket Talker (very helpful for hearing impaired participants)
Masking tape or tape of equal visibility
Exam 9 paperwork ONLY

B. Preparation

On the day of the scheduled Heart Study visit it is best to call the participant or nursing home to confirm the appointment. Instruct the participant that he/she should wear a top that easily opens in the front to facilitate the ECG and remind them to have any available medications they take. With their confirmation letter, a form is included that helps to summarize their medical history since their last exam. Ask them to have this form ready.

When calling a nursing home inform the nurse that access to their patient's chart is necessary. Most nursing homes are accommodating and have the chart set aside for the visit.

Take only current exam paperwork to the exam and leave the last exam folder and all of the originals at FHS. Originals should never leave the FHS building. The Senior Secretary makes photocopies of all of the forms needed and will put them in the chart.

Visiting the Cognitively Impaired

The physical component of the exam requires the cooperation of the participant. The following are some suggestions to be able to effectively communicate with those with dementia.

Effective Communication Suggestions:

1. Be patient
2. Do not try to reason
3. Keep information simple
4. Use given names
5. Use eye contact
6. Give one direction at a time
7. Give clear instructions instead of asking questions
8. Keep communication in the present
9. Use sensitive touch when possible
10. Give frequent acknowledgment and encouragement
11. Ignore misinformation and simply acknowledge the communication

Nursing Home Chart Review Protocol

When visiting a participant in a Nursing Home most of the necessary information may be obtained through the review of the participants Nursing Home chart. When calling to confirm the offsite visit to the Nursing Home, inform the nurse taking care of the participant that you will need to look through his or her chart. Most nurses will ensure that the chart will be available upon your arrival.

1. Updating Sociodemographic Data and Family History

   Upon opening the nursing home chart, one should see a face sheet. This sheet contains all the personal demographic data on their patient, including their next of kin. If the name(s) vary from the most recent ones on the Personal and Family History it should be documented, along with their addresses and phone numbers.

   At the bottom of the face sheet it often lists the admission diagnosis of the patient. This is extremely important, especially if this is their first Nursing Home offsite visit.

2. Medications

   Most charts contain an up-to-date list of the patient's medications. Some facilities keep the medications in a separate chart. If the patient's medications are not listed in their chart, ask for the medication book. Many times the medication sheets for months prior may also still be in the chart, make sure you use the most recent medication list (the dates will be at the bottom of the form).

3. Interim Medical History

   The two sections that are most helpful in locating medical history information are "Consults" and "Medical History". Some nursing homes keep copies of all hospitalization records in a clear sleeve. The "Physician's Notes" and "Nurses Notes" sections are also helpful.

   NOTE: Since all facilities have their own chart organization system it is best to thoroughly examine the whole chart. Some facilities thin their charts more frequently and if only the last month's information is present, then ask to see the whole interim period. This will ensure that nothing is missed.

4. Activities of Daily Living

   To update a participant's activities of daily living the best reference is the MDI or minimum data sheet. This is a computer sheet, usually at the front of the chart, and it is updated about every 4 to 6 months. This sheet lists activities of daily living, hospitalizations, etc. Always refer back to notes and daily documented information to corroborate data, but this gives a nice head start. To truly confirm the current level of functioning of the patient consult with his or her nurse and list nurse as the Proxy.

5. Weight

   If you are unable to obtain the participants weight using the FHS protocol you can use their nursing home chart records. Weight is typically done weekly at nursing home facilities. If you can't find a list of their current weight you can reference their physical exam report. Check to see if the nursing home keeps a separate weight book first before using the physical, we want to use the most recent measurement. Record the weight on file and the date it was obtained.

Medical History

The date of the participant's last exam and the date of the participant's last health history update will be pre-printed at the top of the medical history form. A health status page will be attached to the medical history form listing medical encounters reported by the participant on the health history update form. The forms from the participant's last examination are also provided in a folder behind the current medical history form. The medical history taken from the participant is an update from the Heart Study's last contact with the participant (based on the date of the last Health History Update or last examination). The examiner should also refer to the Summary of Findings form in the participant's chart to verify whether a medical encounter is new or has already been identified. This form records the outcome of all Endpoint reviews and therefore documents all cardiovascular disease events adjudicated by the study.

The health status page may have incomplete data on medical encounters. Be sure to clarify any missing information and record it under medical encounters on the first page of the medical history form.

Medical History Form

1st Examiner Prefix

(0=MD, 1=Tech, for OFFSITE visit)
Note: zero is in as a default, for OFFSITE visits, slash the zero out and write in 1 for Tech

Hospitalization in interim

A hospitalization is considered an overnight stay.
If the participant was in the Emergency Room (E.R.) and then admitted, the event would be considered only for hospitalization and not as E.R. visit.

E.R. visit in interim

An emergency room visit is when the person is both admitted to and discharged from the emergency room the same day.

Day surgery in interim

Day surgery is a surgical procedure performed on an out-patient basis either in an ambulatory surgery department of a hospital or in a physician's office.
The person is in and out the same day.

Major illness with visit to the doctor in interim

Illness with visit to physician is defined as a visit outside of a regular check-up. It can be further clarified by defining it as a visit to the doctor for a specific reason. It is imperative that the reason for the visit be documented.

Check-up in interim by doctor

A check-up is considered to be a routine visit.

Details of all hospitalizations, ER visits, day surgery, and physician visits must be provided as follows:

A. Medical Encounter
Write the details about the medical event. If the participant cannot provide a "medical condition", symptoms leading to the medical encounter should be listed (for example, chest pain, shortness of breath).

B. Month/Year
Record the date of the medical encounter. People often cannot recall the exact month or even the year. Trying to couple the event with a season or holiday sometimes helps.

C. Site of the hospital or office
The hospital and the city and state are most important.

D. Doctor
Record the name of the physician seen. If the participant sees a physician's assistant or a nurse practitioner in the physician's office, obtain both names.

Note: If FHS needs outside hospital records, please obtain details: mo/yr, hospital site.

Medical History – Prescription and Non-Prescription Medication

On home visits, the participant is asked to show the medical technician his/her medication bottles including over-the counter preparations. In the case of a nursing home visit, the technician should record the medications from the participant's medication orders in their nursing home chart.

Copy the name of the medication, the strength including units, and the total number of doses per day/week/month. Include pills, skin patches, eye drops, creams, salves, injections. Include herbal, alternative, and soy-based preparations.

Print the medication name, strength, number per day/week/month, and if taken PRN.

*****List ONLY medications taken regularly in the past month/ongoing medications*****

Medical History

The physician or off-site medical technician will obtain an interim medical history using the standardized exam 9 form. The questions should be asked exactly as written on the form and the participant's response recorded according to the response choices provided on the form. In addition a comment area is provided on the form to record a narrative account of cardiovascular symptoms including chest pain, shortness of breath, syncope, exertional leg discomfort and cerebrovascular symptoms. It is critical that a narrative be provided to clarify the symptoms for investigators adjudicating events in Endpoint Review.

It is also critical to record all health care visits (physician, ER, hospital) the participant has had for the symptom. Outside medical records will be obtained to verify the participant's account of their medical condition.

Additional instructions for obtaining the medical history and properly coding the participant's responses are as follows.

Chest pain (screen MD13)

When the participant states that they have not experienced any chest discomfort, clarify further using the terms *chest pain, chest tightness, chest pressure*.

If the participant states that they never used Nitroglycerin as a way to relieve the discomfort be sure to code as 8= not tried, rather than 0= no relief.

Alcohol Consumption (screen MD09)

Code number of alcoholic beverages as EITHER weekly **OR** monthly as appropriate.

Cerebrovascular, Neurological and Venous Diseases (screen MD15)

It is important to stress that these CVA symptoms are **sudden**, not a gradual progression of a symptom.

1. Sudden Muscular Weakness
   *Since (date of last FHS exam) until today, have you experienced any **sudden** muscular weakness? For example, face drooping or weakness, particularly on one side of your body.*

2. Sudden Speech Difficulty
   *Since (date of last FHS exam) until today, have you experienced any **sudden** difficulty with your speech such as understanding spoken words or trouble speaking?*

3. Sudden Visual Defect
   *Since (date of last FHS exam) until today, have you experienced any **sudden** visual defect?*

4. Sudden Double Vision
Since (date of last FHS exam) until today, have you experienced any double vision?

5. Sudden Loss of Vision in One Eye
*Since (date of last FHS exam) until today, have you experienced any **sudden** loss of vision in one eye, like a shade coming down over your eye?*

6. Sudden Numbness, Tingling
Since (date of last FHS exam) until today, have you experienced any numbness or tingling on one side of your face or one side of your body?

If the participant answers yes, ask is numbness and tingling positional?

CVD Procedures (screen MD17)
The participant is queried regarding CVD procedures since the last Heart Study contact.
If the participant has had more than one procedure of a particular type code only the first procedure and list all other procedures in the comment section.

Clarify the procedure list for the participant as follows:

Heart valvular surgery
Have you had surgery on your heart valves?

Exercise tolerance test
Have you had an exercise stress test or a treadmill test of your heart?

Coronary Arteriogram
This test is an invasive test done in the hospital. An x-ray is taken of your arteries after you receive an injection of a dye that outlines the blood vessels of your heart.

Coronary artery angioplasty/stent/PCI
Angioplasty is a procedure in which a balloon is used to open a narrowed or blocked artery in your heart. (This is also known as Percutaneous Coronary Intervention (PCI)). A stent is a wire mesh tube that is placed in the artery to hold it open. The stent is usually placed in the artery during angioplasty.

Coronary bypass surgery
Have you had bypass surgery also known as CABG (coronary artery bypass grafting)? During bypass surgery the diseased section of your coronary arteries are bypassed with a healthy artery or a vein in order to increase blood flow to your heart muscle.

Permanent pacemaker insertion
Have you had a pacemaker inserted? A pacemaker is used to replace the function of the natural pacemaker in your heart when your heart is beating too slowly. Permanent pacemakers are surgically placed into the chest through a small incision.

AICD
This stands for Automatic Implantable Cardiac Defibrillator (AICD) and is a device that is implanted under the skin of the chest to analyze the rhythm of your heart and discharges an electrical shock if a serious irregularity is detected.

Carotid artery surgery/stent
The carotid artery is located in your neck and carries blood and oxygen to your brain. Carotid artery surgery is a surgical procedure to restore adequate blood flow to your brain. A stent is inserted into the carotid artery to open a narrowed or blocked area of the artery to help maintain an adequate blood flow to the brain.

Thoracic aorta surgery
Have you had surgery on your aorta- the large blood vessel coming from your heart? This surgery is done to repair the aorta for example when there is an aneurysm (a weaknening or bulge in the wall of the aorta) .

Abdominal aorta surgery/stent
Have you had surgery on the large blood vessel in your abdomen (belly) called the aorta? This surgery would be done to repair a problem such as an aneurysm (weakening or bulge in the wall of the artery) or blockage in the aorta.

Femoral or lower extremity surgery/stent/angioplasty
Have you had any surgery to improve the circulation in your legs such as bypass surgery or angioplasty?

Lower extremity amputation
Have you had an amputation of part of your leg or foot?

Other cardiovascular procedures (write in)
Have you had any other tests or procedures on your heart or blood vessels?

For Offsite visits a technician will complete the physician medical history portion of the exam. The form will then be reviewed and completed by a physician. ALL physicians will be asked to share in this responsibility during their assigned clinic time. The physician chart review includes the following:

1. Review the physician exam form and complete all physician opinions regarding endpoints (AP, MI, CI, CHF, stroke, syncope, and IC) based upon the coded and written narratives the technician obtained at the time of the visit.
2. Code the ECG. The MD ECG reading should be added to the letter to the personal physician.
3. Complete the "clinical diagnostic impression"
3. Review the letter to the personal physician making any deletions/additions/changes in medical terminology that are required.
4. Return the chart the SAME day to the technician or the clinic tech at the board in clinic.

NOTE: The area entitled "Examiner's Opinion" at the bottom of every page is not to be completed by the medical technician but by the physician reviewing the chart in clinic. The medical technician does not perform a physical exam. Therefore, the physical exam portion of the medical history form will be left blank on offsite visit.

Blood Pressure Measurement & Maximum Inflation Level

A. Equipment:

1. One standard Litman stethoscope tubing and earpieces with bell: Classic II 3M

2. One standard mercury column sphygmomanometer: Baumanometer (clinic)

3. Aneroid sphygmomanometer (offsite)

4. BP cuffs in four sizes (all Latex free)

    Thigh adult cuff
    Large adult cuff
    Regular adult cuff
    Pediatric cuff

B. Blood Pressure Cuff Placement:

1. Bare participant's left arm to above the point of the shoulder.

2. Determine correct cuff size using guidelines inside the cuff.

3. Palpate the brachial artery.

4. With participant seated, place the appropriate cuff around the upper left arm. The midpoint of the length of the bladder should lie over the brachial artery. Each cuff has an artery marker. The mid-height of the cuff should be at heart level.

5. Place the lower edge of the cuff, with its tubing connections, about one inch (1") above the natural crease across the inner aspect of the elbow.

6. Wrap the cuff snugly about the arm, with the palm of the participant's hand turned upward.

7. If the subject has had a left-sided mastectomy, the right arm may be used for blood pressure measurement. If right arm is used, note it on the form.

C. Determination of Maximal Inflation Level

For each participant, determine the maximal inflation level, or the pressure to which the cuff is to be inflated for blood pressure measurement. This assures that the cuff pressure at the start of the reading exceeds the systolic blood pressure and thus allows the first Kortokoff sound to be heard.

1. Attach the cuff tubing to the sphygmomanometer.

2. Palpate the radial pulse.

3. Inflate the cuff rapidly until the radial pulse is no longer felt (palpated systolic pressure) by inflating rapidly to 70 mmHg, then inflating by 10mmHg increments.

4. Deflate the cuff quickly and completely.

5. The maximal inflation level is 30 mmHg **above** the palpated systolic pressure.

D. Guidelines for Accurate Blood Pressure Readings:

1. The participant should be in a seated position for at least 5 minutes before the blood pressure is measured with both feet remaining flat on the floor.

2. All readings are made to the nearest even digit.

3. Any reading which appears to fall exactly between marking on the mercury column should be read to the next higher marking (i.e. 2, 4, 6, 8, or 0).

4. All readings are made to the top of the meniscus, the rounded surface of the mercury column.

5. When the pressure is released quickly from a high level, a vacuum is formed above the mercury and the meniscus is distorted. Allow a few moments for it to reappear before reading the manometer.

For offsite Blood Pressures: Check that the needle is at the zero mark at the start and the end of the measurement. Place the manometer in direct line of sight with the eye on a line perpendicular to the center of the face of the gauge.

E. Blood Pressure Readings:

1. Following any previous inflation, wait at least 30 seconds after the cuff has completely deflated.

2. By closing the thumb valve and squeezing the bulb, inflate the cuff at a rapid but smooth continuous rate to the maximal inflation level (30 mmHg above palpated systolic pressure).

3. The examiner's eyes should be level with the mid-range of the manometer scale and focused at the level to which the pressure will be raised.

4. Open the thumb valve slightly. Allow the cuff to deflate, maintaining a constant rate of deflation at approximately 2 mmHg per second.

5. Using the bell of the stethoscope, listen throughout the entire range of deflation, from the maximum pressure past the systolic reading (the pressure where the FIRST regular sound is heard), until 10 mmHg BELOW the level of the diastolic reading (that is, 10 mmHg below the level at which the LAST regular sound is heard).

6. Deflate the cuff fully by opening the thumb valve.

7. Remove the stethoscope. Neatly enter systolic and diastolic readings in the spaces provided on the form.

Elevated Blood Pressure

If, during a home visit the blood pressure is:

> **> 200/110** a call is made to a FHS physician who will notify the participant's personal physician. The chart will be marked "expedite" so that the letter to the personal physician is sent out ASAP.

> **> 180/100** the chart is expedited

-The Referral sheet is completed to note that contact was made to an FHS MD during the exam.

-If a phone contact was made by an FHS MD to the participant's personal physician, the FHS MD is to complete a "Record of Telephone Encounter" form.

If, during a nursing home visit the blood pressure is:

> **> 140/90** inform the nurse caring for the participant or the charge nurse

> **> 180/100** inform the nurse caring for the participant or the charge nurse.
> The chart will be marked "expedite" so that the letter to the personal physician is sent out ASAP.

MD Chart Review
Offsite Visits

Offspring Exam 9 and Cohort Exam 32 have started including off-site visits to participants in either a nursing home or personal residence. [redacted] will do the off-site visits. As a technician she will complete the physician portion of the exam. The format is very similar to the medical history update. The exam will then need to be completed by a physician. ALL physicians will be asked to share in this responsibility during their assigned clinic time. Clinic staff will distribute the charts as equitably as possible.

The physician chart review includes the following and be sure to **CHECK BOXES** after completion of each step:

- ☐ Review the physician exam form and complete all physician opinions regarding endpoints (AP, MI, CI, CHF, stroke, IC, etc) based upon the coded and written narratives [redacted] obtained at the time of the visit. Offspring charts do **NOT require a second opinion.**

- ☐ Read and compare the current ECG to the previous ECG. **Code the ECG on the exam form. Add your ECG reading to the letter to the personal physician. Expedite the chart or call the participant's physician if a new major change in the ECG is detected that requires medical follow up.**

- ☐ Review the letter to the personal physician making any deletions/additions/changes in medical terminology that are required **and sign the letter.**

- ☐ Complete the Referral Tracking (page: REF1)chart

- ☐ Return the chart the SAME day to the clinic tech at the board in clinic. **Charts are not to leave the clinic area.**

Important Note:

[redacted] may call the clinic during an offsite visit and ask to speak to a doctor. She will do this if the participant is experiencing problems with their blood pressure or any other health related issues that need immediate follow-up. If [redacted] calls it is the **responsibility of the MD to contact the participants doctor ([redacted] will provide you with the contact information) if they find it necessary. If a doctor is contacted then the clinic doctor is to call [redacted] back with the plan of action.

Offsite Visit Chart Completion

After returning to the Heart Study the following procedure is used to ensure that the chart is processed in an efficient manner.

A. ECG Physician Review

The full size tracing of the ECG and the ECG from the participant's previous exam should be presented to a FHS physician within 24 hours of the visit or within 24 hours of the tech returning to the FHS. This is done for comparison and reading. Should there be any marked ECG changes; the FHS physician should inform the participant's personal physician immediately.

After a contact is made with the PCP, the physician should complete a phone encounter sheet or the referral tracking form to document his/her actions.

The field visit tech will complete the chart the day of the visit or the next day if the visit occurred late in the day or was out of the Metrowest area.

Field visit charts will be processed within 1-2 days of the visit and the tracking sheet will be returned to the offsite tech for confirmation of completion.

B. Chart Review Protocol

1. Review all forms to ensure that all areas are completed. This includes the participant's letter and the physician summary sheet. On the summary sheet, document the medical findings that are new since the last exam and any other significant medical conditions carried over from previous exams.

2. If the participant had a stroke or has shown marked cognitive changes in the interim, a referral is made to the Stroke and/or Dementia study. After completing the referral forms, attach to the front of the chart.

3. A Routing Sheet is used to ensure that the doctor, the Cohort Participant Coordinator, the Offsite Technician and Data technician review the chart.

4. When preparing the chart for the MD to review in clinic, the following documents should be clipped together and put in the front of the chart:
    a) ECG – current and from last exam
    b) Medical History Update
    c) Summary Sheet to MD
    d) Letter to Participant
    e) Referral Tracking Form
    f) Photocopied Summary of Findings from previous letter

5. The chart should be left for the MD to review in clinic. A participant label should be put on the float sheet and the person working the float position should inform the MD that they have a chart to review.

6. It is the responsibility of the MD to review the chart in clinic that morning. The chart should not be brought upstairs.

7. Once the chart is reviewed by the MD the offsite technician should again review the chart for completeness and put the chart in order.

8. The chart should then be given to the Cohort Participant Coordinator. The Cohort Participant Coordinator will update the roster and give the chart to the data technician to type the MD letter.

9. Once the data technician is finished with the chart he/she should return only the routing sheet to the offsite technician. Once this is returned this will indicate the chart is completed.

OFFSITE CHART ORDER FOR DOCTORS

TOP OF CHART

- MD REVIEW FORM
- APPOINTMENT SCHEDULE

INSIDE CHART

- EKG NEW AND ONE FROM LAST CYCLE
- MD EXAM…MD01
- SUMMARY SHEET
- FHS LETTER TO PARTICIPANT
- REFFERAL TRACKING
- LAST EXAM , USE THE COPY(I.E. #8 OR 7)
- LATEST MEDICAL RECORDS

WHEN CHART IS BACK IN ORDER RETURN TO VICKI

- COPIES TO [redacted] OF APPT. SCHEDULE, PROXY FORM (2), HIPPA FORM, AND ADMIT FORM. [redacted] WILL RETURN ADMIT FOR CHART ORDER.
- COPIES OF APT SCHEDULE WITH CHECK TO: [redacted]

OFFSITE PRIORITY ORDER OF EXAM

Part I:

(All medical components):

- Informed Consent
- Blood Pressure
- ECG
- Medical History (physician forms)
- Weight

Part II:

- Tech Questions
- Observed Performance

Weight Offsite Visits

1. The participant should remove slippers or shoes.

2. Prior to asking participant to step on the scale, turn scale on, check to make sure it reads 0.0. The scale should be on a flat, hard surface.

3. Ask the participant to step onto the scale.

4. Instruct the participant to stand in the middle of the scale platform with head erect and eyes looking straight ahead. Weight should be equally distributed on both feet, and participant should not touch or support himself/herself.

5. Read the digital display while participant is on the scale.

6. Have the participant step off the scale.

7. Record the weight to the nearest pound; round up if ≥ 0.5, round down if < 0.5.

9. If participant is unable to stand for weight measurement at a nursing home, record the last weight in nursing home chart and the date the weight was obtained. If the participant is unable to stand on a scale during a home visit, record the weight measurement as 999.

10. Calibrate the scale monthly with 50lb weight

ID: «Idtype» - «Id»

Numerical Data/Anthropometry

☐ Check here if whole page is blank. Reason why_____

|__|__|__| **Technician Number** (for basic information)

Basic Information

«Sex»	**Sex of Participant** 1=Male, 2=Female
|_**0**_|	**Site of Exam** (0=Heart Study, 1=Nursing home, 2=Residence, 3=Other)
|__|__|	**Age of Participant** (number of years)
|__|__|	**What state do you reside in?** *(If reside outside the USA, code ZZ, if plans to wear accelerometer while visiting USA code state of visit)* Code: AL, AK, AS, etc.

Anthropometry

Check Protocol Modification *ONLY if there was one and document it in Comment section*
88*88=Refused, 99*99=Not done or Unk.

|__|__|*|__|__|	**Height** *(inches, to next lower 1/4 inch)*
	☐ **Protocol modification**
|__|__|__|	**Weight** *(to nearest pound)* (400=400 or more 888=refused, 999=Unk.)
	☐ **Protocol modification**
|__|	**In the past year, have you lost more than 10 pounds?** 0=No, 1= Yes, unintentionally, NOT due to dieting or exercise 2= Yes, intentionally, due to dieting or exercise
|__|__|__|	**Technician Number** (for anthropometry)
|__|__|*|__|__|	**Neck Circumference** *(inches, to next lower1/4 inch)*
	☐ **Protocol modification**
|__|__|*|__|__|	**Waist Girth at umbilicus** *(inches, to next lower 1/4 inch).*
	☐ **Protocol modification**
|__|__|*|__|__|	**Hip Girth** *(inches, to next lower 1/4 inch)*
	☐ **Protocol modification**
|__|__|*|__|__|	**Thigh Girth** *(inches, to next lower 1/4 inch)*
	☐ **Protocol modification**

Comments for ALL Protocol Modification *(specify measurement)*

_____

_____

TECH01

☐ Check here if whole page is blank. Reason why_____

Procedures Sheet

0=No, 1=Yes, 8=Offsite visit

|__| **Type of Exam**	1=Complete exam, 2=Split exam(exam completed in 2 visits), 3=short exam (incomplete exam), 8=offsite
|__| **Informed Consent Signed**	0=No, 1=Yes, 2= offspring waiver of consent, LAR, or next-of-kin
|__| **Urine Specimen**	
|__| **Blood Draw**	
|__| **Mini-Mental Status Exam**	
|__| **Anthropometry**	
|__| **Sociodemographic Questions** (self administered)	
|__| **SF-12 Health Survey**	
|__| **CES-D Scale**	
|__| **NAGI, Rosow-Breslau, Katz**	
|__| **Exercise Questionnaire**	
|__| **ECG**	
|__| **P Wave Signal Averaged ECG**	
|__| **If not performed why:** 1=AF, 2=Pacemaker, 3=Pat. ran out of time, 4=Pat. couldn't lie flat, 5=equipment malfunction, 6=other	
|__| **Observed performance (**Timed walk, hand grip, chair stands)	
|__| **Tonometry**	
|__| **Ankle-brachial blood pressure by Doppler.** *(Participants ≥ 40 years)*	
|__| **Spirometry**	0=Not Done, 1=Done, 2=Attempted, not finished, 3= Attempted, tech aborted ,4=Other
|__| **Reason Spirometry not done**	1=Medical exclusion, 2=Refused, 3=equipment problems 4=Other
|__| **Post Albuterol Spirometry**	0=Not Done, 1=Done, 2=Attempted, not finished, 3= Attempted, tech aborted ,4=Other
|__| **Reason Post Alb. Spir. not done**	1=Medical exclusion, 2=Refused, 3=equipment problems 4=Other 5=Do not qualify
|__| **Diffusion Capacity**	0=Not Done, 1=Done, 2=Attempted, not finished, 3= Attempted, tech aborted ,4=Other
|__| **Reason Diffusion not done**	1=Medical exclusion, 2=Refused, 3=equipment problems 4=Other
|__| **Accelerometer**	

TECH02

For Participants Who Wish to Complete Their Exam on a Second Visit (Split Exam)

|__|__|*|__|__|*|__|__|__|__|	**Second Exam Date** *(If participant returns to finish their clinic exam on a date other than the original exam date, then fill in the date they return here. Otherwise leave entire page completely blank)*

Keyers: if Second Exam Date is not filled and page is blank' then leave the page all blank.

*Fill in with 1=yes if procedure **was done** on the **Second** Exam Date and 0=no if procedure **was not done** on the **Second** Exam Date. Note that informed consent from first visit will cover the second visit.*

Procedures Sheet

0=No, 1=Yes, 8=Offsite visit

|__|	**Type of Exam**	1=Complete exam, 2=Split exam(exam completed in 2 visits), 3=short exam (incomplete exam), 8=offsite
|__|	**Urine Specimen**	
|__|	**Blood Draw**	
|__|	**Mini-Mental Status Exam**	
|__|	**Anthropometry**	
|__|	**Sociodemographic Questions** (self administered)	
|__|	**SF-12 Health Survey**	
|__|	**CES-D Scale**	
|__|	**NAGI, Rosow-Breslau, Katz**	
|__|	**Exercise Questionnaire**	
|__|	**ECG**	
|__|	**P Wave Signal Averaged ECG**	
|__|	**If not performed why:** 1=AF, 2=Pacemaker, 3=Pat. ran out of time, 4=Pat. couldn't lie flat, 5=equipment malfunction, 6=other	
|__|	**Observed performance (**Timed walk, hand grip, chair stands)	
|__|	**Tonometry**	
|__|	**Ankle-brachial blood pressure by Doppler.** *(Participants ≥ 40 years)*	
|__|	**Spirometry**	0=Not Done, 1=Done, 2=Attempted, not finished, 3= Attempted, tech aborted ,4=Other
|__|	**Reason Spirometry not done**	1=Medical exclusion, 2=Refused, 3=equipment problems 4=Other
|__|	**Post Albuterol Spirometry**	0=Not Done, 1=Done, 2=Attempted, not finished, 3= Attempted, tech aborted ,4=Other
|__|	**Reason Post Alb. Spir. not done**	1=Medical exclusion, 2=Refused, 3=equipment problems 4=Other 5=Do not qualify
|__|	**Diffusion Capacity**	0=Not Done, 1=Done, 2=Attempted, not finished, 3= Attempted, tech aborted ,4=Other
|__|	**Reason Diffusion not done**	1=Medical exclusion, 2=Refused, 3=equipment problems 4=Other
|__|	**Accelerometer**	

TECH03

☐ Check here if whole page is blank. Reason why_____

Exit Interview

|__|__|__| **Technician Number**

|__| **Procedure sheet reviewed**

|__| **Referral sheet reviewed**

|__| **Left clinic w/ belongings**

0=No
1=Yes
8=Offsite
9=Unk.

|__| **Dietary questionnaire provided** 1=Brought to exam completed or filled out in clinic, 2=Given in clinic to complete at home and send back, 3=Other, 8=Offsite, 9=Unk.

|__| **Left clinic with accelerometer** 0=No, refused, 1=Yes, 2=it will be mailed to them, 8=Offsite, 9=Unk.

|__| **Feedback** 0=No feedback, 1=Positive feedback, 2=Negative feedback, 3=Other, 9=Unk.

Comments_____

_____

_____

CLINIC visit only

|__|__|__| **Technician Number**

|__| **Was there an adverse event in clinic that does not require further medical evaluation?** (0=No, 1=Yes, 9=Unk.)
Comments:_____
_____

OFFSITE visit only

|__|__|__| **Technician Number**

|__| **Was a FHS physician contacted during the examination due to adverse exam finding?** (0=No, 1=Yes, 9=Unk.)
Comments:_____
_____

|__|__|__| **Technician who reviewed TECH portion of exam**

Your exam today was for research purposes only and is not designed to make a medical diagnosis. The exam cannot identify all serious heart and health issues. It is important that you continue regular follow-up with your physician or health care provider.

TECH04

MMSE-Cognitive Function-Part I

☐	Check here if whole page is blank. Reason why_____

I'm going to start by asking questions that require concentration and memory. Some questions are more difficult than others and some will be asked more than one time.

|__|__|__|	**Technician Number**

SCORE	*Write all responses on exam form* 0=incorrect, 1-3=score 1 point for each correct response, 6=item administered, Participant doesn't answer, 9=Unk.
0 1 2 3 6 9	**What Is the Date Today?** *(Month, day, year, correct score=3)*
0 1 6 9	**What Is the Season?**
0 1 6 9	**What Day of the Week Is it?**
0 1 2 3 6 9	**What Town, County and State Are We in?** *(Town, county, state, correct score=3)*
0 1 6 9	**What Is the Name of this Place?** *(any appropriate answer all right, for instance my home, street address, heart study..max score=1)*
0 1 6 9	**What Floor of the Building Are We on?**
0 1 2 3 6 9	**I am going to name 3 objects. After I have said them I want you to repeat them back to me. Are you ready? Apple, Table, Penny. Could you repeat the three items for me** **Remember what they are because I will ask you to name them again in a few minutes.**
|__|__|__|__|__|	**Now I am going to spell a word forward and I want you to spell it backwards. The word is world. W-O-R-L-D.** **Please Spell it in Reverse Order.** *(Letters Are Entered and Scored Later)*
	Score as 66666=Not administered for reason unrelated to cognitive status 00000=Administered, but couldn't do 99999=Unk.
0 1 2 3 6 9	**What are the 3 objects I asked you to remember a few moments ago?**

TECH05

MMSE-Cognitive Function -Part II

☐ Check here if whole page is blank. Reason why_____

SCORE	*Write all responses on exam form* 0=incorrect, 1-3=score 1 point for each correct response, 6=item administered, Participant doesn't answer, 9=Unk.
0 1 6 9	**What Is this Called?** (Watch)
0 1 6 9	**What Is this Called?** (Pencil)
0 1 6 9	**Please Repeat the Following: "No Ifs, Ands, or Buts."** (Perfect=1)
0 1 6 9	**Please Read the Following & Do What it Says** *(performed=1, code 6 if low vision)*
0 1 6 9	**Please Write a Sentence** (*code 6 if low vision)*
0 1 6 9	**Please Copy this Drawing** *(code 6 if low vision)*
0 1 2 3 6 9	**Take this piece of paper in your right hand, fold it in half with both hands, and put in your lap** *(score 1 for each correctly performed act, code 6 if low vision)*

No Yes Maybe Unk. *(coding for below)*				**Factor Potentially Affecting Mental Status Testing**
0	1	2	9	**Not fluent in English**
0	1	2	9	**Poor eyesight**
0	1	2	9	**Poor hearing**
0	1	2	9	**Other, write in** _____

TECH06

Sentence and Design Handout for Participant

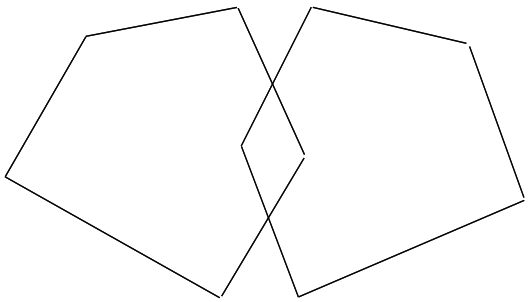
PLEASE WRITE A SENTENCE

_____

_____

_____

PLEASE COPY THIS DESIGN



Socio-demographic Questionnaire
(Tech-administered)

☐ Check here if whole page is blank. Reason why_____

|__|__|__| **Technician Number**

Socio-demographics

|__| **Where do you live?** (0=Private residence, 1=Nursing home, 2=Other, setting (no longer able to live independently) such as assisted living, 9=Unk.)

|__| **Does anyone live with you?** (0=No, 1=Yes, 9=Unk.)
Code Nursing Home Residents as NO

If Yes, fill ☞

|__| Spouse
|__| Significant Other
|__| Children
|__| Friends
|__| Relatives

0=No
1=Yes, more than 3 months per year
2=Yes, less than 3 months per year
9=Unk.

If 0 or 9, skip to next table

Use of Nursing and Community Services

|__| **Have you been admitted to a nursing home (or skilled facility) in the past year?**

|__| **In the past year, have you been visited by a nursing service, or used home, community, or adult day care programs?** (examples: home health aide, visiting nurses, etc)

0=No
1=Yes
9=Unk.

TECH07

Nagi Questions

(Tech-administered)

☐ Check here if whole page is blank. Reason why_____

|__|__|__| **Technician Number**

Nagi Questions

For each activity tell me whether you have:

(0) No Difficulty
(1) A Little Difficulty
(2) Some Difficulty
(3) A Lot Of Difficulty
(4) Unable To Do
(5) Don't Do On Physician or Health Care Provider Orders
(6) Don't Know
(9) Unk.

|__|	**Pulling or pushing large objects like a living room chair**
|__|	**Either stooping, crouching, or kneeling**
|__|	**Reaching or extending arms below shoulder level**
|__|	**Reaching or extending arms above shoulder level**
|__|	**Either writing, or handling, or fingering small objects**
|__|	**Standing in one place for long periods, say 15 minutes**
|__|	**Sitting for long periods, say 1 hour**
|__|	**Lifting or carrying weights under 10 pounds** *(like a bag of potatoes)*
|__|	**Lifting or carrying weights over 10 pounds** *(like a very heavy bag of groceries)*

TECH08

Rosow-Breslau Scale and Katz Activities of Daily Living
(Tech-administered)

☐ Check here if whole page is blank. Reason why_____

|__|__|__| **Technician Number**

Rosow-Breslau Questions

|__|	**Are you able to do heavy work around the house, like shoveling snow or washing windows, walls, or floors without help?**	0=No 1=Yes 9=Unk.
|__|	**Are you able to walk half a mile without help? (About 4-6 blocks)**	
|__|	**Are you able to walk up and down one flight of stairs without help?**	

Katz ADLs

During the Course of a Normal Day, can you do the following activities independently or do you need help from another person or use special equipment or a device?
0=No help needed, independent,
1=Uses device, independent,
2=Human assistance needed, minimally dependent,
3=Dependent,
4=Does not do during a normal day,
9=Unk.

|__|	**Dressing** (undressing and redressing) *Devices such as: velcro, elastic laces*
|__|	**Bathing** (including getting in and out of tub or shower) *Devices such as: bath chair, long handled sponge, hand held shower, safety bars*
|__|	**Eating** *Devices such as: rocking knife, spork, long straw, plate guard.*
|__|	**Transferring**(getting in and out of a chair) *Devices such as: sliding board, grab bars, special seat*
|__|	**Toileting Activities** (using bathroom facilities and handle clothing) *Devices such as: special toilet seat, commode*

TECH09

Fractures

☐ Check here if whole page is blank. Reason why_____

|__|__|__| **Technician Number**

Fractures

|__| **Since Your Last Clinic Visit Have You Broken Any Bones?**
(0=No, 1=Yes, 2=Maybe, 9=Unk.)

If Yes, fill ☞

|__|__| **Location of fracture:**

|__|__| **Location of second fracture** (if more than one)**:**

|__|__| **Location of third fracture** (if more than two)**:**

Code for Location (*code Unk. as 99***)**
1= Clavicle (collar bone)
2=Upper arm (humerus) or elbow
3=Forearm or wrist
4=Hand
5=Back *(If disc disease only, code as no)*
6=Pelvis
7=Hip
8=Leg
9=Foot
10=Other, specify_____

TECH10

Physical Activity Questionnaire Part 1--Framingham Heart Study
Tech-administered

☐ Check here if whole page is blank. Reason why_____

|__|__|__| **Technician Number**

Rest and Activity for a Typical Day over the past year (A typical day = most days of the week) (*Activities must equal 24 hours*)	**Number of hours**
Sleep - Number of hours that you typically sleep?	_____
Sedentary - Number of hours typically sitting? Such as reading, watching TV, using the computer, doing handcrafts	_____
Slight Activity - Number of hours with activities such as standing, walking?	_____
Moderate Activity - Number of hours with activities such as housework (vacuum, dust, yard chores, climbing stairs; light sports such as bowling, golf)?	_____
Heavy Activity - Number of hours with activities such as heavy household work, heavy yard work such as stacking or chopping wood, exercise such as intensive sports--jogging, swimming etc.?	_____
Total number of hours *(should be the total of above items)*	**24**

|__|	**Over the past 7 days, how often did you participate in SITTING ACTIVITIES such as reading, watching TV, using the computer, or doing handcrafts?**
	0 = Never 1 = Seldom/1-2 days 2 = Sometimes/3-4 days 3 = Often/5-7 days 8 = refused 9 = Don't know/Unknown
|__|	**Over the past 7 days, how many hours per day did you engage in these sitting activities?**
	1 = less than 1 hour 2 = 1 hour but less than 2 hours 3 = 2-4 hours 4 = more than 4 hours 8 = refused 9 = Don't know/Unknown

TECH11

Physical Activity Questionnaire Part 2--Framingham Heart Study

Tech-administered

☐ Check here if whole page is blank. Reason why_____

|__|__|__| **Technician Number**

I am going to read a list of activities. Please tell me which activities you have done in the past year.

	During the past year did you (do)? 0=No, 1=Yes, 8=Refused, 9=Unk.	**In a typical 2 week period of time, how often do you** *(name of activity)*	**Average time/session** hours	minutes	**Number months/year** 0-12
|__|	**Walk** *(walking to work, walking the dog, walking in the mall)*	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Calisthenics/general exercise** (yoga, pilates)	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Exercise cycle, ski or stair machine** (*treadmill, elliptical, stair master, etc.)*	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Exercises to increase muscle strength or endurance -Weight training** *(free weights, machines)*	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Moderate/strenuous household chores** *(vacuuming, scrubbing floors, washing windows, carrying wood)*	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Jog**	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Bike**	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Dance**	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Aerobics**	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Swim**	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Tennis**	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Golf (no cart)**	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Lawn work or yard care*** *(Mowing the lawn, snow or leaf removal)*	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Outdoor Gardening**	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Hike**	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Light sport or recreational activities** *(bowling, golf with a cart, shuffleboard, fishing, ping-pong)*	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Other*, write in**_____ _____	|__|__|	|__|__|	|__|__|	|__|__|

TECH12

CES-D Scale

Tech-administered

☐ Check here if whole page is blank. Reason why_____

|__|__|__| **Technician Number**

The questions below ask about your feelings. For each statement, please say how often you felt that way during the past week.

	Circle best answer for each question			
DURING THE PAST WEEK	**Rarely or none of the time (less than 1 day)**	**Some or a little of the time (1-2 days)**	**Occasionally or moderate amount of time (3-4 days)**	**Most or all of the time (5-7 days)**
***I was bothered by things that usually don't bother me.**	**0**	**1**	**2**	**3**
I did not feel like eating; my appetite was poor.	**0**	**1**	**2**	**3**
I felt that I could not shake off the blues, even with help from my family and friends.	**0**	**1**	**2**	**3**
I felt that I was just as good as other people.	**0**	**1**	**2**	**3**
I had trouble keeping my mind on what I was doing.	**0**	**1**	**2**	**3**
***I felt depressed.**	**0**	**1**	**2**	**3**
I felt that everything I did was an effort.	**0**	**1**	**2**	**3**
I felt hopeful about the future.	**0**	**1**	**2**	**3**
I thought my life had been a failure.	**0**	**1**	**2**	**3**
I felt fearful.	**0**	**1**	**2**	**3**
***My sleep was restless.**	**0**	**1**	**2**	**3**
I was happy.	**0**	**1**	**2**	**3**
I talked less than usual.	**0**	**1**	**2**	**3**
I felt lonely.	**0**	**1**	**2**	**3**
People were unfriendly.	**0**	**1**	**2**	**3**
I enjoyed life.	**0**	**1**	**2**	**3**
I had crying spells.	**0**	**1**	**2**	**3**
I felt sad.	**0**	**1**	**2**	**3**
I felt that people disliked me	**0**	**1**	**2**	**3**
I could not "get going"	**0**	**1**	**2**	**3**

** Indicates that the technician should preface the statement with "During the past week"*

TECH13

Proxy form

☐ Check here if whole page is blank. Reason why_____

|__| **Proxy used to complete this exam (**0=No, 1=Yes, 1 proxy, 2=Yes, more than 1 proxy, 9=Unk.)

if yes, fill ☞

Proxy Name _____

|__| **Relationship** (1=1st Degree Relative(spouse, child), 2=Other Relative, 3=Friend, 4=Health Care Professional, 5=Other, 9=Unk.

|__|__|*|__|__| **How long have you known the participant?** (Years, months; 99.99=Unk.) example: 3m=00*03

|__| **Are you currently living in the same household with the participant?** (0=No, 1=Yes, 9=Unk.)

|__| **How often did you talk with the participant during the prior 11 months?** (1=Almost every day, 2=Several times a week, 3=Once a week, 4=1 to 3 times per month, 5=Less than once a month, 9=Unk.)

Proxy Name _____

|__| **Relationship** (1=1st Degree Relative(spouse, child), 2=Other Relative, 3=Friend, 4=Health Care Professional, 5=Other, 9=Unk.

|__|__|*|__|__| **How long have you known the participant?** (Years, months; 99.99=Unk.) example: 3 m=00*03

|__| **Are you currently living in the same household with the participant?** (0=No, 1=Yes, 9=Unk.)

|__| **How often did you talk with the participant during the prior 11 months?** (1=Almost every day, 2=Several times a week, 3=Once a week, 4=1 to 3 times per month, 5=Less than once a month, 9=Unk.)

TECH014

Observed performance Part 1
Technician Administered

☐ Check here if whole page is blank. Reason why_____	

|__|__|__|	**Technician Number**

HAND GRIP TEST *Measured to the nearest kilogram*		
Right hand		
Trial 1	99=Unk.	|__|__|
Trial 2	99=Unk.	|__|__|
Trial 3	99=Unk.	|__|__|
Left hand		
Trial 1	99=Unk.	|__|__|
Trial 2	99=Unk.	|__|__|
Trial 3	99=Unk.	|__|__|

☐	**Check if this test not completed or not attempted.**
|__|	**If not attempted or completed, why not?** 1=Physical limitation, 2=Refused, 3=Other _____write in, 9=Unk.

Protocol modification for Hand Grip , Chair stands and Walk testing
☐ **Check for Protocol modification**

Comments: _____

_____

_____

_____

TECH15

Observed performance Part 2
Technician Administered

☐ Check here if whole page is blank. Reason why_____	
|__|__|__|	**Technician Number**

Repeated Chair Stands (5)

Time to complete five stands in seconds (99.99=Unk.)	|__|__|*|__|__|
If less than five stands, enter the number (9=Unk.)	|__|
IF OFFSITE visit, Chair height (in inches, 99*99=Unk.)	|__|__|*|__|__|
☐ **Check if this test not completed or not attempted.**	
|__| **If not attempted or completed, why not?** (1=Physical limitation, 2=Refused, 3=Other _____write in, 9=Unk.)	

Measured Walks

Walking aid used: 0=No aid, 1=Cane, 2=Walker, 3=Wheelchair, 4=Other, 9=Unk. |__|

First Walk

Walk time (in seconds, 99.99=Unk.)	|__|__|*|__|__|
Laser walk time (in seconds, 99.99=Unk.)	|__|__|*|__|__|
☐ **Check if this test not completed or not attempted.**	
|__| **If not attempted or completed, why not?** (1=Physical limitation, 2=Refused, 3=Other _____write in, 9=Unk.)	

Second Walk

Walk time (in seconds, 99.99=Unk.)	|__|__|*|__|__|
Laser walk time (in seconds, 99.99=Unk.)	|__|__|*|__|__|
☐ **Check if this test not completed or not attempted.**	
|__| **If not attempted or completed, why not?** (1=Physical limitation, 2=Refused, 3=Other _____write in, 9=Unk.)	

Quick Walk

Walk time (in seconds, 99.99=Unk.)	|__|__|*|__|__|
Laser walk time (in seconds, 99.99=Unk.)	|__|__|*|__|__|
☐ **Check if this test not completed or not attempted.**	
|__| **If not attempted or completed, why not?** (1=Physical limitation, 2=Refused, 3=Other _____write in, 9=Unk.)	

Ankle Brachial Blood Pressure Measurements. Participants ≥40 years

☐ Check here if whole page is blank Reason why_____

.|__|__|__| **Technician Number** for Doppler Ankle Brachial Blood Pressure.

|__| **Have you had any problems with blood clots in your legs?**

If yes, fill ☞ ***do NOT proceed with testing in the extremity with the blood clot***

|__| **Are you being treated for this problem now?**

0=No
1=Yes

|__| **Cuff size, arm**
|__| **Cuff size, ankle**

0= pediatric, 1= regular adult
2= large adult, 3= thigh

|__|__|__| **Right arm**
|__|__|__| **Right ankle**
|__|__|__| **Left ankle**
|__|__|__| **Left arm**

300=≥300 mmHg
888= Not Done
999= Unk.

REPEAT SYSTOLIC BLOOD PRESSURE MEASUREMENTS (reverse order)

|__|__|__| **Left arm**
|__|__|__| **Left ankle**
|__|__|__| **Right ankle**
|__|__|__| **Right arm**

300=≥300 mmHg
888= Not Done
999= Unk.

THIRD SYSTOLIC BLOOD PRESSURE MEASUREMENT (order as in repeat SBP). To be obtained if initial and repeat SBP at any site differ by more than 10 mmHg. For site that differs.

|__|__|__| **Right arm**
|__|__|__| **Right ankle**
|__|__|__| **Left ankle**
|__|__|__| **Left arm**

300=≥300 mmHg
888= Not Done
999= Unk.

|__| **Right Ankle blood pressure site**
|__| **Left Ankle blood pressure site**

0= posterior tibial (ankle)
1= dorsalis pedis (foot), 8=Not Done

EXCLUSIONS:

*Enter exclusion **ONLY** if there is an 888 above*

Right	Left		
|__|	|__|	**Lower Extremity Exclusions**	1= venous stasis ulceration, or DVT 2= amputation, 3= other_____
|__|	|__|	**Upper Extremity Exclusions**	1=Mastectomy, 3= Other_____

☐ **Check if Protocol modification,** write in_____

Comments _____

_____

TECH17

Respiratory Disease Questionnaire Part 1
Technician Administered

DATE of last exam *«Lexam»*

DATE of last medical history update *«Lupdate»*

☐ Check here if whole page is blank. Reason why_____

|__|__|__| **Technician Number**

Respiratory Diagnoses

|__| **Have you ever had asthma?** (0=No, 1=Yes, 9=Unk.)

If yes, fill ☞

- |__| **Do you still have it?**
- |__| **Was it diagnosed by a doctor or other health care professional?**
- |__|__| **At what age did it start?** *(Age in years 88=N/A, 99=Unk.*
- |__|__| **If you no longer have it, at what age did it stop?** *(Age in years) 88=still have it, 99=Unk.*
- |__| **Have you received medical treatment for this in the past 12 months?**

|__| **Have you ever had hay fever** (allergy involving the nose and/or eyes)**?** (0=No, 1=Yes, 9=Unk.)

If yes, fill ☞

- |__| **Do you still have it?** (0=No, 1=Yes, 9=Unk.)

Have you ever had any of the following conditions diagnosed by a doctor or other health care professional? (0=No, 1=Yes, 9=Unk.)

- |__| **Chronic Bronchitis**
- |__| **Emphysema**
- |__| **COPD** (Chronic obstructive pulmonary disease)
- |__| **Sleep Apnea**
- |__| **Pulmonary Fibrosis**

Inhaler Use (0=No, 1=Yes)

|__| **Do you take inhalers or bronchodilators?**

If yes, fill ☞

- |__| **Do you take any of the inhaled medications**?- albuterol, ProAir, Proventil, Ventolin, pirbuterol, Maxair, levalbuterol, Xopenex, metaproterenol, Alupent, or ipratropium, Atrovent, Combivent

  If yes, fill ☞ |__|__| How many hours ago did you last use the medication, either by inhaler or nebulizer? *if last used >48 hrs ago code 88, 99= Unk.* **Time in hours 1-48**

- |__| **Do you take any of the following inhaled medications?** salmeterol, Serevent, Advair, formoterol, Foradil, Symbicort, arformoterol, Brovana, tiotropium, or Spiriva,

  If yes, fill ☞ |__|__| How many hours ago did you last use the medication, either by inhaler or nebulizer? *if last used >48 hrs ago code 88, 99=Unk.* **Time in hours 1-48**

TECH18

Respiratory Disease Questionnaire Part 2
Technician Administered

☐ Check here if whole page is blank. Reason why_____

Acute Respiratory Illnesses Since Last Exam

Since your last exam or medical history update

|__| **Have you been hospitalized because of breathing trouble or wheezing?** (0=No, 1=Yes, 9=Unk.)

If yes, fill ☞

|__|__| **How many times has this occurred?**

|__| **Were any of these hospitalizations due to a lung or bronchial problem, for example COPD, asthma, bronchitis, emphysema, or pneumonia?** (0=No, 1=Yes, 9=Unk.)

|__| **Have you required an emergency room visit or an unscheduled visit to a doctor's office or clinic because of breathing trouble or wheezing?** (0=No, 1=Yes, 9=Unk.)

If yes, fill ☞

|__|__| **How many times has this occurred?**

|__| **Were any of these emergency room or unscheduled visits due to a lung or bronchial problem, for example COPD, asthma, bronchitis, emphysema, or pneumonia?** (0=No, 1=Yes, 9=Unk.)

|__| **Have you had pneumonia (including bronchopneumonia)?** (0=No, 1=Yes, 9=Unk.)

If yes, fill ☞

|__|__| **How many times have you had pneumonia?**

The following questions are about problems which occur when you **DO NOT** have a cold or the flu. Please list problems that occurred IN THE PAST 12 MONTHS only

|__| **Have you had a problem with sneezing or a runny or blocked nose when you DID NOT have a cold or the flu?** (0=No, 1=Yes, 9=Unk.)

If yes, fill ☞

|__| **Has this nose problem been accompanied by itchy-watery eyes?** (0=No, 1=Yes, 9=Unk.)

In which of the months did this nose problem occur? (0=No, 1=Yes) *Fill in ALL months.*

|__| January	|__| July
|__| February	|__| August
|__| March	|__| September
|__| April	|__| October
|__| May	|__| November
|__| June	|__| December

TECH19

Sociodemographic questions.
Self-administered (Offsite - tech-administered)

|__|__|__| **Technician Number** for OFFSITE visit ONLY

What is your current marital status? *(check ONE)*	
☐ 1	single/never married
☐ 2	married/living as married/living with partner
☐ 3	separated
☐ 4	divorced
☐ 5	widowed
☐ 9	prefer not to answer

Please choose which of the following best describes your current employment status? *(check ONE)*	
☐ 0	homemaker, not working outside the home
☐ 1	employed (or self-employed) full time
☐ 2	employed (or self-employed) part time
☐ 3	employed, but on leave for health reasons
☐ 4	employed, but temporarily away from my job
☐ 5	unemployed or laid off
☐ 6	retired from my usual occupation and not working
☐ 7	retired from my usual occupation but working for pay
☐ 8	retired from my usual occupation but volunteering
☐ 9	prefer not to answer
☐ 10	unemployed due to disability

What is your current occupation?

Write in _____

|__|__| **Using the occupation coding sheet choose the code that best describes your occupation.**

☐ **YES**	☐ **NO**	**Do you have some form of health insurance?**
☐ **YES**	☐ **NO**	**Do you have prescription drug coverage?**

TECH20

Medication Questionnaire

Self-administered (Offsite - tech-administered)

☐	**Check if NO medication taken and leave the page BLANK**

This questionnaire refers to medication recommended to you by your doctor or health care provider. For the question below, please check YES or NO

☐ **YES**	☐ **NO**	**Did you ever forget to take your medicine?**
☐ **YES**	☐ **NO**	**Are you careless at times about taking your medicine?**
☐ **YES**	☐ **NO**	**When you feel better do you stop taking your medicine?**
☐ **YES**	☐ **NO**	**Sometimes if you feel worse when you take the medicine, do you stop taking it?**

How often do you forget to take your medicine? *(Circle only ONE)*	
1.	Never
2.	More than once per week
3	Once per week
4.	More than once per month
5.	Once per month
6.	Less than once per month.

TECH21

SF-12® Health Survey (Standard)
Self-administered

This questionnaire asks for your views about your health. This information will help you keep track of how you feel and how well you are able to do your usual activities.

Please answer every question by marking one box. If you are unsure about how to answer a question, please give the best answer you can.

---

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐	☐	☐	☐	☐

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
2. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐	☐	☐
3. Climbing **several** flights of stairs	☐	☐	☐

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Yes	No
4. Accomplished less than you would like	☐	☐
5. Were limited in the **kind** of work or other activities	☐	☐

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	Yes	No
6. Accomplished less than you would like	☐	☐
7. Didn't do work or other activities as **carefully** as usual	☐	☐

TECH22

SF-12® Health Survey (Standard)
Self-administered

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐	☐	☐	☐	☐

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks...

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
9. Have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
10. Did you have a lot of energy?	☐	☐	☐	☐	☐	☐
11. Have you felt downhearted and blue?	☐	☐	☐	☐	☐	☐

12. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

TECH23

Sleep Questionnaire. Part 1
Self-administered

What is the chance that you would doze off or fall asleep (not just "feel tired") in each of the following situations? (Circle one response for each situation. If you are never or rarely in the situation, please give your best guess for that situation)

	None	Slight	Moderate	High
Sitting and reading	**0**	**1**	**2**	**3**
Watching TV	**0**	**1**	**2**	**3**
Sitting inactive in a public place (such as theater or a meeting)	**0**	**1**	**2**	**3**
Riding as a passenger in a car for an hour without a break	**0**	**1**	**2**	**3**
Lying down to rest in the afternoon when circumstances permit	**0**	**1**	**2**	**3**
Sitting and talking to someone	**0**	**1**	**2**	**3**
Sitting quietly after a lunch without alcohol	**0**	**1**	**2**	**3**
In a car, while stopped in traffic for a few minutes	**0**	**1**	**2**	**3**

TECH24

Sleep Questionnaire Part 2
Self-administered

During the past month...	
when have you usually gone to bed at night?	|__|__|:|__|__| |__| |__| hours : min AM PM
how long has it usually taken you to fall asleep each night?	|__|__|:|__|__| hours : min
when have you usually gotten up in the morning?	|__|__|:|__|__| |__| |__| hours : min AM PM
how much *actual sleep* did you get at night?	|__|__|:|__|__| hours : min

When you experience the following situations, how likely is it for you to have difficulty sleeping?
Circle an answer even if you have not experienced these situations recently.

	Not likely	Somewhat likely	Moderately likely	Very likely
Before an important meeting the next day	**0**	**1**	**2**	**3**
After a stressful experience during the day	**0**	**1**	**2**	**3**
After a stressful experience in the evening	**0**	**1**	**2**	**3**
After getting bad news during the day	**0**	**1**	**2**	**3**
After watching a frightening movie or TV show	**0**	**1**	**2**	**3**
After having a bad day at work	**0**	**1**	**2**	**3**
After an argument	**0**	**1**	**2**	**3**
Before having to speak in public	**0**	**1**	**2**	**3**
Before going on vacation the next day	**0**	**1**	**2**	**3**

|__|	**On average over the past year, how often do you snore?**	0= Never 1= Less than 1 night per week 2= 1-2 nights per week 3= 3-5 nights per week 4= 6-7 nights per week 9= Don't know
|__|	**On average over the past year, how often do you have times when you stop breathing while you are asleep?**	

TECH25

Sleep Questionnaire Part 3
Self-administered

One hears about "morning" and "evening" types of people. Which ONE of these types do you consider yourself to be? Please **check ONE box** below

☐ 1	**Definitely a "morning" type**
☐ 2	**Rather more a "morning" than an "evening" type**
☐ 3	**Neither a "morning" nor an "evening" type**
☐ 4	**Rather more an "evening" than a "morning" type**
☐ 5	**Definitely an "evening" type**

|__|__| hour **|__|__| min** **☐ AM** **☐ PM**	**Considering only your "feeling best" rhythm, at what time would you get up if you were entirely free to plan your day?**
|__|__| hour **|__|__| min** **☐ AM** **☐ PM**	**Considering only your "feeling best" rhythm, at what time would you go to bed if you were entirely free to plan your evening?**

Have you ever been told by a doctor or other health professional that you have any of the following?

(Circle one response for each item)	No	Yes	Don't know
Sleep apnea or obstructive sleep apnea	**0**	**1**	**9**
if yes, fill ☞ Do you wear a mask ("CPAP") or other device at night to treat sleep apnea?	**0**	**1**	**9**
Insomnia	**0**	**1**	**9**
Restless legs	**0**	**1**	**9**

TECH26

Framingham Study Vascular Function Participant Worksheet

(circle on)e			**Keyer 1:** _____	**Keyer 2:** _____
0	**1**	**9**	**Have you had any caffeinated drinks in the last 6 hours?** (0=No, 1=Yes, 9=Unk.)	
		if yes fill ☞	|__|__| **How many cups?** (99=Unk.)	
0	**1**	**9**	**Have you eaten anything else including a fat free cereal bar this morning?** (0=No, 1=Yes, 9=Unknown)	
0	**1**	**9**	**Have you smoked cigarettes in the last 6 hours?** (0=No, 1=Yes, 9=Unk.)	
		if yes fill ☞	|__|__|:|__|__| **If yes, how many hours and minutes since your last cigarette?** (99:99=Unk.)	

Tonometry

|__|__|/|__|__|/|__|__|__|__|	**Date of Tonometry scan?** (99/99/9999=Unk.)
|__|__|__|	**Tonometry Sonographer ID**
|__|__|__|-|__|__|__|	**Tonometry CD number**
0 **1**	**Was Tonometry done?** 0= No, test was not attempted or done 1= Yes, test was done, even if all 4 pulses could not be acquired and recorded.
If no fill ☞	**Reason why: (***Check all that apply)*
	☐ Subject refusal
	☐ Subject discomfort
	☐ Time constraint
	☐ Equipment problem, specify _____
	☐ Other, specify _____

Not for Data Entry.

Distances:
_____Carotid(mm) _____Brachial(mm) _____Radial(mm) _____Femoral(mm)

Date of exam

_____/_____/_____

Framingham Heart Study

Summary Sheet to Personal Physician

Blood Pressure	First Reading	Second Reading
Systolic		
Diastolic		

ECG Diagnosis _____

_____

The following tests are done on a routine basis: Blood Glucose, Blood Lipids, Pulmonary Function Test (results enclosed).

Summary of Findings_____

☐ 1. **No history or physical exam findings to suggest cardiovascular disease**
(check box if applicable)

_____

_____

_____

_____

_____

_____

_____

_____
Examining Physician

The Heart Study Clinic examination is not comprehensive and does not take the place of a routine physical examination.

Referral Tracking

☐ Check here if whole page is blank. Reason why_____

|__| **if yes fill below** **Was further medical evaluation recommended for this participant?** 0=No, 1=Yes, 9=Unk.

RESULT	Reason for further evaluation: *(Check ALL that apply)*.	
☐	**Blood Pressure** **result** _____/_____ mmHg **result** _____/_____ mmHg	SBP or DBP Phone call ≥ 200 or ≥110 Expedite ≥ 180 or ≥100 Elevated ≥ 140 or ≥90
	Write in abnormality	
☐	**Abnormal laboratory result**_____	
☐	**ECG abnormality** _____	
☐	**Clinic Physician** *identified medical problem*_____	
☐	**Other** _____	

Method used to inform participant of need for further medical evaluation *(Check ALL that apply)*	
☐	**Face-to-face in clinic**
☐	**Phone call**
☐	**Result letter**
☐	**Other**

Method used to inform participant's personal physician of need for further medical evaluation *(check ALL that apply)*	
☐	**Phone call**
☐	**Result letter mailed**
☐	**Result letter FAX'd** *(inform staff if Fax needed)*
☐	**Other**

Date referral made: _____/____/_____

ID number of person completing the referral: _____

Notes documenting conversation with participant or participant's personal physician:_____

TECH27

Medical History—Hospitalizations, ER Visits, MD Visits

DATE _____

DATE of last exam *«Lexam»*

DATE of last medical history update *«Lupdate»*

Health Care

Since your last exam or medical history update

|__|__|__|	**1st Examiner ID** _____ 1st Examiner Name
|_0_|	**1st Examiner Prefix** (0=MD, 1=Tech. for OFFSITE visit)
|__|	**Hospitalizations** (*not just E.R.*) (0=No; 1=yes, hospitalization, 2=yes, more than 1 hospitalization, 9=Unk.)
|__|	**E.R. Visits** (0=No, 1=Yes, 1 visit, 2=Yes, more than 1 visit, 9=Unk.)
|__|	**Day Surgery** (0=No, 1=Yes, 9=Unk.)
|__|	**Major illness with visit to doctor** (0=No, 1=Yes, 1 visit, 2=Yes, more than 1 visit; 9=Unk.)
|__|	**Check up by doctor or other health care provider?** (0=No, 1=Yes, 9=Unk.)
|__|	**Have you had a fever or infection in <u>past two weeks</u>?** (0=No, 1=Yes, 9=Unk.)
|__|__| |__|__| |__|__|__|__| MM DD YYYY	**Date of this FHS exam** *(Today's date - See above)*

Medical Encounter	Month/Year (of last visit)	Name & Address of Hospital or Office	Doctor

MD01

Medical History—Medications

|__|	**Do you take aspirin regularly?** (0=No, 1=Yes, 9=Unk.)	
If yes,	|__|__|	**Number of aspirins taken regularly** (99=Unk.)	
fill☞	|__|	**Frequency per** (1=Day, 2=Week 3=Month, 4=Year, 9=Unk.)	
	|__|__|__|	**Usual dose** (write in mgs, 999=Unk.)	Examples: 081=baby,160=half dose, 250= like in Excedrin, 325=usual dose, 500=extra strength

Since your last exam

(0=No, 1=Yes, 9=Unk.)

|__| **Have you been told by doctor you have high blood pressure or hypertension?**
|__| **Have you taken medication for high blood pressure or hypertension?**
|__| **Have you been told by doctor you have high blood cholesterol or high triglycerides?**
|__| **Have you taken medication for high blood cholesterol or high triglycerides?**
|__| **Have you been told by doctor you have high blood sugar or diabetes?**
|__| **Have you taken medication for high blood sugar or diabetes?**
|__| **Have you taken medication for cardiovascular disease? (for example angina/chest pain, heart failure, atrial fibrillation/heart rhythm abnormality, stroke, leg pain when walking, peripheral artery disease)**

MD02

Medical History – Prescription and Non-Prescription Medications

Copy the name of medicine, the strength including units, and the total number of doses per day/week/month/year. Include vitamins and minerals.

|__| **Medication bag with medications or bottles/packs brought to exam?** (0=No 1=Yes)

*****List medications taken regularly in past month/ongoing medications*****
Code ASPIRIN ONLY on screen MD02.

☐ **Check if NO medication taken**

Medication Name (Print first 20 letters)	**Strength** (include mg, IU, etc)	**Route** 1= oral, 2=topical, 3=injection, 4=inhaled, 5=drops,6=nasal 88=other	**Number per** (circle one) #	**Number per** (circle one) day/week/month/year 1 / 2 / 3 / 4	**PRN** 0=no, 1=yes,9=Unk.	**Check if OTC med**
EXAMPLE: S A M P L E D R U G N A M E	100 mg	1	1	D W M Y	0	☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐

Continue on the next page→

MD03

Medical History – Prescription and Non-Prescription Medications

Medication Name (Print first 20 letters)	Strength (include mg, IU, etc)	Route 1= oral, 2=topical, 3=injection, 4=inhaled, 5=drops,6=nasal 88=other	Number per (circle one) #	Number per (circle one) day/week/month/year 1 / 2 / 3 / 4	PRN 0=no, 1=yes, 9-Unk	Check if OTC med.
EXAMPLE: SAMPLE DRUG NAME	100 mg	1	1	D W M Y	0	☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐

MD04

Medical History–Female Reproductive History Part 1

☐	**Check here if Male Participant (and skip to Smoking Questions page 48/MD08)**

«Meno»	**Check here if definitely menopausal (and skip to Female History Part 3 page 47)** (***preloaded from previous exam)***

|__|	**Since your last exam have you taken or used birth control pills, shots, or hormone implants for birth control or medical indications (not post menopausal hormone replacement)?** (0=no, 1=yes, now, 2=yes, not now, 9=Unk.)	
|__|	**Have you been pregnant since last exam?** (0=No, 1=Yes, 9=Unk.)	
If yes, fill☞	|__|__|	**Number of pregnancies?**	fill in number
	|__|__|	**Number of live births?**	
	|__|	**During any of these pregnancies, were you told you had high blood pressure or hypertension?**	0=No 1=Yes 9=Unk.
	|__|	**During any of these pregnancies, were you told you had eclampsia, pre-eclampsia (toxemia)?**	
	|__|	**During any of these pregnancies, were you told you had high blood sugar or diabetes?**	

MD05

Medical History–Female Reproductive History Part 2

What is the best way to describe your periods? *Check the BEST answer* – ***only one***

☐	**Not stopped**
☐	**Periods stopped due to pregnancy, breastfeeding, or hormonal contraceptive** (for example: depo-provera, progestin releasing IUD, extended release birth control pill)
☐	**Periods stopped due to low body weight, heavy exercise, or due to medication or health condition such as thyroid disease, pituitary tumor, hormone imbalance, stress,**
	Write in cause _____
☐	**Periods stopped for less than 1 year (perimenopausal)**
	|__|__| **Number of months since last period** 99=Unk.
☐	**Periods stopped for 1 year or more**
☐	**Periods stopped, but now have periods induced by hormones.**
	|__|__| **Number months stopped before hormones started.** 99=Unk.

|__|__|*|__|__|*|__|__|__|__| month day year	**When was the first day of your last menstrual period?** 99/99/9999=Unk. **88/88/8888**= periods stopped for more than 1 year or using postmenopausal hormones *If periods stopped due to pregnancy, breastfeeding, hormonal contraception or health condition code date of last menstrual period*
|__|__|	**Age when periods stopped** (00=not stopped, 99=Unk.) *If periods now induced by hormones, code age when periods naturally stopped.* *If periods stopped due to pregnancy, breastfeeding, or hormonal contraception code as 0=not stopped*
|__|	**Was your menopause natural or the result of surgery, chemotherapy, or radiation?** (0=still menstruating, 1=natural, 2=surgical, 3=chemo/radiation, 4=other, 9=Unk.) *If periods stopped due to pregnancy, breast feeding, or hormonal contraception code as 0=still menstruating*

MD06

Medical History–Female Reproductive History Part 3

Surgery History

|__| **Since your last exam have you had a hysterectomy (uterus/womb removed)?** (0=No, 1=Yes, 9=Unk.)

If yes, fill☞

|__|__| **Age at hysterectomy?** 99=Unk.

|__|__|*|__|__|__|__| **Date of surgery** (mo/yr) 99/9999=Unk.

|__| **Since last exam have you had an operation to remove one or both of your ovaries?** (0=No, 1=Yes, 9=Unk.)

If yes, fill☞

|__|__| **Age when ovaries removed?** *If more than one surgery, use age <u>at last surgery</u>* 99=Unk.

Number of ovaries removed? (check one)

☐	☐	☐	☐
1=one ovary	2=two ovaries	3= unknown number of ovaries	4= part of an ovary

|__| **Have you since your last exam taken hormone replacement therapy (estrogen/progesterone) or a selective estrogen receptor modulator (such as evista or raloxifene)?** (0=No, 1=Yes, now, 2=Yes, not now, 9=Unk.)

Comments_____

_____

_____

_____

_____

MD07

Medical History--Smoking

Cigarettes

|__| **Since your last exam have you smoked cigarettes regularly?** (0=No, 1=Yes, 9=Unk.)

If yes, fill☞

|__| **Have you smoked cigarettes regularly in the last year?** *(No means less than 1 cigarette a day for 1 year.)* (0=No, 1=Yes, 9=Unk.)

|__| **Do you now smoke cigarettes (as of 1 month ago)?** (0=No, 1=Yes, 9=Unk.)

|__|__| **How many cigarettes do you smoke per day now?** (99=Unk.)

Questions below refer to "since your last exam"

|__|__| **During the time you were smoking, on average how many cigarettes per day did you smoke** (99=Unk.)

|__|__| **If you have stopped smoking cigarettes completely, how old were you when you stopped?** (Age stopped, 00=Not stopped, 99=Unk.)

|__| **When you were smoking, did you ever stop smoking for >6 months?** (0=No, 1=Yes, 9=Unk.)

If yes, fill☞ |__|__| **For how many years in total did you stop smoking cigarettes** (01=6 months – 1 year, 99=Unk.)

Pipes or Cigars

|__| **Since your last exam, have you regularly smoked a pipe or cigar?**

If yes, fill☞ |__| Do you smoke a pipe or cigar now

0=No
1=Yes
9=Unk.

Comments:_____

_____

_____

MD08

Medical History –Alcohol Consumption

Now I will ask you questions regarding your alcohol use.

Do you drink any of the following beverages at least once a month? (0=No, 1=Yes, 9=Unk.)	
|__|	Beer
|__|	Wine
|__|	Liquor/spirits

If yes, what is your average number of servings in a typical week or month over past year? (999=Unk.)

Code alcohol intake as EITHER weekly OR monthly as appropriate.

Beverage	Per week	Per month
Beer (12oz bottle, glass, can)	|__|__|__|	|__|__|__|
Wine (red or white, 4oz glass)	|__|__|__|	|__|__|__|
Liquor/spirits (1oz cocktail/highball)	|__|__|__|	|__|__|__|

|__|__|__| **At what age did you stop drinking alcohol?** (0= Not stopped, 888=Never drank, 999=Unk.)

|__|	**Over the past year, on average on how many days per week did you drink an alcoholic beverage of any type?** (0=No drinks, 1=1or less, 9=Unk.)
|__|__|	**Over the past year, on a typical day when you drink, how many drinks do you have?** (0=No drinks, 1=1or less, 99=Unk.)
|__|__|	**What was the maximum number of drinks you had in 24 hr. period during the past month?** (0=No drinks, 1=1or less, 99=Unk.)
|__|	**Since last exam has there been a time when you drank 5 or more alcoholic drinks of any kind almost daily?** (0=No, 1=Yes, 9=Unk.)

☐ **Check if over past year participant drinks less than one alcoholic drink of any type per month.**

Comments:_____

_____

_____

MD09

Medical History—Respiratory Symptoms Part I

Cough (0=No, 1=Yes, 9=Unk.)

|__| **Do you usually have a cough?** *(Exclude clearing of the throat)*

|__| **Do you usually have a cough at all on getting up or first thing in the morning?**

If **YES** to **either** question above **answer** the following:

|__| **Do you cough like this on most days for three consecutive months or more during the past year?**

|__|__| **How many years have you had this cough?** *(# of years)* 1=1 year or less 99=Unk.

Phlegm (0=No, 1=Yes, 9=Unk.)

|__| **Do you usually bring up phlegm from your chest?**

|__| **Do you usually bring up phlegm at all on getting up or first thing in the morning?**

If **YES** to **either** question above **answer** the following:

|__| **Do you bring up phlegm from your chest on most days for three consecutive months or more during the year?**

|__|__| **How many years have you had trouble with phlegm?** *(# of years)* 1=1 year or less 99=Unk.

Wheeze (0=No, 1=Yes, 9=Unk.)

In the past 12 months…

|__| **Have you had wheezing or whistling in your chest at any time?**

if yes, fill all☞

|__| **How often have you had this wheezing or whistling?**
0=Not at all 1=MOST days or nights 2=A few days or nights a WEEK
3=A few days or nights a MONTH 4=A few days or nights a YEAR 9=Unk.

|__| **Have you had this wheezing or whistling in the chest when you had a cold?**

|__| **Have you had this wheezing or whistling in the chest apart from colds?**

|__| **Have you had an attack of wheezing or whistling in the chest that had made you feel short of breath?**

MD10

Medical History—Respiratory Symptoms Part II

Nocturnal chest symptoms (0=No, 1=Yes, 9=Unk.)

In the past 12 months…

|__| **Have you been awakened by shortness of breath?**

|__| **Have you been awakened by a wheezing/whistling in your chest?**

|__| **Have you been awakened by coughing?**

if yes, fill all☞

|__| **How often have you been awakened by coughing?**
0=Not at all 1=MOST days or nights 2=A few days or nights a WEEK
3=A few days or nights a MONTH 4=A few days or nights a YEAR 9=Unk.

Shortness of breath (0=No, 1=Yes, 9=Unk.)

Since your last exam…

|__| **Are you troubled by shortness of breath when hurrying on level ground or walking up a slight hill?**

if yes, fill all☞

|__| **Do you have to walk slower than people of your age on level ground because of shortness of breath?**

|__| **Do you have to stop for breath when walking at your own pace on level ground?**

|__| **Do you have to stop for breath after walking 100 yards (or after a few minutes) on level ground?**

|__| **Do you/have you needed to sleep on two or more pillows to help you breathe (Orthopnea)?**

|__| **Have you since last exam had swelling in both your ankles (ankle edema)?**

|__| **Have you been told by your doctor you had heart failure or congestive heart failure?**

if yes, fill☞

Name of doctor _____

Date of visit |__|__|*|__|__|*|__|__|__|__| 99/99/9999=Unk.

|__| **Have you been hospitalized for heart failure?** *(Provide details on MD01-Health Care page 41)*

CHF First Examiner Opinion

|__| **First examiner believes CHF** 0=No,1=Yes 2=Maybe, 9=Unk.

Comments_____

_____

_____

MD11

Physical Exam—Blood Pressure

Physician Blood Pressure First reading	
Systolic	**BP cuff size**
|__|__|__| to nearest 2 mm Hg	|__| 0=pedi,1=reg.adult, 2=large adult, 3= thigh, 9=Unk.
Diastolic	**Protocol modification**
|__|__|__| to nearest 2 mm Hg	|__| 0=No, 1=Yes, 9=Unk.

Comments for Protocol modification_____

_____

_____

_____

MD12

Medical History—Chest pain

|__| **Since your last exam have you experienced any chest discomfort?** *(please provide narrative comments in addition to completing the appropriate boxes)*

0=No, 1=Yes, 2=Maybe, 9=Unk.

if yes, fill ☞ and below

|__| **Chest discomfort with exertion or excitement**

|__| **Chest discomfort when quiet or resting**

Chest Discomfort Characteristics

|__|__|*|__|__|__|	**Date of onset** *(mo/yr)*	99/9999=Unk.
|__|__|__|	**Usual duration** *(minutes)*	1=1 min or less, 900=15 hrs or more, 999=Unk.
|__|__|__|	**Longest duration** *(minutes)*	1=1 min or less, 900=15 hrs or more, 999=Unk.
|__|	**Location**	0=No, 1=Central sternum and upper chest, 2=L Up Quadrant, 3=L Lower ribcage, 4=R Chest, 5=Other, 6=Combination, 9=Unk.
|__|	**Radiation**	0=No, 1=Left shoulder or L arm, 2=Neck, 3=R shoulder or arm, 4=Back, 5=Abdomen, 6=Other, 7=Combination, 9=Unk.
|__|__|__|	**Number of episodes of chest pain in past month**	999=Unk.
|__|__|__|	**Number of episodes of chest pain in past year.**	999=Unk.
|__|	**Type**	1=Pressure, heavy, vise, 2=Sharp, 3=Dull, 4=Other, 9=Unk.

|__|	**Relief by Nitroglycerin in <15 minutes**	0=No,
|__|	**Relief by Rest in <15 minutes**	1=Yes,
|__|	**Relief Spontaneously in <15 minutes**	*8=Not tried*
|__|	**Relief by Other cause in <15 minutes**	9=Unk.

|__| **Since your last exam have you been told by a doctor you had a heart attack or myocardial infarction?** 0=No, 1=Yes, 2=Maybe, 9=Unk.

if yes, fill l ☞

Name of doctor _____

Date of visit |__|__|*|__|__|*|__|__|__|__| 99/99/9999=Unk.

CHD First Examiner Opinions

0=No, 1=Yes, 2=Maybe, 8=No revasculation 9=Unk.

|__| **Angina pectoris**

if yes,fill ☞ |__| **Angina pectoris since revascularization procedure**

|__| **Coronary insufficiency**

|__| **Myocardial infarct**

Comments_____

_____

_____

Medical History—Atrial Fibrillation/Syncope

Since your last exam or medical history update…

|__| **Have you been told you have/had atrial fibrillation?** 0=No, 1=Yes, 2=Maybe, 9=Unk.

if yes,fill☞ |__|__|*|__|__|*|__|__|__|__| **Date of first episode** 99/99/9999=Unk.

|__| **ER/hospitalized or saw M.D.** 0=No, 1=Hosp/ER, 2=Saw M.D., 9=Unk.

if yes, fill☞ _____ **Name of the Hospital** (write Unk. if unknown)

_____ **Name of M.D.** (write Unk. if unknown)

|__| **Do you have a family history of a heart rhythm problem called atrial fibrillation?** 0=No, 1=Yes, 9=Unk

if yes,fill☞	**Mother**	**Father**	**Siblings**	**Children**	0=No, 1=Yes, 9=Unk.
	|__|	|__|	|__|	|__|	

|__| **Have you fainted or lost consciousness?** *(If event immediately preceded by head injury or accident code 0=No)* 0=No, 1=Yes, 2=Maybe, 9=Unk..

if yes, fill all☞

|__|__|__| **Number of episodes in the past two years** 999=Unk.

|__|__|*|__|__|__|__| **Date of first episode** *(mo/yr)* 99/9999=Unk.

|__|__|__| **Usual duration of loss of consciousness** *(minutes)* 999=Unk.,1=1 min or less

|__| **Did you have any injury caused by the event?** 0=No, 1=Yes, 2=Maybe, 9=Unk.

|__| **ER/hospitalized or saw M.D.** 0=No, 1=Hosp/ER, 2=Saw M.D., 9=Unk.

if yes, fill☞ _____ **Name of the Hospital** (write Unk.. if unknown)

_____ **Name of M.D.** (write Unk. if unknown)

|__| **Have you had a head injury with loss of consciousness?** 0=No, 1=Yes, 2=Maybe, 9=Unk.

if yes, fill☞ |__|__| * |__|__| * |__|__|__|__| **Date of serious head injury with loss of consciousness** 99/99/9999=Unk.

|__| **Have you had a seizure**? 0=No, 1=Yes, 2=Maybe, 9=Unk.

if yes,fill☞ |__|__| * |__|__| * |__|__|__|__| **Date of most recent seizure** 99/99/9999=Unk.

|__| **Are you being treated for a seizure disorder?** 0=No, 1=Yes, 2=Maybe, 9=Unk.

Syncope First Examiner Opinion

|__| **Syncope** (0=No, 1=Yes, 2=Maybe, 3=Presyncope, 9=Unk.) *needs second opinion*

if yes, fill☞

|__| **Cardiac syncope**

|__| **Vasovagal syncope**

|__| **Other-Specify:** _____

0=No, 1=Yes, 2=Maybe, 9=Unk.

Comments:_____

_____**MD14**

Medical History—Cerebrovascular Diseases

Since your last exam or medical history update have you had…

|__|	**Sudden muscular weakness**	0=No,
|__|	**Sudden speech difficulty**	
|__|	**Sudden visual defect**	1=Yes,
|__|	**Sudden double vision**	
|__|	**Sudden loss of vision in one eye**	2=Maybe,
|__|	**Sudden numbness, tingling**	9=Unk.
if yes, fill ☞	|__|	**Numbness and tingling is positional**	
|__|	**Head CT scan *OTHER THAN FOR THE FHS***	0=No,1=Yes, 2= Maybe,9=Unk.
if yes, fill ☞	|__|__| * |__|__| * |__|__|__|__|	**Date**	99/99/9999=Unk.
	_____	**Place**	
|__|	**Head MRI scan *OTHER THAN FOR THE FHS***	0=No,1=Yes, 2= Maybe,9=Unk.
if yes, fill ☞	|__|__| * |__|__| * |__|__|__|__|	**Date**	99/99/9999=Unk.
	_____	**Place**	
|__|	**Seen by neurologist** *(write in who and when below)* _____	
|__|	**Have you been told by a doctor you had a stroke or TIA** (transient ischemic attack, mini-stroke)**?**	0=No,
|__|	**Have you been told by a doctor you have Parkinson Disease?**	1=Yes,
|__|	**Have you been told by a doctor you have memory problems, dementia or Alzheimer's disease?**	2=Maybe,
|__|	**Do you feel or do other people think that you have memory problems that prevent you from doing things you've done in the past?**	9=Unk.
|__|	**Do you feel like your memory is becoming worse?**	

Cerebrovascular Disease First Examiner Opinion

|__|	**TIA or stroke took place**	0=No, 1=Yes,2=Maybe, 9=Unk.
if yes or maybe fill ☞	|__|__|*|__|__|__|__|	**Date** (*mo/yr*, 99/9999=Unk.) **Observed by**_____
	|__|__|*|__|__|*|__|__|	**Duration** (*use format days/hours/mins*, 99/99/99=Unk.)
	|__|	**Hospitalized or saw M.D.** (0=No, 1=Hosp.,2=Saw M.D, 9=Unk.) Name_____ Address_____

Comments_____

Medical History--Venous and Peripheral Arterial Disease

Venous Disease

Since your last exam or medical history update have you had…

|__| **Deep Vein Thrombosis - DVT** (blood clots in legs or arms)

|__| **Pulmonary Embolus – PE** (blood clot in lungs)

0=No,1=Yes, 2=Maybe, 9=Unk.

Peripheral Arterial Disease

Since your last exam have you had…

|__| **Do you get discomfort in either leg on walking?** (0=No, 1=Yes, 9=Unk.)

if yes, fill ☞

|__| **Does this discomfort ever begin when you are standing still or sitting?** (0=no, 1=yes, 9=Unk.)

|__|__| **When walking at an ordinary pace on level ground, how many city blocks until symptoms develop** (1=1 block or less, 99=Unk.) *where 10 blocks=1 mile, code as no if more than 98 blocks required to develop symptoms*

Left	Right	Claudication symptoms	0=No, 1=Yes, 9=Unk.
|__|	|__|	**Discomfort in calf while walking**
|__|	|__|	**Discomfort in lower extremity (not calf) while walking** Write in site of discomfort_____
	|__|	**Occurs with first steps (code worse leg)**
	|__|	**Do you get the discomfort when you walk up hill or hurry?**
	|__|	**Does the discomfort ever disappear while you are still walking?**
	|__|	**What do you do if you get discomfort when you are walking?** (1=stop, 2=slow down, 3=continue at same pace, 9=Ukn.)
	|__|__|__|	**Time for discomfort to be relieved by stopping (minutes)** (000=No relief with stopping, 999=Unk.)
	|__|__|	**Number of days/month of lower limb discomfort** (1=1 day/month or less, 99=Unk.)

|__| **Since your last exam have you been told by a doctor you have intermittent claudication or peripheral artery disease?** (0=No, 1=Yes, 9=Unk.)

if yes, fill ☞

Name of doctor _____

Date of visit |__|__|*|__|__|*|__|__|__|__| 99/99/9999=Unk.

|__| **Since your last exam have you been told by a doctor you have spinal stenosis?** (0=No, 1=Yes, 9=Unk.)

Intermittent Claudication First Examiner Opinion

|__| **Intermittent Claudication** 0=No, 1=Yes, 2=Maybe, 9=Unk.

Comments

_____

_____

MD16

Medical History-- CVD Procedures

Since your last exam or medical history update did you have any of the following cardiovascular procedures?

0=No, 1=Yes 2=Maybe, 9=Unk.	Cardiovascular Procedures *(if procedure was repeated code only first and provide narrative)*
|__|	**Heart Valvular Surgery**
if yes fill☞	|__|__|__|__| Year done (9999=Unk.)
|__|	**Exercise Tolerance Test**
if yes fill☞	|__|__|__|__| Year done (9999=Unk.)
|__|	**Coronary arteriogram**
if yes fill ☞	|__|__|__|__| Year done (9999=Unk.)
|__|	**Coronary artery angioplasty or stent**
if yes fill☞	|__|__|__|__| Year done (9999=Unk.)
|__|	**Coronary bypass surgery**
if yes fill☞	|__|__|__|__| Year done (9999=Unk.)
|__|	**Permanent pacemaker insertion**
if yes fill ☞	|__|__|__|__| Year done (9999=Unk.)
|__|	**AICD**
if yes fill ☞	|__|__|__|__| Year done (9999=Unk.)
|__|	**Carotid artery surgery or stent**
if yes fill ☞	|__|__|__|__| Year done (9999=Unk.)
|__|	**Thoracic aorta surgery**
if yes fill ☞	|__|__|__|__| Year done (9999=Unk.)
|__|	**Abdominal aorta surgery**
if yes fill ☞	|__|__|__|__| Year done (9999=Unk.)
|__|	**Femoral or lower extremity surgery**
if yes fill ☞	|__|__|__|__| Year done (9999=Unk.)
|__|	**Lower extremity amputation**
if yes fill ☞	|__|__|__|__| Year done (9999=Unk.)
|__|	**Other Cardiovascular Procedure (write in below)**
if yes fill ☞	|__|__|__|__| Year done (9999=Unk.) Description_____

Write in *other procedures, year done, and location if more than one.*

Comments:_____

Physical Exam—Blood Pressure

Physician Blood Pressure Second reading	
Systolic	**BP cuff size**
|__|__|__| to nearest 2 mm Hg	|__| 0=pedi,1=reg.adult, 2=large adult, 3= thigh, 9=Unk.
Diastolic	**Protocol modification**
|__|__|__| to nearest 2 mm Hg	|__| 0=No, 1=Yes, 9=Unk.

Comments for Protocol modification_____

_____

_____

_____

_____

History of Kidney Disease		
|__|	**Have you had a kidney stone in the past 10 years?** (0=No, 1=Yes, 9=Unk.)	
if yes, fill☞ |__|	**ER/hospitalized or saw M.D.** **(**0=No, 1=Hosp/ER, 2=Saw M.D., 9=Unk.)	
if yes, fill☞	_____	**Name of the Hospital** (write Unk.. if unknown)
	_____	**Name of M.D.** (write Unk. if unknown)

MD18

Cancer Site or Type

|__| **Since your last exam or medical history update have you had a cancer or a tumor?**
(0=No and skip to next page MD20; If 1=Yes, 2=Maybe, 9=Unk. please continue)

Check ALL that apply	Site of Cancer or Tumor	Year First Diagnosed	Cancer	Maybe cancer	Benign	Name Diagnosing M.D.	City/State of M.D.
			Check ONE				
			1	2	3		
☐	**Esophagus**		☐	☐	☐		
☐	**Stomach**		☐	☐	☐		
☐	**Colon**		☐	☐	☐		
☐	**Rectum**		☐	☐	☐		
☐	**Pancreas**		☐	☐	☐		
☐	**Larynx**		☐	☐	☐		
☐	**Trachea/Bronchus/ Lung**		☐	☐	☐		
☐	**Leukemia**		☐	☐	☐		
☐	**Skin**		☐	☐	☐		
☐	**Breast**		☐	☐	☐		
☐	**Cervix/Uterus**		☐	☐	☐		
☐	**Ovary**		☐	☐	☐		
☐	**Prostate**		☐	☐	☐		
☐	**Bladder**		☐	☐	☐		
☐	**Kidney**		☐	☐	☐		
☐	**Brain**		☐	☐	☐		
☐	**Lymphoma**		☐	☐	☐		
☐	**Other/Unk.** _____		☐	☐	☐		

|__| **Diagnostic biopsy done**? (0=No, 1=Yes, 9=Unk.)

if yes fill ☞ ___ - ___ -_____ **Date** **Location of biopsy**_____

Hosp./office name_____ **Address (city/state)**_____

Comment *(If participant has more details concerning tissue diagnosis, other hospitalization, procedures, and treatments)*

_____

_____

MD19

Physical Exam—Respiratory, Heart, Abdomen

OFFSITE VISIT – leave page BLANK

Respiratory		
|__|	**Wheezing on auscultation**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**Rales**	
|__|	**Abnormal breath sounds**	

Heart		
|__|	**S3 Gallop**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**S4 Gallop**	
|__|	**Systolic Click**	
|__|	**Neck vein distention at 90 degrees** (sitting upright)	

\|__\| **if yes, fill below** — **Systolic murmur(s)** — 0=No, 1=Yes, 2=Maybe, 9=Unk.

Murmur Location	Grade 0=No sound 1 to 6 for grade of sound heard 9=Unk.	Type 0=None 1=Ejection 2=Regurgitant 3=Other 9=Unk.	Radiation 0=None 1=Axilla 2=Neck 3=Back 4=Rt. chest 9=Unk.	Origin 0=None, indet. 1=Mitral 2=Aortic 3=Tricuspid 4=Pulm 9=Ukn.
Apex	|__|	|__|	|__|	|__|
Left Sternum	|__|	|__|	|__|	|__|
Base	|__|	|__|	|__|	|__|

\|__\| **if yes, fill** ☞ — **Diastolic murmur(s)** — 0=No, 1=Yes, 2=Maybe, 9=Unk.

\|__\| **Valve of origin for diastolic murmur(s)** (1=Mitral, 2=Aortic, 3=Both, 4=Other, 8=N/A, 9=Unk)

Abdominal Abnormalities		
|__|	**Liver enlarged**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**Surgical scar**	
|__|	**Abdominal aneurysm**	
|__|	**Abdominal bruit**	

Comments _____

_____

_____

Physical Exam--Peripheral Vessels—Veins and Arterial pulses

OFFSITE VISIT – leave page BLANK

Left	Right	Lower Extremity Abnormalities
|__|	|__|	**Stem varicose veins** *(Do not code reticular or spider varicosities)* (0=No abnormality 1=Yes 9=Unk.)
|__|	|__|	**Ankle edema** (0=No, 1=Yes, 2=Maybe, 8=absent due to amputation 9=Unk.)
|__|	|__|	**Amputation level** (0=No, 1=Toes only, 2=Foot, 3=below Knee, 4=above Knee, 5= Other, write in_____, 9=Unk.)

Artery	Pulse (0=Normal, 1=Abnormal, 9=Unk.)		Bruit (0=Normal, 1=Abnormal, 9=Unk.)	
	Left	Right	Left	Right
Femoral	|__|	|__|	|__|	|__|
Popliteal			|__|	|__|
Post Tibial	|__|	|__|		
Dorsalis Pedis	|__|	|__|		

Comments_____

_____

_____

MD21

Physical Exam--Neurological Exam

OFFSITE VISIT – leave page BLANK

Neurological Exam			
Left	**Right**		
|__|	|__|	**Carotid Bruit**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|		**Speech disturbance**	
|__|		**Disturbance in gait**	
|__|		**Other neurological abnormalities on exam** Specify_____	

Comments _____

_____

_____

_____

MD22

Electrocardiograph--Part I

OFFSITE ONLY		
|__|__|__|	**MD Id#**	_____ **MD Name**

Rates and Intervals		
|__|__|__|	**Ventricular rate per minute**	(999=Unk.)
|__|__|__|	**P-R Interval** (milliseconds)	(999=Fully Paced, Atrial Fib, or Unk.)
|__|__|__|	**QRS interval** (milliseconds)	(999=Fully Paced, Unk.)
|__|__|__|	**Q-T interval** (milliseconds)	(999=Fully Paced, Unk.)
|__|__|__|__|__|	**QRS angle** (put plus or minus as needed)	(e.g. -045 for minus 45 degrees, +090 for plus 90, 9999=Fully paced or Unk.)

Rhythm-predominant	
|__|	**0 or 1 = Normal sinus,** (including s.tach, s.brady, s arrhy, 1 degree AV block) **3 = 2nd degree AV block, Mobitz I (Wenckebach)** **4 = 2nd degree AV block, Mobitz II** **5 = 3rd degree AV block / AV dissociation** **6 = Atrial fibrillation / atrial flutter** **7 = Nodal** **8 = Paced** **9 = Other or combination of above (list)**

Ventricular conduction abnormalities		
|__|	**IV Block**	(0=No, 1=Yes, 9=Fully paced or Unk.)
if yes, fill ☞	|__| **Pattern**	(1=Left, 2=Right, 3=Indeterminate, 9=Unk.)
	|__| **Complete (QRS interval=.12 sec or greater)**	(0=No, 1=Yes, 9=Unk.)
	|__| **Incomplete (QRS interval = .10 or .11 sec)**	(0=No, 1=Yes, 9=Unk.)
|__|	**Hemiblock**	(0=No, 1=Left Ant, 2=Left Post, 9=Fully paced or Unk.)
|__|	**WPW Syndrome**	(0=No, 1=Yes, 2=Maybe, 9=Fully paced or Unk.)

Arrhythmias	
|__|	**Atrial premature beats** (0=No, 1=Atr, 2=Atr Aber, 9=Unk.)
|__|	**Ventricular premature beats** (0=No, 1=Simple, 2=Multifoc, 3=Pairs, 4=Run, 5=R on T, 9=Unk.)
|__|__|	**Number of ventricular premature beats in 10 seconds** (see 10 second rhythm strip)

MD23

Electrocardiograph-Part II

Myocardial Infarction Location		
|__|	**Anterior**	0=No, 1=Yes, 2=Maybe, 9=Fully paced or Unk.
|__|	**Inferior**	
|__|	**True Posterior**	

Left Ventricular Hypertrophy Criteria		
|__|	**R > 20mm in any limb lead**	0=No, 1=Yes, 9=Fully paced, Complete LBBB or Unk.
|__|	**R > 11mm in AVL**	
|__|	**R in lead I plus S in lead III ≥ 25mm**	
	Measured Voltage	
*|__|__|	**R AVL in mm** (at 1 mv = 10 mm standard) **Be sure to code these voltages**	
*|__|__|	**S V3 in mm** (at 1 mv = 10 mm standard) **Be sure to code these voltages**	
	R in V5 or V6-----S in V1 or V2	
|__|	**R≥ 25mm**	0=No, 1=Yes, 9=Fully paced, Complete LBBB or Unk.
|__|	**S≥ 25mm**	
|__|	**R or S ≥ 30mm**	
|__|	**R + S ≥ 35mm**	
|__|	**Intrinsicoid deflection ≥.05 sec**	
|__|	**S-T depression (strain pattern)**	

Hypertrophy, enlargement, and other ECG Diagnoses	
|__|	**Nonspecific S-T segment abnormality** (0=No, 1=S-T depression, 2=S-T flattening, 3=Other, 9=Fully paced or Unk.)
|__|	**Nonspecific T-wave abnormality** (0=No, 1=T inversion, 2=T flattening, 3=Other, 9=Fully paced or Unk.)
|__|	**U-wave present** (0=No, 1=Yes, 2=Maybe, 9=Paced or Unk.)
|__|	
|__|	**RVH** (0=No, 1=Yes, 2=Maybe, 9=Fully paced or Unk.; **If complete RBBB OR LBBB present, RVH=9**)
|__|	**LVH** (0=No, 1=LVH with strain, 2=LVH with mild S-T Segment Abn, 3=LVH by voltage only, 9=Fully paced or Unk., **If complete LBBB present, LVH=9)**

Comments_____

_____

_____

MD24

Clinical Diagnostic Impression--Part I

Heart Diagnoses		
|__|	**Rheumatic Heart Disease**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**Aortic Valve Disease**	
|__|	**Mitral Valve Disease**	
|__|	**Arrhythmia**	
|__|	**Other Heart Disease (includes congenital)**	
	(Specify)_____	

Peripheral Vascular Disease		
|__|	**Other Peripheral Vascular Disease**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**Other Vascular Diagnosis**	
	(Specify)_____	

Neurological Disease		
|__|	**Stroke/ TIA**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**Dementia**	
|__|	**Parkinson's Disease**	
|__|	**Adult Seizure Disorder**	
|__|	**Migraine**	
|__|	**Other Neurological Disease**	
	(Specify)_____	

Comments _____

_____

_____

_____

MD25

Clinical Diagnostic Impression--Part II. Non Cardiovascular Diagnoses

Endocrine		
|__|	**Thyroid Disease**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**Diabetes Mellitus**	
|__|	**Other endocrine disorders,** specify_____	
GU/GYN		
|__|	**Renal disease,** specify_____	0=No, 1=Yes, 2=Maybe, 8=male/female 9=Unk.
|__|	**Prostate disease**	
|__|	**Gynecologic problems,** specify_____	
Pulmonary		
|__|	**Emphysema**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**Pneumonia**	
|__|	**Asthma**	
|__|	**Other pulmonary disease,** specify_____	
Rheumatologic Disorders		
|__|	**Gout**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**Degenerative joint disease**	
|__|	**Rheumatoid arthritis**	
|__|	**Other musculoskeletal or connective tissue disease,** specify_____	
GI		
|__|	**Gallbladder disease**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**GERD/ulcer disease**	
|__|	**Liver disease**	
|__|	**Other GI disease,** specify_____	
Blood		
|__|	**Hematologic disorder**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**Bleeding disorder**	
Infectious Disease		
|__|	**Infectious Disease**	0=No, 1=Yes, 2=Maybe, 9=Unk.
if yes ☞	specify_____	
Mental Health		
|__|	**Depression**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**Anxiety**	
|__|	**Psychosis**	
|__|	**Other Mental health,** specify_____	
Other		
|__|	**Eye**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**ENT**	
|__|	**Skin**	
|__|	**Other,** specify_____	

Comments

_____

_____

MD26

Second Examiner Opinions

OFFSITE VISIT – leave page BLANK

|__|__|__| **2nd Examiner ID number** _____ **2nd Examiner Last Name**

Coronary Heart Disease

(Provide initiators, qualities, radiation, severity, timing, presence after procedures done)

Item requires 2nd opinion *Check ALL that apply.*	2nd opinion		
☐	|__|	**Congestive Heart Failure**	0=No, 1=Yes, 2=Maybe, 9=Unk.
☐	|__|	**Cardiac Syncope**	
☐	|__|	**Angina Pectoris**	
☐	|__|	**Coronary Insufficiency**	
☐	|__|	**Myocardial Infarct**	

Comments about heart disease _____

_____

_____

Intermittent Claudication

(Provide initiators, qualities, radiation, severity, timing, presence after procedures done)

Item requires 2nd opinion *Check ALL that apply.*	2nd opinion		
☐	|__|	**Intermittent Claudication**	0=No, 1=Yes, 2=Maybe, 9=Unk.

Comments about peripheral artery disease _____

_____

Cerebrovascular Disease

(Provide initiators, qualities, severity, timing, presence after procedures done)

Item requires 2nd opinion *Check ALL that apply.*	2nd opinion		
☐	|__|	**Stroke**	0=No, 1=Yes, 2=Maybe, 9=Unk.
☐	|__|	**TIA**	

Comments about possible cerebrovascular disease_____

_____

_____

Any Additional Comments for Second Examiner Opinions.

ID: «Idtype» - «Id»

Numerical Data/Anthropometry

☐ Check here if whole page is blank. Reason why_____

|__|__|__| **Technician Number** (for basic information)

Basic Information

«Sex»	**Sex of Participant** 1=Male, 2=Female
|__|	**Site of Exam** (0=Heart Study, 1=Nursing home, 2=Residence, 3=Other)
|__|__|	**Cuántos años tiene?** Age of Participant (number of years)
|__|__|	**En qué estado vive?** State do you reside in? *(If reside outside the USA, code ZZ, if plans to wear accelerometer while visiting USA code state of visit)* Code: AL, AK, AS, etc.

Anthropometry

Check Protocol Modification *ONLY if there was one and document it in Comment section*

88*88=Refused, 99*99=Not done or Unk. ***Voy a medir…***

|__|__|*|__|__|	**Height** *(inches, to next lower 1/4 inch)*	***la altura***
	☐ **Protocol modification**	
|__|__|__|	**Weight** *(to nearest pound)* (400=400 or more 888=refused, 999=Unk.)	***el peso***
	☐ **Protocol modification**	
|__|	**En el ultimo año, ha perdido más de 5 kilos?** **In the past year, have you lost more than 10 pounds?** 0=No, 1= Yes, unintentionally, NOT due to dieting or exercise 2= Yes, intentionally, due to dieting or exercise	
|__|__|__|	**Technician Number** (for anthropometry)	***Voy a medir…***
|__|__|*|__|__|	**Neck Circumference** *(inches, to next lower1/4 inch)*	***el cuello***
	☐ **Protocol modification**	
|__|__|*|__|__|	**Waist Girth at umbilicus** *(inches, to next lower 1/4 inch).*	***la cintura***
	☐ **Protocol modification**	
|__|__|*|__|__|	**Hip Girth** *(inches, to next lower 1/4 inch)*	***la cadera***
	☐ **Protocol modification**	
|__|__|*|__|__|	**Thigh Girth** *(inches, to next lower 1/4 inch)*	***el muslo***
	☐ **Protocol modification**	

Comments for ALL Protocol Modification *(specify measurement)*

_____

_____

TECH01

☐ Check here if whole page is blank. Reason why_____

Procedures Sheet

0=No, 1=Yes, 8=Offsite visit

|__| **Type of Exam**	1=Complete exam, 2=Split exam(exam completed in 2 visits), 3=short exam (incomplete exam), 8=offsite
|__| **Informed Consent Signed**	0=No, 1=Yes, 2= offspring waiver of consent, LAR, or next-of-kin
|__| **Urine Specimen**	
|__| **Blood Draw**	
|__| **Mini-Mental Status Exam**	
|__| **Anthropometry**	
|__| **Sociodemographic Questions**	
|__| **SF-12 Health Survey**	
|__| **CES-D Scale**	
|__| **NAGI, Rosow-Breslau, Katz**	
|__| **Exercise Questionnaire**	
|__| **ECG**	
|__| **P Wave Signal Averaged ECG**	
|__| **If not performed why:** 1=AF, 2=Pacemaker, 3=Pat. ran out of time, 4=Pat. couldn't lie flat, 5=equipment malfunction, 6=other	
|__| **Observed performance (**Timed walk, hand grip, chair stands)	
|__| **Tonometry**	
|__| **Ankle-brachial blood pressure by Doppler.** *(Participants ≥ 40 years)*	
|__| **Spirometry**	0=Not Done, 1=Done, 2=Attempted, not finished, 3= Attempted, tech aborted ,4=Other
|__|__| **Reason Spirometry not done**	1=Medical exclusion, 2=Refused, 3=equipment problems 4=Other
|__| **Post Albuterol Spirometry**	0=Not Done, 1=Done, 2=Attempted, not finished, 3= Attempted, tech aborted ,4=Other
|__|__| **Reason Post Alb. Spir. not done**	1=Medical exclusion, 2=Refused, 3=equipment problems 4=Other 5=Do not qualify
|__| **Diffusion Capacity**	0=Not Done, 1=Done, 2=Attempted, not finished, 3= Attempted, tech aborted ,4=Other
|__|__| **Reason Diffusion not done**	1=Medical exclusion, 2=Refused, 3=equipment problems 4=Other
|__| **Accelerometer**	

TECH02

For Participants Who Wish to Complete Their Exam on a Second Visit (Split Exam)

|__|__|*|__|__|*|__|__|__|__|	**Second Exam Date** *(If participant returns to finish their clinic exam on a date other than the original exam date, then fill in the date they return here. Otherwise leave entire page completely blank)*

Keyers: if Second Exam Date is not filled and page is blank' then leave the page all blank.

*Fill in with 1=yes if procedure **was done** on the **Second** Exam Date and 0=no if procedure **was not done** on the **Second** Exam Date. Note that informed consent from first visit will cover the second visit.*

Procedures Sheet

0=No, 1=Yes, 8=Offsite visit

|__|	**Type of Exam**	1=Complete exam, 2=Split exam(exam completed in 2 visits), 3=short exam (incomplete exam), 8=offsite
|__|	**Urine Specimen**	
|__|	**Blood Draw**	
|__|	**Mini-Mental Status Exam**	
|__|	**Anthropometry**	
|__|	**Sociodemographic Questions**	
|__|	**SF-12 Health Survey**	
|__|	**CES-D Scale**	
|__|	**NAGI, Rosow-Breslau, Katz**	
|__|	**Exercise Questionnaire**	
|__|	**ECG**	
|__|	**P Wave Signal Averaged ECG**	
|__|	**If not performed why:** 1=AF, 2=Pacemaker, 3=Pat. ran out of time, 4=Pat. couldn't lie flat, 5=equipment malfunction, 6=other	
|__|	**Observed performance (**Timed walk, hand grip, chair stands)	
|__|	**Tonometry**	
|__|	**Ankle-brachial blood pressure by Doppler.** *(Participants ≥ 40 years)*	
|__|	**Spirometry**	0=Not Done, 1=Done, 2=Attempted, not finished, 3= Attempted, tech aborted ,4=Other
|__|__|	**Reason Spirometry not done**	1=Medical exclusion, 2=Refused, 3=equipment problems 4=Other
|__|	**Post Albuterol Spirometry**	0=Not Done, 1=Done, 2=Attempted, not finished, 3= Attempted, tech aborted ,4=Other
|__|__|	**Reason Post Alb. Spir. not done**	1=Medical exclusion, 2=Refused, 3=equipment problems 4=Other 5=Do not qualify
|__|	**Diffusion Capacity**	0=Not Done, 1=Done, 2=Attempted, not finished, 3= Attempted, tech aborted ,4=Other
|__|__|	**Reason Diffusion not done**	1=Medical exclusion, 2=Refused, 3=equipment problems 4=Other 5=Do not qualify
|__|	**Accelerometer**	

TECH03

☐ Check here if whole page is blank. Reason why_____

Exit Interview

|__|__|__| **Technician Number**

|__| **Procedure sheet reviewed**

|__| **Le recomendó el doctor que viera a alguien?** Referral sheet reviewed

|__| **Se lleva todo lo que trajo? No deja nada en el locker?** Left clinic w/ belongings

0=No
1=Yes
8=Offsite
9=Unk.

|__| **Nos dió el cuestionario de la dieta?** Dietary questionnaire provided
1=Brought to exam completed or filled out in clinic,
2=Given in clinic to complete at home and send back, 3=Other, 8=Offsite, 9=Unk.

|__| **Lleva el acelerómetro?** Left clinic with accelerometer 0=No, refused, 1=Yes, 2=it will be mailed to them, 8=Offsite, 9=Unk.

|__| **Tiene comentarios o sugerencias?** Feedback 0=No feedback, 1=Positive feedback, 2=Negative feedback, 3=Other, 9=Unk.

Comments_____

_____

_____

CLINIC visit only

|__|__|__| **Technician Number**

|__| **Was there an adverse event in clinic that does not require further medical evaluation?** (0=No, 1=Yes, 9=Unk.)
Comments:_____
_____

OFFSITE visit only

|__|__|__| **Technician Number**

|__| **Was a FHS physician contacted during the examination due to adverse exam finding?** (0=No, 1=Yes, 9=Unk.)
Comments:_____
_____

|__|__|__| **Technician who reviewed TECH portion of exam**

El examen de hoy fue hecho con propósitos de investigación médica solamente, y no está diseñado para hacer diagnósticos clínicos. Este examen no puede identificar todos los problemas del corazón y salud en general. Es importante que usted continúe viendo a su doctor para examenes físicos regulares.

TECH04

MMSE-Cognitive Function-Part I

☐ Check here if whole page is blank. Reason why_____

Voy a hacerle unas preguntas que requieren concentración y memoria. Algunas preguntas son mas difíciles que otras y algunas se preguntan mas de una vez.

I'm going to start by asking questions that require concentration and memory. Some questions are more difficult than others and some will be asked more than one time.

|__|__|__| **Technician Number**

SCORE	*Write all responses on exam form* 0=incorrect, 1-3=score 1 point for each correct response, 6=item administered, Participant doesn't answer, 9=Unk.
0 1 2 3 6 9	**Cuál es la fecha de hoy?** What Is the Date Today? *(Month, day, year, correct score=3)*
0 1 6 9	**En que estación del año estamos?** What Is the Season?
0 1 6 9	**Que día de la semana es?** What Day of the Week Is it?
0 1 2 3 6 9	**En qué pueblo, condado y estado estamos?** What Town, County and State Are We in? *(Town, county, state, correct score=3)*
0 1 6 9	**Como se llama este lugar?** What Is the Name of this Place? *(any appropriate answer all right, for instance my home, street address, heart study..max score=1)*
0 1 6 9	**En qué piso estamos?** What Floor of the Building Are We on?
0 1 2 3 6 9	**Voy a nombrar 3 objetos. Cuando haya terminado quiero que los repita después de mí. Listo? Manzana, Tabla, Centavo. Puede repetirlos? Recuérdelos porque le voy a pedir que me los repita en unos minutos**. I am going to name 3 objects. After I have said them I want you to repeat them back to me. Are you ready? Apple, Table, Penny. Could you repeat the three items for me . Remember what they are because I will ask you to name them again in a few minutes.
|__|__|__|__|__|	**Ahora voy a decir una palabra y quiero que me la deletree al revés (para atrás). La palabra es mundo. M-U-N-D-O Por favor deletreélo al revés.** Now I am going to spell a word forward and I want you to spell it backwards. The word is world. W-O-R-L-D. Please Spell it in Reverse Order. *(Letters Are Entered and Scored Later)*
	Score as 66666=Not administered for reason unrelated to cognitive status 00000=Administered, but couldn't do 99999=Unk.
0 1 2 3 6 9	**Cuáles eran los 3 objetos que le pedí que recordara hace unos momentos?** What are the 3 objects I asked you to remember a few moments ago?

TECH05

MMSE-Cognitive Function -Part II

☐ Check here if whole page is blank. Reason why_____

SCORE	*Write all responses on exam form* 0=incorrect, 1-3=score 1 point for each correct response, 6=item administered, Participant doesn't answer, 9=Unk.
0 1 6 9	**Cómo se llama esto**? **(Reloj)** What Is this Called? (Watch)
0 1 6 9	**Como se llama esto? (Lápiz)** What Is this Called? (Pencil)
0 1 6 9	**Por favor repita lo siguiente: "No hay pero que valga"** Please Repeat the Following: "No Ifs, Ands, or Buts." (Perfect=1)
0 1 6 9	**Por favor lea esto y hága lo que dice.** Please Read the Following & Do What it Says *(performed=1, code 6 if low vision)*
0 1 6 9	**Por favor escriba una oración.** Please Write a Sentence *(code 6 if low vision)*
0 1 6 9	**Por favor copie este dibujo.** Please Copy this Drawing *(code 6 if low vision)*
0 1 2 3 6 9	**Tome este papel con su mano derecha, dóblelo por la mitad con las dos manos y póngaselo en el regazo (sobre sus piernas)** Take this piece of paper in your right hand, fold it in half with both hands, and put in your lap *(score 1 for each correctly performed act, code 6 if low vision)*

No	Yes	Maybe	Unk.	Factor Potentially Affecting Mental Status Testing
	(coding for below)			
0	1	2	9	**Not fluent in English**
0	1	2	9	**Poor eyesight**
0	1	2	9	**Poor hearing**
0	1	2	9	**Other, write in** _____

TECH06

Sentence and Design Handout for Participant

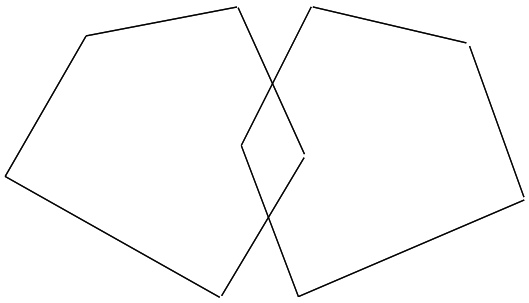
POR FAVOR ESCRIBA UNA ORACION
PLEASE WRITE A SENTENCE

_____

_____

_____

POR FAVOR COPIE ESTE DIBUJO
PLEASE COPY THIS DESIGN



Socio-demographic Questionnaire
(Tech-administered)

☐ Check here if whole page is blank. Reason why_____

|__|__|__| **Technician Number**

Socio-demographics

|__| **Dónde vive?** Where do you live? (0=Private residence, 1=Nursing home, 2=Other, setting (no longer able to live independently) such as assisted living, 9=Unk.)

|__| **Alguien más vive con usted?** Does anyone live with you? (0=No, 1=Yes, 9=Unk.)
Code Nursing Home Residents as NO

If Yes, fill ☞

|__| Esposo	Spouse
|__| Pareja	Significant Other
|__| Hijos	Children
|__| Amigos	Friends
|__| Parientes	Relatives

If 0 or 9, skip to next table

0=No
1=Yes, more than 3 months per year
2=Yes, less than 3 months per year
9=Unk.

Use of Nursing and Community Services

|__| **En el último año, llegó a vivir en un hogar para ancianos o en un asilo?**
Have you been admitted to a nursing home (or skilled facility) in the past year?

|__| **En el último año ha sido visitado por enfermeras de agencia o ha usado programas de servicios comunitarios para asistencia?**

In the past year, have you been visited by a nursing service, or used home, community, or adult day care programs? (examples: home health aide, visiting nurses, etc)

0=No
1=Yes
9=Unk.

TECH07

Nagi Questions

(Tech-administered)

☐ Check here if whole page is blank. Reason why_____

|__|__|__| **Technician Number**

Nagi Questions

Dígame si tiene dificultad en hacer estas cosas: ¿Tiene alguna dificultad para …?
For each activity tell me whether you have:

(0) Ninguna dificultad	No Difficulty
(1) Un poco de dificultad	A Little Difficulty
(2) Alguna dificultad	Some Difficulty
(3) Mucha dificultad	A Lot Of Difficulty
(4) No lo puede hacer	Unable To Do
(5) No lo hace porque se lo ordenó un doctor o médico	Don't Do On Physician or Health Care Provider Orders
(6) No lo sabe	Don't Know
(9) Se desconoce	Unk.

|__|	**Jalar o empujar cosas grandes como un sillón** Pulling or pushing large objects like a living room chair
|__|	**Agacharse o arrodillarse** Either stooping, crouching, or kneeling
|__|	**Extender los brazos abajo del nivel del hombro** Reaching or extending arms below shoulder level
|__|	**Extender los brazos arriba del nivel del hombro** Reaching or extending arms above shoulder level
|__|	**Escribir, agarrar o manipular objetos pequeños** Either writing, or handling, or fingering small objects
|__|	**Estarse de pie por largos períodos, como 15 minutos** Standing in one place for long periods, say 15 minutes
|__|	**Estar sentado por largos ratos, como 1 hora** Sitting for long periods, say 1 hour
|__|	**Levantar o cargar cosas de menos de 5 kilos** (como una bolsa de papas) Lifting or carrying weights under 10 pounds *(like a bag of potatoes)*
|__|	**Levantar o cargar cosas de más de 5 kilos** (como una bolsa pesada del mercado) Lifting or carrying weights over 10 pounds *(like a very heavy bag of groceries)*

TECH08

Rosow-Breslau Scale and Katz Activities of Daily Living
(Tech-administered)

☐ Check here if whole page is blank. Reason why_____

|__|__|__| **Technician Number**

Rosow-Breslau Questions

|__| **Puede hacer trabajo pesado de casa como quitar nieve, lavar ventanas, paredes o pisos sin ayuda?** Are you able to do heavy work around the house, like shoveling snow or washing windows, walls, or floors without help?	0=No 1=Yes 9=Unk.
|__| **Puede caminar media milla sin ayuda (4 o 6 cuadras)** Are you able to walk half a mile without help? (About 4-6 blocks)	
|__| **Puede subir y bajar un piso de escaleras sin ayuda?** Are you able to walk up and down one flight of stairs without help?	

Katz ADLs

Durante un día normal, puede hacer las siguientes actividades independientemente o necesita ayuda de otra persona o de dispositivos o aparatos especiales?

During the Course of a Normal Day, can you do the following activities independently or do you need help from another person or use special equipment or a device?

0=No necesita ayuda, lo hace independientemente	No help needed, independent
1=Usa aparato, pero lo hace independientemente	Uses device, independent
2=Necesita ayuda de alguien, un poco dependiente	Human assistance needed, minimally dependent
3=Dependiente	Dependent
4=No lo hace en un día normal	Does not do during a normal day,
9=Se desconoce	Unk.

|__| **Vestirse** (desvestirse y vestirse) Dressing (undressing and redressing) *Devices such as: velcro, cordones elásticos* *elastic laces*
|__| **Bañarse** (incluyendo meterse y salirse de la regadera o bañera) Bathing (including getting in and out of tub or shower) *Devices such as: silla de baño, esponja de mango largo, regadera de mano, barras de seguridad.* *bath chair, long handled sponge, hand held shower, safety bars*
|__| **Comer** Eating *Devices such as: cuchillo o tenedor especial, popote (pajilla) largo, plato especial.* *rocking knife, spork, long straw, plate guard*
|__| **Transferirse de un lugar a otro** (sentarse o pararse de una silla) *Devices such as: barra deslizante, barandal,asiento especial.* Transferring (getting in and out of a chair) *sliding board, grab bars, special seat*
|__| **Ir al baño** (usar las facilidades del baño y lidiar con la ropa) Toileting Activities (using bathroom facilities and handle clothing) *Devices such as: escusado especial, cómodo* *special toilet seat, commode*

TECH09

Fractures

☐ Check here if whole page is blank. Reason why_____

|__|__|__| **Technician Number**

Fractures

|__| **Desde su última visita, se ha roto algún hueso?**
Since your last clinic visit have you broken any bones?
(0=No, 1=Yes, 2=Maybe, 9=Unk.)

If Yes, fill ☞

|__|__| **Location of fracture:**

|__|__| **Location of second fracture** (if more than one)**:**

|__|__| **Location of third fracture** (if more than two)**:**

Code for Location (*code Unk. as 99***)**	
1=Clavícula (hueso del cuello)	Clavicle (collar bone)
2=Brazo o codo (húmero)	Upper arm (humerus) or elbow
3=Antebrazo o muñeca	Forearm or wrist
4=Mano	Hand
5=Espalda (si solo una vertebra, ponga no)	Back *(If disc disease only, code as no)*
6=Pelvis	Pelvis
7=Cadera	Hip
8=Pierna	Leg
9=Pie	Foot
10= Otro, especifique _____	Other, specify

TECH10

Physical Activity Questionnaire Part 1--Framingham Heart Study
Tech-administered

☐ Check here if whole page is blank. Reason why_____

|__|__|__| **Technician Number**

Rest and Activity for a Typical Day over the past year (A typical day = most days of the week)(*Activities must equal 24 hours*) **"En un día típico, entre semana, cuánto tiempo se la pasa haciendo las siguientes actividades?"**	**Number of hours**
Sueño – Cuantas horas duerme normalmente? *Sleep- # of hours that you typically sleep?*	_____
Sedentario – Cuantas horas al día se la pasa sentado? *Sedentary- # of hours typically sitting?*	_____
Actividad ligera – Cuantas horas se la pasa caminando o de pie? *Slight Activity--Number of hours with activities such as standing, walking?*	_____
Actividad moderada – Cuantas horas al día hace trabajo de casa como aspirar, limpiar, subir escaleras o deportes ligeros como boliche o golf? *Moderate Activity--Number of hours with activities such as housework (vacuum, dust, yard chores, climbing stairs; light sports such as bowling, golf)?*	_____
Actividad pesada – Cuantas horas al día hace trabajos pesados en la casa o en el patio; como cortar o acomodar madera, o hacer ejercicio intenso como correr, nadar, etc.? *Heavy Activity--Number of hours with activities such as heavy household work, heavy yard work such as stacking or chopping wood, exercise such as intensive sports--jogging, swimming etc.?*	_____
Total number of hours *(should be the total of above items)*	**24**

|__| **En los últimos 7 días, que tan seguido se sentó para leer, ver TV, usar la computadora o hacer cosas manuales?**
Over the past 7 days, how often did you participate in SITTING ACTIVITIES such as reading, watching TV, using the computer, or doing handcrafts?

0 = Nunca	Never
1 = Poco/1-2 días	Seldom/1-2 days
2 = A veces /3-4 días	Sometimes/3-4 days
3 = Seguido /5-7 días	Often/5-7 days
8 = Rehusa contestar	refused
9 = No sabe / no se sabe	Don't know/Unknown

|__| **En los últimos 7 días, cuántas horas al día estuvo sentado haciendo estas actividades?**
Over the past 7 days, how many hours per day did you engage in these sitting activities?

1 = menos de 1 hora	less than 1 hour
2 = entre 1 y 2 horas	1 hour but less than 2 hours
3 = entre 2 y 4 horas	2-4 hours
4 = más de 4 horas	more than 4 hours
8 = Rehusa contestar	refused
9 = No sabe / no se sabe	Don't know/Unknown

TECH11

Physical Activity Questionnaire Part 2--Framingham Heart Study

Tech-administered

☐ Check here if whole page is blank. Reason why_____

|__|__|__| **Technician Number**

Le voy a leer una lista de actividades. Dígame si hizo alguna de estas actividades en el último año.

I am going to read a list of activities. Please tell me which activities you have done in the past year.

En el último año hizo esta actividad? During the past year did you (do)? 0=No, 1=Yes, 8=Refused, 9=Unk.		**En un período típico de 2 semanas, qué tan seguido lo hizo?** In a typical 2 week period of time, how often do you *(name of activity)*	**En promedio, cuánto tiempo por sesión** Average time/session hours	minutes	**Por cuántos meses en el año?** Number months/year 0-12
|__|	**Caminar** Walk *(walking to work, walking the dog, walking in the mall)*	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Gimnasia o ejercicio general (yoga,pilates)** Calisthenics/general exercise	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Ejercicio con elíptica, bicicleta fija o de esquiar.** Exercise cycle, ski or stair machine	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Ejercicio para incrementar la fuerza muscular y resistencia** Exercises to increase muscle strength or endurance -Weight training *(free weights, machines)*	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Actividades moderadas o pesadas de casa** (aspirar, lavar pisos o ventanas, cargar madera) Moderate/strenuous household chores *(vacuuming, scrubbing floors, washing windows, carrying wood)*	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Trotar o hacer Jogging** Jog	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Bicicleta** Bike	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Bailar** Dance	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Aerobicos** Aerobics	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Nadar** Swim	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Tenis** Tennis	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Golf (sin carro)** Golf (no cart)	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Cortar pasto** *(quitar hojas y nieve)* *Lawn, yard care (lawn mowing snow/leaf remval)*	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Jardinería** Outdoor Gardening	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Excursión al campo** Hike	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Deportes o actividades ligeras (boliche, pescar, ping pong)** Light sport or recreational activities *(bowling, golf with a cart, shuffleboard, fishing, ping-pong)*	|__|__|	|__|__|	|__|__|	|__|__|
|__|	**Otro*, escriba** Other*, write in _____	|__|__|	|__|__|	|__|__|	|__|__|

TECH12

CES-D Scale
Tech-administered

☐ Check here if whole page is blank. Reason why_____

|__|__|__| **Technician Number**

Las siguientes preguntas son acerca de su estado de ánimo durante la última semana. Por favor responda qué tan seguido se sintió así en la última semana. Las respuestas son…

The questions below ask about your feelings. For each statement, please say how often you felt that way during the past week.

During the past week…	**Circule lo que mas se acerque** *Circle best answer*			
En la última semana…	*Rarely* **Raramente** o para nada (menos de 1 día)	*Little time* **Pocas veces** (1-2 días)	*Occasionally* **Algunas veces** (3-4 días)	*Most time* **Muchas veces** (5-7 días)
***Me molestaron cosas que generalmente no me molestan** *I was bothered by things…*	**0**	**1**	**2**	**3**
Se me quitó el apetito *my appetite was poor*	**0**	**1**	**2**	**3**
Me sentí apagado y que nada ni nadie me podía ayudar *I could not shake off the blues*	**0**	**1**	**2**	**3**
Sentí que soy tan bueno como los demás *I felt I was just as good as the others*	**0**	**1**	**2**	**3**
Tuve problemas para concentrarme en lo que hacía *Had trouble focusing*	**0**	**1**	**2**	**3**
***Me sentí deprimido** *I felt depressed*	**0**	**1**	**2**	**3**
Sentí que lo que hice me costó mucho trabajo *I felt everything was an effort*	**0**	**1**	**2**	**3**
Me sentí con esperanzas sobre el futuro *I felt hopeful about the future*	**0**	**1**	**2**	**3**
Pensé que mi vida ha sido un fracaso *I thought my life has been a failure*	**0**	**1**	**2**	**3**
Me sentí con miedo *I felt fearful*	**0**	**1**	**2**	**3**
***Dormí sin descansar** *My sleep was restless*	**0**	**1**	**2**	**3**
Me sentí felíz *I was happy*	**0**	**1**	**2**	**3**
Hablé menos de lo usual *I talked less tan usual*	**0**	**1**	**2**	**3**
Me sentí solo *I felt lonely*	**0**	**1**	**2**	**3**
La gente no fué amigable *People were unfriendly*	**0**	**1**	**2**	**3**
Disfruté de la vida *I enjoyed life*	**0**	**1**	**2**	**3**
Me dió por llorar *I had crying spells*	**0**	**1**	**2**	**3**
Me sentí triste *I felt sad*	**0**	**1**	**2**	**3**
Sentí que no le agrado a los demás *I felt that people dislike me*	**0**	**1**	**2**	**3**
Sentí que no podía empezar a hacer cosas *I couldn't get going*	**0**	**1**	**2**	**3**

* Indicates that the technician should preface the statement with "During the past week"

TECH13

Proxy form

☐ Check here if whole page is blank. Reason why_____

|__| **Proxy used to complete this exam (**0=No, 1=Yes, 1 proxy, 2=Yes, more than 1 proxy, 9=Unk.)

if yes, fill ☞

Nombre del representante **Proxy Name**

_____

|__| **Relación o parentesco** Relationship (1=1st Degree Relative(spouse, child), 2=Other Relative, 3=Friend, 4=Health Care Professional, 5=Other, 9=Unk.

|__|__|*|__|__| **Hace cuánto conoce al participante?** How long have you known the participant? (Years, months; 99.99=Unk.) example: 3m=00*03

|__| **Vive actualmente en la misma casa que el participante?** Are you currently living in the same household with the participant? (0=No, 1=Yes, 9=Unk.)

|__| **Qué tan seguido habló con el participante en los últimos 11 meses?** How often did you talk with the participant during the prior 11 months? (1=Almost every day, 2=Several times a week, 3=Once a week, 4=1 to 3 times per month, 5=Less than once a month, 9=Unk.)

Nombre del representante **Proxy Name**

|__| **Relación o parentesco** Relationship (1=1st Degree Relative(spouse, child), 2=Other Relative, 3=Friend, 4=Health Care Professional, 5=Other, 9=Unk.

|__|__|*|__|__| **Hace cuánto conoce al participante?** How long have you known the participant? (Years, months; 99.99=Unk.) example: 3m=00*03

|__| **Vive actualmente en la misma casa que el participante?** Are you currently living in the same household with the participant? (0=No, 1=Yes, 9=Unk.)

|__| **Qué tan seguido habló con el participante en los últimos 11 meses?** How often did you talk with the participant during the prior 11 months? (1=Almost every day, 2=Several times a week, 3=Once a week, 4=1 to 3 times per month, 5=Less than once a month, 9=Unk.)

TECH014

Observed performance Part 1
Technician Administered

☐ Check here if whole page is blank.	Reason why_____

|__|__|__|	**Technician Number**

HAND GRIP TEST *Measured to the nearest kilogram*		
Right hand		
Trial 1	99=Unk.	|__|__|
Trial 2	99=Unk.	|__|__|
Trial 3	99=Unk.	|__|__|
Left hand		
Trial 1	99=Unk.	|__|__|
Trial 2	99=Unk.	|__|__|
Trial 3	99=Unk.	|__|__|

☐	**Check if this test not completed or not attempted.**
|__|	**If not attempted or completed, why not?** 1=Physical limitation, 2=Refused, 3=Other _____write in, 9=Unk.

Protocol modification for Hand Grip , Chair stands and Walk testing
☐ **Check for Protocol modification**

Comments: _____

_____

_____

_____

TECH15

Observed performance Part 2
Technician Administered

☐ Check here if whole page is blank. Reason why_____	
|__|__|__|	**Technician Number**

Repeated Chair Stands (5)

Time to complete five stands in seconds (99.99=Unk.) |__|__|*|__|__|

If less than five stands, enter the number (9=Unk.) |__|

IF OFFSITE visit, Chair height (in inches, 99*99=Unk.) |__|__|*|__|__|

|__| **Check if this test not completed or not attempted.**

|__| **If not attempted or completed, why not?**
(1=Physical limitation, 2=Refused, 3=Other _____write in, 9=Unk.)

Measured Walks

Walking aid used: 0=No aid, 1=Cane, 2=Walker, 3=Wheelchair, 4=Other, 9=Unk. |__|

First Walk

Walk time (in seconds, 99.99=Unk.) |__|__|*|__|__|

Laser walk time (in seconds, 99.99=Unk.) |__|__|*|__|__|

☐ **Check if this test not completed or not attempted.**

|__| **If not attempted or completed, why not?**
(1=Physical limitation, 2=Refused, 3=Other _____write in, 9=Unk.)

Second Walk

Walk time (in seconds, 99.99=Unk.) |__|__|*|__|__|

Laser walk time (in seconds, 99.99=Unk.) |__|__|*|__|__|

☐ **Check if this test not completed or not attempted.**

|__| **If not attempted or completed, why not?**
(1=Physical limitation, 2=Refused, 3=Other _____write in, 9=Unk.)

Quick Walk

Walk time (in seconds, 99.99=Unk.) |__|__|*|__|__|

Laser walk time (in seconds, 99.99=Unk.) |__|__|*|__|__|

☐ **Check if this test not completed or not attempted.**

|__| **If not attempted or completed, why not?**
(1=Physical limitation, 2=Refused, 3=Other _____write in, 9=Unk.)

Ankle Brachial Blood Pressure Measurements. Participants ≥40 years

☐ Check here if whole page is blank Reason why_____

.|__|__|__| **Technician Number** for Doppler Ankle Brachial Blood Pressure.

|__| **Ha tenido problemas con coágulos en las piernas?** *Have you had any problems with blood clots in your legs?*

If yes, fill ☞ ***do NOT proceed with testing in the extremity with the blood clot***

|__| **Está siendo tratado por este problema ahora?** Are you being treated for this problem now?

0=No
1=Yes

|__| **Cuff size, arm**
|__| **Cuff size, ankle**

0= pediatric, 1= regular adult
2= large adult, 3= thigh

|__|__|__| **Right arm**
|__|__|__| **Right ankle**
|__|__|__| **Left ankle**
|__|__|__| **Left arm**

300=≥300 mmHg
888= Not Done
999= Unk.

REPEAT SYSTOLIC BLOOD PRESSURE MEASUREMENTS (reverse order)

|__|__|__| **Left arm**
|__|__|__| **Left ankle**
|__|__|__| **Right ankle**
|__|__|__| **Right arm**

300=≥300 mmHg
888= Not Done
999= Unk.

THIRD SYSTOLIC BLOOD PRESSURE MEASUREMENT (order as in repeat SBP). To be obtained if initial and repeat SBP at any site differ by more than 10 mmHg. For site that differs.

|__|__|__| **Right arm**
|__|__|__| **Right ankle**
|__|__|__| **Left ankle**
|__|__|__| **Left arm**

300=≥300 mmHg
888= Not Done
999= Unk.

|__| **Right Ankle blood pressure site**
|__| **Left Ankle blood pressure site**

0= posterior tibial (ankle)
1= dorsalis pedis (foot)

EXCLUSIONS:

*Enter exclusion **ONLY** if there is an 888 above*

Right	Left		
|__|	|__|	**Lower Extremity Exclusions**	1= venous stasis ulceration, or DVT 2= amputation, 3= other_____
|__|	|__|	**Upper Extremity Exclusions**	1=Mastectomy, 3= Other_____

☐ **Check if Protocol modification,** write in_____

Comments _____

_____

TECH17

Respiratory Disease Questionnaire Part 1

Technician Administered

DATE of last exam *«Lexam»*

DATE of last medical history update *«Lupdate»*

☐ Check here if whole page is blank. Reason why_____

|__|__|__| **Technician Number**

Respiratory Diagnoses

|__| **Ha tenido asma?** Have you ever had asthma? (0=No, 1=Yes, 9=Unk.)

If yes, fill ☞

|__| **Todavía tiene asma?** Do you still have it?

|__| **Fue diagnosticado?** Was it diagnosed by a doctor or other health care professional?

|__|__| **Cuántos años tenía cuando empezó?** At what age did it start? *(Age in years 88=N/A, 99=Unk.*

|__|__| **Si ya no tiene, cuando paró**? If you no longer have it, at what age did it stop? *(Age in years) 88=still have it, 99=Unk.*

|__| **Le han dado tratamiento en el último año?** Have you received medical treatment for this in the past 12 months?

|__| **Ha tenido fiebre de heno? (alergia en los ojos/nariz)** Have you ever had hay fever (allergy involving the nose and/or eyes)? (0=No, 1=Yes, 9=Unk.)

If yes, fill ☞

|__| **Todavía lo tiene?** Do you still have it? (0=No, 1=Yes, 9=Unk.)

Ha sido diagnosticado por un doctor o medico con…? Have you ever had any of the following conditions diagnosed by a doctor or other health care professional? (0=No, 1=Yes, 9=Unk.)

|__| **Bronquitis crónica** *Chronic Bronchitis*

|__| **Enfisema** *Emphysema*

|__| **Enfermedad obstructiva pulmonar crónica** *COPD (Chronic obstructive pulmonary disease)*

|__| **Apnea del sueño** *Sleep Apnea*

|__| **Fibrosis Pulmonar** *Pulmonary Fibrosis*

Inhaler Use (0=No, 1=Yes)

|__| **Usa broncodilatadores?** Do you take inhalers or bronchodilators?

If yes, fill ☞

|__| **Usa alguna de las siguientes medicinas inhaladas o con nebulizador?** Albuterol, ProAir, Proventil, Ventolin, pirbuterol, Maxair, levalbuterol, Xopenex, metaproterenol, Alupent, or ipratropium, Atrovent, Combivent.

If yes, fill ☞ |__|__| **Hace cuantas horas lo usó la última vez?** How many hours ago did you use the medication, by inhaler or nebulizer? *if last used >48 hrs ago code 88, 99= Unk.* **Time in hours 1-48**

|__| **Usa alguno de estos inhaladores?** Do you take any of the following inhaled medications? salmeterol, Serevent, Advair, formoterol, Foradil, Symbicort, arformoterol, Brovana, tiotropium, or Spiriva,

If yes, fill ☞ |__|__| **Hace cuantas horas lo usó la última vez?** How many hours ago did you use the medication by inhaler or nebulizer? *if last used >48 hrs ago code 88, 99=Unk.* **Time in hours 1-48**

TECH18

Respiratory Disease Questionnaire Part 2
Technician Administered

☐ Check here if whole page is blank. Reason why_____

Acute Respiratory Illnesses Since Last Exam

Desde su último examen o actualización médica… Since your last exam or medical history update...

|__| **Ha sido hospitalizado por problemas de respiración o asma?** Have you been hospitalized because of breathing trouble or wheezing? (0=No, 1=Yes, 9=Unk.)

If yes, fill ☞ |__|__| **Cuantas veces ocurrió?** How many times has this occurred?

|__| **Alguna de estas hospitalizaciones fue por problemas del pulmón o bronquios, ej. COPD, asma, bronquitis, enfisema o pulmonía?** Were any of these hosp. due to a lung or bronchial problem, ie COPD, asthma, bronchitis, emphysema, or pneumonia? (0=No, 1=Yes, 9=Unk.)

|__| **Tuvo que ir a emergencias o al doctor inesperadamente por problemas de respiración o asma?** Have you required ER visit or an unscheduled visit to a doctor/clinic because of breathing trouble or wheezing? (0=No, 1=Yes, 9=Unk.)

If yes, fill ☞ |__|__| **Cuantas veces ocurrió?** How many times has this occurred?

|__| **Alguna de estas emergencias o visitas al doctor sin cita, fue por problemas del pulmón o bronquios, ej. COPD, asma, bronquitis, enfisema o pulmonía?** Were any of these ER or unscheduled visits due to a lung or bronchial problem; ie.COPD, asthma, bronchitis, emphysema, or pneumonia? (0=No, 1=Yes, 9=Unk.)

|__| **Ha tenido pulmonía, incluyendo bronconeumonía?** Have you had pneumonia including bronchopneumonia? (0=No, 1=Yes, 9=Unk.)

If yes, fill ☞ |__|__| **Cuántas veces ha tenido pulmonía?** How many times have you had pneumonia?

Las siguientes preguntas son sobre problemas que tenga cuando **NO** tiene gripa o catarro. Por favor dígame si ha tenido estos problemas en el último año.

*The following questions are about problems which occur when you **DO NOT** have a cold or the flu. List problems that occurred in the past 12 months only.*

|__| **Ha tenido problemas de estornudos, goteo de nariz o nariz tapada cuando NO tenía catarro o gripa?** Have you had a problem with sneezing or a runny or blocked nose when you DID NOT have a cold or the flu? (0=No, 1=Yes, 9=Unk.)

If yes, fill ☞ |__| **Este problema estaba acompañado con ojos irritados o lagrimosos?** Has this nose problem been accompanied by itchy-watery eyes? (0=No, 1=Yes, 9=Unk.)

En qué meses ocurrió esto? In which of the months did this nose problem occur? (0=No, 1=Yes) *Fill in ALL months.*

|__| **Enero**	January	|__| **Julio**	July
|__| **Febrero**	February	|__| **Agosto**	August
|__| **Marzo**	March	|__| **Septiembre**	September
|__| **Abril**	April	|__| **Octubre**	October
|__| **Mayo**	May	|__| **Noviembre**	November
|__| **Junio**	June	|__| **Diciembre**	December

TECH19

Cuestionario Sociodemográfico

Administrado por uno mismo

Sociodemographic questions.
Self-administered (Offsite - tech-administered)

|__|__|__| **Technician Number** for OFFSITE visit ONLY

Cual es su estado civil? *(marque SOLAMENTE UNA opción)*		*What is your current marital status? (check ONE)*
☐ 1	soltero, nunca ha estado casado	single/never married
☐ 2	casado, viviendo como casado o con pareja	married/living as married/living with partner
☐ 3	separado	separated
☐ 4	divorciado	divorced
☐ 5	viudo	widowed
☐ 9	prefiere no contestar	prefer not to answer

Qué describe mejor su situación de trabajo? *(Marque SOLO UNA casilla)*

Please choose which of the following best describes your current employment status? (check ONE)

☐ 0	Ama de casa, sin trabajar fuera del hogar	homemaker, not working outside the home
☐ 1	Empleado (incluye con trabajo propio) a tiempo completo	employed (or self-employed) full time
☐ 2	Empleado (incluye con trabajo propio) medio tiempo	employed (or self-employed) part time
☐ 3	Empleado pero temporalmente fuera por razones de salud	employed, but on leave for health reasons
☐ 4	Empleado pero temporalmente fuera de su trabajo	employed, but temporarily away from my job
☐ 5	Desempleado	unemployed or laid off
☐ 6	Jubilado de su ocupación habitual y sin trabajo	retired from my usual occupation and not working
☐ 7	Jubilado de su ocupación habitual pero con otro trabajo	retired from my usual occupation but working for pay
☐ 8	Jubilado de su ocupación habitual pero trabajando como voluntario	retired but volunteering
☐ 9	Prefiere no contester	prefer not to answer
☐ 10	Desempleado por discapacidad	unemployed due to disability

Cuál es su ocupación actual? Por favor, What is your current occupation?

escríbala _____

|__|__| **Usando la página con códigos de ocupaciones, escriba el código que más se acerque a su ocupación actual.** Using the occupation coding sheet choose the code that best describes your occupation

☐ **SI**	☐ **NO**	**Tiene algún seguro médico?**	Do you have some form of health insurance?
☐ **SI**	☐ **NO**	**Tiene cobertura de medicamentos recetados?**	Do you have prescription drug coverage?

TECH20

Cuestionario sobre medicinas

Administrado por uno mismo

Medications questions
Self-administered (Offsite - tech-administered)

☐ **Cheque aquí si NO toma medicinas y deje esta página en blanco**
Check if NO medication taken and leave the page BLANK

Este cuestionario es sobre medicinas prescritas por su doctor o proveedor de salud. Para las preguntas siguientes marque SI o NO

This questionnaire refers to medication recommended to you by your doctor or health care provider.For the question below, please check YES or NO

☐ **SI**	☐ **NO**	**Se le olvida a veces tomar sus medicinas?** Did you ever forget to take your medicine?
☐ **SI**	☐ **NO**	**Se descuida a veces sobre tomar sus medicinas?** Are you careless at times about taking your medicine?
☐ **SI**	☐ **NO**	**En cuanto se empieza a sentir major, deja de tomar sus medicinas?** When you feel better do you stop taking your medicine?
☐ **SI**	☐ **NO**	**A veces, si se siente peor con la medicinas, deja de tomarlas?** Sometimes if you feel worse when you take the medicine, do you stop taking it?

Qué tan seguido se olvida de tomar sus medicinas? *(Circule UN NÚMERO SOLAMENTE)*
How often do you forget to take your medicine? *(Circle only one)*

1.	**Nunca**	Never
2.	**Más de una vez por semana**	More than once per week
3	**Una vez por semana**	Once per week
4.	**Más de una vez por semana**	More than once per month
5.	**Una vez al mes**	Once per month
6.	**Menos de una vez al mes**	Less than once per month

TECH21

SF-12® Cuestionario sobre la Salud

Health Survey (Standard)

Administrado por uno mismo

Self-administered

Este cuestionario es para saber sus puntos de vista respecto a su salud. Esta información le ayudará a seguir con atención cómo se siente y qué tan bien puede realizar sus actividades diarias. Por favor responda a cada pregunta checando una casilla. Si no está seguro de cómo responder a alguna pregunta, por favor dé la respuesta que crea más cercana.

This questionnaire asks for your views about your health. This information will help you keep track of how you feel and how well you are able to do your usual activities.
Please answer every question by marking one box. If you are unsure about how to answer a question, please give the best answer you can.

1. En general, diría usted que su salud es:

In general, would you say your health is:

excellent	*very good*	*good*	*fair*	*poor*
Excelente	**Muy buena**	**Buena**	**Regular**	**Mala**
☐	☐	☐	☐	☐

Las siguientes preguntas son acerca de actividades que Ud. haría en un día normal. ¿su salud le pone limitaciones para realizar estas actividades? Si es así, ¿En qué medida?

Does your health limit you in these activities? If so, how much?

	Yes,limited a lot **Si, me limita mucho**	*Yes, limited little* **Si, me limita un poco**	*Not at all* **No me limita en absoluto**
2. **Actividades moderadas**, como mover una mesa, pasar la aspiradora, jugar boliche o golf (si lo hiciera). *Moderate activities: moving a table, vacuum cleaner, bowling, or playing golf*	☐	☐	☐
3. Subir **varios** pisos de escaleras *Climbing several flights of stairs*	☐	☐	☐

Durante las últimas 4 semanas, ¿ha tenido alguno de los siguientes problemas en su trabajo u otras actividades regulares por causa de su salud física?

During the past 4 weeks, have you had any of the following problems with your work or other regular activities as a result of your physical health?

	Si	**No**
4. Lograr hacer menos de lo que hubiera querido *Accomplished less than you would like*	☐	☐
5. Ha tenido limitaciones en **el tipo** de trabajo u otras actividades *Were limited in the kind of work or other activities*	☐	☐

Durante las últimas 4 semanas, ¿ha tenido alguno de los siguientes problemas en su trabajo u otras actividades regulares por causa de algún problema emocional (como sentirse deprimido o angustiado)?

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems?

	Si	**No**
6. Lograr hacer menos de lo que hubiera querido *Accomplished less than you'd like*	☐	☐
7. No hizo el trabajo u otras actividades con **el cuidado** de siempre *Didn't do work or other activities as carefully as usual*	☐	☐

TECH22

SF-12® Cuestionario sobre la Salud *Health Survey (Standard)*
Administrado por uno mismo *Self-administered*

8. En las últimas 4 semanas, ¿en qué medida el tener dolor corporal ha interferido con su trabajo normal (incluyendo tanto el trabajo fuera de casa como los quehaceres domésticos)?

During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all **Para nada**	*A little* **Un poco**	*moderately* **Moderadamente**	*Quite a bit* **Bastante**	*extremelly* **Extremadamente**
☐	☐	☐	☐	☐

Estas preguntas se refieren a cómo se siente Ud. y cómo le han ido las cosas durante las últimas 4 semanas. Para cada pregunta, por favor dé la respuesta que más se acerca a la manera como se ha sentido.

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling

Durante las últimas 4 semanas, ¿que tan seguido…

During the past 4 weeks, how often…

	All the time **Todo el tiempo**	*most of the time* **La mayor parte del tiempo**	*a good bit of the time* **Gran parte del tiempo**	*some of the time* **Parte del tiempo**	*a little of the time* **Una pequeña parte del tiempo**	*none of the time* **En ningún momento**
9. Se ha sentido tranquilo y en paz? *Have you felt calm and peaceful?*	☐	☐	☐	☐	☐	☐
10. Se ha sentido con mucha energía? *Did you have a lot of energy?*	☐	☐	☐	☐	☐	☐
11. Se ha sentido triste y desanimado? *Have you felt downhearted and blue?*	☐	☐	☐	☐	☐	☐

12. Durante las últimas 4 semanas ¿cuánto tiempo ha sentido que problemas de salud o problemas emocionales han interferido con sus actividades sociales (como visitar amigos, parientes, etc.)?

During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time **Todo el tiempo**	*Most of the time* **La mayor parte del tiempo**	*Some time* **Parte del tiempo**	*Little time* **Un pequeña parte del tiempo**	*None of the time* **En ningún momento**
☐	☐	☐	☐	☐

TECH23

Cuestionario sobre el sueño. Parte 1
Administrado por uno mismo

Sleep questionnaire. Part12
Self-administered

Qué posibilidad hay de que se quede dormido (no solo que se sienta cansado) en cada una de las siguientes circunstancias? (circule un número para cada situación. Si nunca se encuentra en esa situación, ponga como cree que se sentiría en esa situación)

What is the chance that you would doze off or fall asleep (not just "feel tired") in each of the following situations? (Circle one response for each situation. If you are never or rarely in the situation, please give your best guess for that situation)

	Ninguna *No*	Ligera *Slight*	Moderada *Moderate*	Alta *High*
Sentado leyendo *Sitting and reading*	**0**	**1**	**2**	**3**
Viendo televisión *Watching TV*	**0**	**1**	**2**	**3**
Sentado inactivo en un lugar público (como un cine o en una junta) *Sitting inactive in a public place (such as theatre or a meeting)*	**0**	**1**	**2**	**3**
Sentado como pasajero en un vehículo por una hora *Riding as a passenger in a car for an hour without a break*	**0**	**1**	**2**	**3**
Acostado para descansar durante la tarde si las circunstancias lo permiten *Lying down to rest in the afternoon when circumstances permit*	**0**	**1**	**2**	**3**
Sentado hablando con alguien *Sitting and talking with someone*	**0**	**1**	**2**	**3**
Sentado tranquilamente después de comer, sin alcohol *Sitting quietly after a lunch without alcohol*	**0**	**1**	**2**	**3**
En un coche, mientras ha parado por el tráfico por unos minutos *In a car, while stopped in traffic for a few minutes*	**0**	**1**	**2**	**3**

TECH24

Cuestionario sobre el sueño. Parte 2
Administrado por uno mismo

Sleep questionnaire. Part 2
Self-administered

En el último mes...	*During the past month...*
A qué hora se ha ido a la cama? *when have you usually gone to bed at night?*	|__|__|:|__|__| |__| |__| horas : min AM PM
Cuánto ha tardado en quedarse dormido cada noche? how long has it usually take you to fall asleep each night?	|__|__|:|__|__| horas : min
A qué hora se levanta por la mañana? when have you usually gotten up in the morning?	|__|__|:|__|__| |__| |__| horas : min AM PM
Cuántas horas duerme de verdad durante la noche? how much *actual sleep* did you get at night?	|__|__|:|__|__| horas : min

Cuando experimenta alguna de las siguientes situaciones, qué tan probable es que le cueste trabajo poder dormir? Circule las respuestas a todas la preguntas, incluso si no ha tenido esa experiencia recientemente.

When you experience the following situations, how likely is it for you to have difficulty sleeping?Circle an answer even if you have not experienced these situations recently.

	NO Not likely	**Poco posible** Somewhat likely	**Moderadamente posible** Moderately likely	**Muy posible** Very likely
Antes de una junta importante Before an important meeting the next day	**0**	**1**	**2**	**3**
Después de un día estresante After a stressful experience during the day	**0**	**1**	**2**	**3**
Después de una experiencia estresante en la noche After a stressful experience in the evening	**0**	**1**	**2**	**3**
Después de haber tenido malas noticias en el día After getting bad news during the day	**0**	**1**	**2**	**3**
Después de ver algo de horror en la TV After watching a frightening movie or TV show	**0**	**1**	**2**	**3**
Después de un mal día de trabajo After having a bad day at work	**0**	**1**	**2**	**3**
Después de tener un argumento After an argument	**0**	**1**	**2**	**3**
Antes de tener que hablar en público Before having to speak in public	**0**	**1**	**2**	**3**
Antes de salir de vacaciones el día siguiente Before going on vacation the next day	**0**	**1**	**2**	**3**

|__|	**En promedio en el último año, que tan seguido ronca?** On average over the past year, how often do you snore?	0= Never 1= Less than 1 night per week 2= 1-2 nights per week 3= 3-5 nights per week 4= 6-7 nights per week 9= Don't know
|__|	**En promedio en el último año, que tan seguido tiene períodos en que deja de respirar mientras duerme?** On average over the past year, how often do you have times when you stop breathing while you are asleep?	

TECH25

Cuestionario sobre el sueño. Parte 3

Administrado por uno mismo

Sleep questionnaire. Part 3

Self-administered

Uno escucha de personas que son tempraneras o noctámbulas. En cuál de estas categorías se encuentra usted? **Cheque solo UNA casilla**.

One hears about "morning" and "evening" types of people. Which one of these types do you consider yourself to be? Check box

☐ 1	**Definitivamente tempranera**	Definitely a "morning" type
☐ 2	**Mas bien tempranera que noctámbula**	Rather more a "morning" than an "evening" type
☐ 3	**Ni tempranera ni noctámbula, normal**	Neither a "morning" nor an "evening" type
☐ 4	**Mas bien noctámbula**	Rather more an "evening" than a "morning" type
☐ 5	**Definitivamente noctámbula**	Definitely an "evening" type

|__|__| |__|__| ☐ ☐ **hora min AM PM**	**Si no tuviera nada de qué preocuparse, a quá hora se despertaría naturalmente por la mañana?** Considering only your "feeling best" rhythm, at what time would you get up if you were entirely free to plan your day?
|__|__| |__|__| ☐ ☐ **hora min AM PM**	**Si no tuviera nada de qué preocuparse, a quá hora se iría a dormir naturalmente por la noche?** Considering only your "feeling best" rhythm, at what time would you go to bed if you were entirely free to plan your evening?

Alguna vez le ha dicho un doctor o medico que tiene alguna de estas cosas?

Have you ever been told by a doctor or other health professional that you have any of the following?

(Circule UNA respuesta para cada cosa) Circle one response for each item	*No* **NO**	*Yes* **SI**	*Don't know* **No sé**
Apnea del sueño o apnea del sueño obstructiva Sleep apnea or obstructive sleep apnea	**0**	**1**	**9**
Si marcó sí, ☞ **Usa una mascara CPAP u otra cosa por la noche para tartar la apnea del sueño?** Do you wear a mask ("CPAP") or other device at night to treat sleep apnea?	**0**	**1**	**9**
Insomnia Insomnia	**0**	**1**	**9**
Síndrome de piernas inquietas Restless legs	**0**	**1**	**9**

TECH26

Framingham Study Vascular Function Participant Worksheet

(circle on)e			**Keyer 1:** _____	**Keyer 2:** _____
0	**1**	**9**	**Ha tomado algo con cafeína en las últimas 6 horas?** *Have you had any caffeinated drinks in the last 6 hours?* (0=No, 1=Yes, 9=Unk.)	
		if yes fill ☞	|__|__| **Cuantas tazas?** *How many cups?* (99=Unk.)	
0	**1**	**9**	**Ha comido algo esta mañana, incluyendo una barra de cereal sin grasa?** *Have you eaten anything else including a fat free cereal bar this morning?* (0=No, 1=Yes, 9=Unknown)	
0	**1**	**9**	**Ha fumado cigarros en las últimas 6 horas***? Have you smoked cigarettes in the last 6 hours?* (0=No, 1=Yes, 9=Unk.)	
		if yes fill ☞	|__|__|:|__|__| **If yes, hace cuántas horas y minutos?** *How many hours and minutes since your last cigarette?* (99:99=Unk.)	

Tonometry

|__|__|/|__|__|/|__|__|__|__|	**Date of Tonometry scan?** (99/99/9999=Unk.)
|__|__|__|	**Tonometry Sonographer ID**
|__|__|__|-|__|__|__|	**Tonometry CD number**
0 **1**	**Was Tonometry done?** 0= No, test was not attempted or done 1= Yes, test was done, even if all 4 pulses could not be acquired and recorded.
If no fill ☞	**Reason why: (***Check all that apply)*
	☐ Subject refusal
	☐ Subject discomfort
	☐ Time constraint
	☐ Equipment problem, specify _____
	☐ Other, specify _____

Not for Data Entry.

Distances:

_____Carotid(mm) _____Brachial(mm) _____Radial(mm) _____Femoral(mm)

Date of exam

_____/_____/_____

Framingham Heart Study

Summary Sheet to Personal Physician

Blood Pressure	First Reading	Second Reading
Systolic		
Diastolic		

ECG Diagnosis _____

_____

The following tests are done on a routine basis: Blood Glucose, Blood Lipids, Pulmonary Function Test (results enclosed). Echocardiogram findings will be forwarded at a later date **only if <u>abnormal.</u>**

Summary of Findings_____

☐ 1. **No history or physical exam findings to suggest cardiovascular disease**
(check box if applicable)

_____

_____

_____

_____

_____

_____

_____

_____
Examining Physician

The Heart Study Clinic examination is not comprehensive and does not take the place of a routine physical examination.

Referral Tracking

☐ Check here if whole page is blank. Reason why_____

|__| **Was further medical evaluation recommended for this participant?** 0=No, 1=Yes, 9=Unk.

if yes fill below

RESULT	Reason for further evaluation: *(Check ALL that apply)*.	
☐	**Blood Pressure** **result** _____/_____ mmHg **result** _____/_____ mmHg	SBP or DBP Phone call ≥ 200 or ≥110 Expedite ≥ 180 or ≥100 Elevated ≥ 140 or ≥90
	Write in abnormality	
☐	**Abnormal laboratory result**_____	
☐	**ECG abnormality** _____	
☐	**Clinic Physician** *identified medical problem*_____	
☐	**Other** _____	

Method used to inform participant of need for further medical evaluation

(Check ALL that apply)

☐	**Face-to-face in clinic**
☐	**Phone call**
☐	**Result letter**
☐	**Other**

Method used to inform participant's personal physician of need for further medical evaluation *(check ALL that apply)*

☐	**Phone call**
☐	**Result letter mailed**
☐	**Result letter FAX'd** *(inform staff if Fax needed)*
☐	**Other**

Date referral made: _____/____/_____

ID number of person completing the referral: _____

Notes documenting conversation with participant or participant's personal physician:_____

TECH27

Medical History—Hospitalizations, ER Visits, MD Visits

DATE _____

DATE of last exam *«Lexam»*

DATE of last medical history update *«Lupdate»*

Health Care

Since your last exam or medical history update

|__|__|__|	**1st Examiner ID** _____ 1st Examiner Name
|_0_|	**1st Examiner Prefix** (0=MD, 1=Tech. for OFFSITE visit)
|__|	**Ha tenido hospitalizaciones?** (no sólo emergencias) *Hospitalizations (not just E.R.)* (0=No; 1=yes, hospitalization, 2=yes, more than 1 hospitalization, 9=Unk.)
|__|	**Ha ido a emergencias** ER (0=No, 1=Yes, 1 visit, 2=Yes, more than 1 visit, 9=Unk.)
|__|	**Cirugía saliendo el mismo día?** *Day Surgery* (0=No, 1=Yes, 9=Unk.)
|__|	**Visitas al doctor por cosas graves?** *Major illness with visit to doctor* (0=No, 1=Yes, 1 visit, 2=Yes, more than 1 visit; 9=Unk.)
|__|	**Chequeo médico por un doctor o enfermera?** *Check up by doctor or other health care provider?* (0=No, 1=Yes, 9=Unk.)
|__|	**Fiebre o alguna infección en las <u>últimas 2 semanas</u>?** *Have you had a fever or infection in the past two weeks?* (0=No, 1=Yes, 9=Unk.)
|__|__| |__|__| |__|__|__|__| MM DD YYYY	**Date of this FHS exam** *(Today's date - See above)*

Medical Encounter	Month/Year (of last visit)	Name & Address of Hospital or Office	Doctor

MD01

Medical History—Medications

|__| **Toma aspirina regularmente?** *aspirin regularly?* (0=No, 1=Yes, 9=Unk)		
If yes,	|__|__|	**Cuántas?** *Number of aspirins taken regularly* (99=Unk.)	
fill☞	|__|	**Qué tan seguido?** *Frequency per* (1=Day, 2=Week 3=Month, 4=Year, 9=Unk)	
	|__|__|__|	**De cuántos miligramos?** *Usual dose* (write in mgs, 999=Unk..)	Examples: 081=baby,160=half dose, 250= like in Excedrin , 325=usual dose, 500=extra strength

Desde su último examen *Since your last exam*

(0=No, 1=Yes, 9=Unk)

|__| **Le ha dicho algún doctor que tiene hipertensión o la presión alta?** *Have you been told by doctor you have high blood pressure or hypertension?*
|__| **Ha tomado medicinas para hipertensión o la presión alta?** *Have you taken medication for high blood pressure or hypertension?*
|__| **Le ha dicho algún doctor que tiene alto el colesterol o los triglicéridos?** *Have you been told by doctor you have high blood cholesterol or high triglycerides?*
|__| **Ha tomado medicinas para colesterol o triglicéridos?** *Have you taken medication for high blood cholesterol or high triglycerides?*
|__| **Le ha dicho algún doctor que tiene diabetes o altos niveles de azúcar?** *Have you been told by doctor you have high blood sugar or diabetes?*
|__| **Ha tomado medicinas para la diabetes?** *Have you taken medication for high blood sugar or diabetes?*
|__| **Ha tomado medicinas para el corazón? (como angina, dolor de pecho, insuficiencia cardiaca, fibrilación auricular, anormalidades del ritmo cardiaco, derrame cerebral, dolor de las piernas cuando camina o enfermedad de las arterias perifericas?** *Have you taken medication for cardiovascular disease? (angina/chest pain, heart failure, atrial fibrillation/heart rhythm abnormality, stroke, leg pain when walking, peripheral artery disease)*

MD02

Medical History – Prescription and Non-Prescription Medications

Copy the name of medicine, the strength including units, and the total number of doses per day/week/month/year. Include vitamins and minerals.

Medication bag with medications or bottles/packs brought to exam?
Trajo su bolsa con medicinas, incluyendo botellas y cajas al examen?

|__| **Trajo sus medicinas?** *...if no* **Toma medicinas?**
(0=No 1=Yes)

List medications taken regularly in past month/ongoing medications
"Tomó estas medicinas regularmente en el último mes?"
_ *Code ASPIRIN ONLY on screen MD02.*

☐ **Check if NO medication taken**

Medication Name (Print first 20 letters)	**Strength** (include mg, IU, etc)	**Route** 1= oral, 2=topical, 3=injection, 4=inhaled, 5=drops,6=nasal 88=other	**Number per** (circle one) #	day/week/month/year 1 / 2 / 3 / 4	**PRN** 0=no, 1=yes,9=Unk.	**Check if OTC med**
EXAMPLE: SAMPLE DRUG NAME	100 mg	1	1	D W M Y	0	☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐

Continue on the next page→

Medical History – Prescription and Non-Prescription Medications

Medication Name (Print first 20 letters)	**Strength** (include mg, IU, etc)	**Route** 1= oral, 2=topical, 3=injection, 4=inhaled, 5=drops,6=nasal 88=other	**Number per** (circle one) #	**Number per** (circle one) day/week/month/year 1 / 2 / 3 / 4	**PRN** 0=no, 1=yes, 9-Unk	**Check if OTC med.**
EXAMPLE: SAMPLE DRUG NAME	100 mg	1	1	D W M Y	0	☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
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				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐
				D W M Y		☐

MD04

Medical History–Female Reproductive History Part 1

☐ **Check here if Male Participant (and skip to Smoking Questions page 48/MD08)**

«Meno» **Check here if definitely menopausal (and skip to Female History Part 3 page 47) (*preloaded from previous exam)***

|__| **Desde su último examen, ha tomado o usado pastillas, inyecciones o implantes como anticonceptivos o por razones médicas (no por reemplazo de hormonas)?** Since your last exam have you taken or used birth control pills, shots, or hormone implants for birth control or medical indications (not post menopausal hormone replacement)? (0=no, 1=yes, now, 2=yes, not now, 9=Unk.)

|__| **Ha estado embarazada desde su último examen?** (0=No, 1=Yes, 9=Unk.)
Have you been pregnant since last exam?

If yes, fill☞

|__|__| **Cuántos embarazos?** *Number of pregnancies?*

|__|__| **Número de nacimientos vivos?** *Number of live births?*

fill in number

|__| **Durante alguno de estos embarazos, le dijeron que tenía hipertensión?** *During any of these pregnancies, were you told you had high blood pressure or hypertension?*

|__| **Durante alguno de estos embarazos, le dijeron que tuvo eclampsia o pre-eclampsia?** *During any of these pregnancies, were you told you had eclampsia, pre-eclampsia (toxemia)*

|__| **Durante alguno de estos embarazos, le dijeron que tuvo diabetes?** *During any of these pregnancies, were you told you had high sugar or diabetes?*

0=No
1=Yes
9=Unk.

MD05

Medical History–Female Reproductive History Part 2

Cómo describiría sus períodos menstruales? *(indique la MEJOR respuesta -sólo una).*

What is the best way to describe your periods? Check the BEST answer – only one.

☐ **No han cesado** *Not stopped*

☐ **Han cesado por embarazo, lactancia o por anticonceptivos hormonales** (depo-provera, progestin releasing IUD, extended release birth control pill) *Periods stopped due to pregnancy, breast feeding, or hormonal contraceptive*

☐ **Han cesado por bajar de peso, hacer ejercicio pesado o por condiciones médicas; como tiroides, desbalance de hormonas, tumor en pituitaria, estrés, etc.**
Periods stopped due to low body weight, heavy exercise, or due to medication or health condition

Que lo causó? *Write in cause* _____

☐ **Han cesado por menos de 1 año.** *Periods stopped for less than 1 year* **(perimenopausal)**

|__|__| **Número de meses desde el último período** Number of months since last period 99=Unk.

☐ **Han cesado por un año o más.** *Periods stopped for 1 year or more*

☐ **Sus períodos cesaron, pero ahora los tiene de nuevo inducidos por hormonas.**
Periods stopped, but now have periods induced by hormones.

|__|__| **Número de meses en que no menstruó** Number of months stopped before hormones started 99=Unk.

|__|__|*|__|__|*|__|__|__|__| **Cuándo fué el primer día de su último periodo menstrual?** When was the first day of your last menstrual period? 99/99/9999=Unk. **88/88/8888**= periods stopped for more than 1 year or using postmenopausal hormone. *If periods stopped for pregnancy, breastfeeding, hormonal contraception or health condition code date of last menstrual period*

|__|__| **A qué edad dejó de tenerlos?** *Age when periods stopped* (00=not stopped, 99=Unk.)
If periods now induced by hormones, code age when periods naturally stopped.
If periods stopped due to pregnancy, breastfeeding, or hormonal contraception code as 0=not stopped

|__| **Su menopausia fué natural? o causada por cirugía, quimioterapia o radiación?**
Was your menopause natural or the result of surgery, chemotherapy, or radiation?
(0=still menstruating, 1=natural, 2=surgical, 3=chemo/radiation, 4=other, 9=Unk.)
If periods stopped due to pregnancy, breast feeding, or hormonal contraception code as 0=still menstruating

MD06

Medical History–Female Reproductive History Part 3

Surgery History

|__| **Desde su último examen, ha tenido una histerectomía? (el útero o matríz removidos)?**
Since your last exam have you had a hysterectomy (uterus/womb removed)? (0=No, 1=Yes, 9=Unk.)

If yes, fill☞

|__|__| **De qué edad la tuvo?** *Age at hysterectomy?* 99=Unk.

|__|__|*|__|__|__|__| **Fecha de la cirugía?** *Date of surgery* (mo/yr) 99/9999=Unk.

|__| **Desde su último examen, ha tenido alguna operación para remover uno o los dos ovarios?**
Since last exam have you had an operation to remove one or both of your ovaries?
(0=No, 1=Yes, 9=Unk.)

If yes, fill☞

|__|__| **Cuántos años tenía?** *Age when ovaries removed? If more than one surgery, use age <u>at last surgery</u>* 99=Unk.

Cuántos ovarios le removieron? *Number of ovaries removed?* (check one)

☐	☐	☐	☐
1=one ovary	2=two ovaries	3= unknown number of ovaries	4= part of an ovary

|__| **Desde su último examen, ha tomado terapia de reemplazo de hormonas? (estrogeno/progesterona o Evista o Raloxifen?** (0=No, 1=Yes, now, 2=Yes, not now, 9=Unk.)

Have you since your last exam taken hormone replacement therapy (estrogen/progesterone) or a selective estrogen receptor modulator (such as evista or raloxifene)?

Comments_____

_____

_____

_____

_____

_____

MD07

Medical History--Smoking

Cigarros *Cigarettes*

|__| **Desde su último examen, ha fumado cigarros regularmente?** *Smoked cigarettes regularly?* (0=no, 1=yes, 9=Unk.)

If yes, fill☞

|__| **Ha fumado regularmente en el último año?** *Smoked cigarettes regularly in the last year? (No means less than 1 cigarette a day for 1 year.)* (0=no, 1=yes, 9=Unk.)

|__| **Fuma ahora? De un mes para acá?** *Do you now smoke cigarettes (as of 1 month ago)?* (0=no, 1=yes, 9=Unk.)

|__|__| **Cuántos cigarros fuma al día?** *Cigarettes smoke per day now?* (99=Unk.)

Ahora, desde su último examen.. Questions below refer to "since your last exam"

|__|__| **En promedio, en todo el tiempo que fumó, cuántos fumaba al día?** *During the time you were smoking, on average how many cigarettes per day did you smoke* (99=Unk.)

|__|__| **Si dejó de fumar por completo, cuántos años tenía cuandó dejó de fumar?** *If you have stopped smoking cigarettes completely, how old were you when you stopped?* (Age stopped, 00=not stopped, 99=Unk.)

|__| **Cuando estaba fumando, alguna vez dejó de fumar por más de seis meses?** *When you were smoking, did you ever stop smoking for >6 months?* (0=no, 1=yes, 9=Unk.)

If yes, fill☞ |__|__| **En total, por cuántos años en total dejó de fumar?** *For how many years in total did you stop smoking cigarettes* (1=6 months – 1 year, 99=Unk.)

Pipas o Puros *Pipes or Cigars*

|__| **Desde su último examen ha fumado pipa o puros regularmente?** *Since your last exam, have you regularly smoked a pipe or cigar?*

0=No
1=Yes
9=Unk.

If yes, fill☞ |__| **Sigue fumando pipa o puro?** *Do you smoke a pipe or cigar now?*

Comments:_____

_____

_____

MD08

Medical History –Alcohol Consumption

Ahora le voy a preguntar sobre su consumo de alcohol.

Now I will ask you questions regarding your alcohol use.

Toma por lo menos una vez al mes... *Do you drink any of the following beverages at least once a month?* (0=no, 1=yes, 9=Unk.)		
|__|	**Cerveza**	*Beer*
|__|	**Vino**	*Wine*
|__|	**Licores**	*Liquor/spirits*

En promedio cuánto ha bebido a la semana o al mes durante el último año? *If yes, what is your average number of servings in a typical week or month over past year?* **(999=Unknown)**

Code alcohol intake as EITHER weekly OR monthly as appropriate.

Beverage		Por semana *per week*	Por mes *per month*
Cerveza	*Beer* (12oz bottle, glass, can)	|__|__|__|	|__|__|__|
Vino	*Wine* (red or white, 4oz glass)	|__|__|__|	|__|__|__|
Licor	*Liquor/spirits* (1oz cocktail/highball)	|__|__|__|	|__|__|__|

|__|__|__| **A qué edad dejó de tomar alcohol? (O nunca ha tomado?)** *At what age did you stop drinking alcohol? (never drinker?)* (0= not stopped, 888=Never drinker 999=Unk.)

|__|	**En promedio durante el último año, cuántos días a la semana bebe algo con alcohol?** *Over the past year, on average on how many days per week did you drink an alcoholic beverage of any type?* (0=no drinks, 1=1or less, 9=Unk.)
|__|__|	**En el último año, cuando ha tomado, cuántas bebidas toma?** *Over the past year, on a typical day when you drink, how many drinks do you have?* (0=no drinks, 1=1or less, 99=Unk.)
|__|__|	**En el último mes, cuál fue la máxima cantidad de bebidas que tomó en un período de 24 horas?** *What was the maximum number of drinks you had in 24 hr. period during the past month?* (0=no drinks, 1=1or less, 99=Unk.)
|__|	**Desde su último examen, ha habido alguna temporada en que ha tomado más de cinco bebidas casi todos los días?** *Since last exam has there been a time when you drank 5 or more alcoholic drinks of any kind almost daily?* (0=no, 1=yes, 9=Unk.)

☐ **Check if over past year participant drinks less than one alcoholic drink of any type per month.**

Comments:_____

_____

_____

MD09

Medical History—Respiratory Symptoms Part I

Tos *Cough* (0=No, 1=Yes, 9=Unk.)

|__| **Generalmente tiene tos? (no para aclarar la garganta)**
Do you usually have a cough? (excluding to clear throat)

|__| **Tose al levantarse por la mañana?**
Do you usually have a cough at all on getting up or first thing in the morning?

If **YES** to **either** question above **answer** the following:

|__| **En el último año, ha tenido esta tos casi todos los días por tres meses consecutivos?**
Do you cough like this on most days for three consecutive months or more during the past year?

|__|__| **Hace cuántos años ha tenido esta tos?** *How many years have you had this cough? (# of years.)* 1=1 year or less 99=Unk.

Flema *Phlegm* (0=No, 1=Yes, 9=Unk.)

|__| **Por lo general le salen flemas desde el pecho?**
Do you usually bring up phlegm from your chest?

|__| **Le salen flemas al levantarse por la mañana?**
Do you usually bring up phlegm at all on getting up or first thing in the morning?

If **YES** to **either** question above **answer** the following:

|__| **En el último año, ha tenido flemas por tres meses consecutivos casi todos los días?** *Do you bring up phlegm from your chest on most days for three consecutive months or more during the year?*

|__|__| **Hace cuántos años ha tenido este problema con flemas?**
How many years have you had trouble with phlegm? (# of years) 1=1 year or less 99=Unk.

Wheeze (0=No, 1=Yes, 9=Unk.)

En los últimos doce meses *in the last 12 months*

|__| **Ha tenido asma o jadeado o producido silbidos desde su pecho en algún momento?** *Have you had wheezing or whistling in your chest at any time?*

if yes, fill all☞

|__| **Que tan seguido le sucede esto?** *How often does this happen?*
0=Not at all 1=MOST days or nights 2=A few days or nights a WEEK
3=A few days or nights a MONTH 4=A few days or nights a YEAR 9=Unk

|__| **Le pasa cuando tiene gripa?** *Have you had this wheezing or whistling in the chest when you had a cold?*

|__| **Le ha pasado cuando NO tiene gripa?** *Have you had this wheezing or whistling in the chest apart from colds?*

|__| **Ha tenido un ataque de asma con dificultad para respirar?** *Have you had an attack of wheezing or whistling in the chest that had made you feel short of breath?*

MD10

Medical History—Respiratory Symptoms Part II

Nocturnal chest symptoms (0=No, 1=Yes, 9=Unk.)

En los últimos doce meses *in the last 12 months*

|__| **Se ha despertado por dificultad para respirar?** *Have you been awakened by shortness of breath?*

|__| **Se ha despertado por un ataque de asma o jadeos o silbidos en el pecho?** *Have you been awakened by a wheezing/whistling in your chest?*

|__| **Se ha despertado por toser?** *Have you been awakened by coughing?*

if yes, fill all☞ |__| **Qué tan seguido se ha despertado por toser?** *How often have you been awakened by coughing?*
0=Not at all 1=MOST days or nights 2=A few days or nights a WEEK
3=A few days or nights a MONTH 4=A few days or nights a YEAR 9=Unk.

Shortness of breath (0=No, 1=Yes, 9=Unk.)

Desde su último examen… *since your last exam…*

|__| **Cuando camina de prisa a nivel plano o a paso normal cuesta arriba, se le ha ido el aliento?** *Are you troubled by shortness of breath when hurrying on level ground or walking up a slight hill?*

if yes, fill all☞

|__| **Tiene que caminar más despacio que otras personas de su misma edad porque se le vá el aliento?** *Do you have to walk slower than people of your age on level ground because of shortness of breath?*

|__| **Se ha tenido que parar a tomar el aliento cuando camina a paso normal a nivel plano?** *Do you have to stop for breath when walking at your own pace on level ground?*

|__| **Se ha tenido que parar a tomar el aliento después de caminar 100 metros, o después de unos minutos?** *Do you have to stop for breath after walking 100 yards (or after a few minutes) on level ground?*

|__| **Ha tenido que dormir con dos o más almohadas para ayudarse a respirar?** *Do you/have you needed to sleep on two or more pillows to help you breathe (Orthopnea)?*

|__| **Desde su último examen, se le han hinchado ambos tobillos?** *Have you since last exam had swelling in both your ankles (ankle edema)?*

|__| **Ha sido diagnosticado por un doctor con insuficiencia cardiaca o falla cardiaca o insuficiencia cardiaca congestiva?** *Have you been told by your doctor you had heart failure or congestive heart failure?*

if yes, fill l☞

Nombre del doctor _____

En qué fecha? *Date of visit* |__|__|*|__|__|*|__|__|__|__| 99/99/9999=Unk.

|__| **Lo han hospitalizado por insuficiencia cardiaca?** *Have you been hospitalized for heart failure?* *(Provide details on MD01-Health Care page 41)*

CHF First Examiner Opinion

|__| **First examiner believes CHF** 0=No,1=Yes 2=Maybe, 9=Unk..

Comments_____

_____

_____

Physical Exam—Blood Pressure

Physician Blood Pressure First reading	
Systolic	**BP cuff size**
|__|__|__| to nearest 2 mm Hg	|__| 0=pedi,1=reg.adult, 2=large adult, 3= thigh, 9=Unk.
Diastolic	**Protocol modification**
|__|__|__| to nearest 2 mm Hg	|__| 0=No, 1=Yes, 9=Unk.

Comments for Protocol modification_____

_____

_____

_____

MD12

Medical History—Chest pain

|__|	**Desde su último examen, ha tenido alguna molestia en el pecho?** *Since your last exam have you experienced any chest discomfort? (please provide narrative comments in addition to completing the appropriate boxes)*		0=No, 1=Yes, 2=Maybe, 9=Unk.
if yes, fill☞ and below |__|	**Con esfuerzo o agitación**	*With exertion or excitement*	
|__|	**Cuando está tranquilo o descansando**	*When quiet or resting*	

Chest Discomfort Characteristics

|__|__|*|__|__|__|__|	**En qué fecha empezó?** *Date onset (mo/yr)*	99/9999=Unk.
|__|__|__|	**Cuánto dura?** *(min.) Usual duration*	1=1 min or less, 900=15 hrs or more, 999=Unk.
|__|__|__|	**Cuánto es lo más que ha durado?** *(min.) Longest duration*	1=1 min or less, 900=15 hrs or more, 999=Unk.
|__|	**Dónde le duele?** *Location*	0=No, 1=Central sternum and upper chest, 2=L Up Quadrant, 3=L Lower ribcage, 4=R Chest, 5=Other, 6=Combination, 9=Unk.
|__|	**Se extiende a otros lados?** *Radiation*	0=No, 1=Left shoulder or L arm, 2=Neck, 3=R shoulder or arm, 4=Back, 5=Abdomen, 6=Other, 7=Combination, 9=Unk.
|__|__|__|	**Cuántas veces sucedió en el último mes?** *Episodes in past month*	999=Unk.
|__|__|__|	**Cuántas veces sucedió en el último año?** *Episodes in past year*	999=Unk.
|__|	**Tipo de dolor** *Type*	1=Pressure, heavy, vise, 2=Sharp, 3=Dull, 4=Other, 9=Unk.

|__|	**Mejora con nitroglicerina en <15 minutos**	*Nitroglicerine*	0=No,
|__|	**Mejora con descanso en <15 minutos**	*Rest*	1=Yes,
|__|	**Mejora sin hacer nada en <15 minutos**	*Spontaneously*	*8=Not tried*
|__|	**Mejora por otra causa en <15 minutos**	*Other*	9=Unk.

|__|	**Desde su último examen, le ha dicho un doctor que ha tenido ataque al corazón o infarto al miocardio?** *Since your last exam have you been told by a doctor you had a heart attack or myocardial infarction?*	0=No, 1=Yes, 2=Maybe, 9=Unk.
if yes, fill l☞	**Nombre del doctor** _____	
	Fecha de la visita *Date of visit* |__|__|*|__|__|*|__|__|__|__|	99/99/9999=Unk.

CHD First Examiner Opinions

|__|	**Angina pectoris**	0=No, 1=Yes, 2=Maybe, 9=Unk.
if yes,fill☞ |__|	**Angina pectoris since revascularization procedure**	
|__|	**Coronary insufficiency**	
|__|	**Myocardial infarct**	

Comments_____

_____

MD13

Medical History—Atrial Fibrillation/Syncope

Desde su último examen o actualización médica…

Since your last exam or medical history update….

|__| **Le han dicho que tiene o haya tenido fibrilación auricular?** *Have you been told you have/had atrial fibrillation?* 0=No, 1=Yes, 2=Maybe, 9=Unk.

if yes,fill☞ |__|__|*|__|__|*|__|__|__|__| **En que fecha?** Date of first episode 99/99/9999=Unk.

|__| **Fue a emergencias, hospital o al doctor? ER/hospitalized or saw M.D.** 0=No, 1=Hosp/ER, 2=Saw M.D., 9=Unk.

if yes, fill☞ _____ **Qué hospital?** Name of the Hospital (write Unk. if unknown)

_____ **Qué doctor?** Name of M.D. (write Unk. if unknown)

|__| **Hay antecedentes en su familia de problemas del ritmo cardiaco llamado fibrilación auricular?** Do you have a family history of a heart rhythm problem called atrial fibrillation? 0=No, 1=Yes, 9=Unk

if yes,fill☞ **Mamá** Mother |__| **Papá** Father |__| **Hermanos** Siblings |__| **Hijos** Children |__| 0=No, 1=Yes, 9=Unk.

|__| **Se ha desmayado o ha perdido la conciencia?** *Have you fainted or lost consciousness? (If event immediately preceded by head injury or accident code 0=No)* 0=No, 1=Yes, 2=Maybe, 9=Unk..

if yes, fill all☞

|__|__|__| **Cuántas veces en los últimos dos años?** *episodes in past two years* 999=Unk.

|__|__|*|__|__|__|__| **Fecha?** *(mo/yr)* *Date of first episode* 99/9999=Unk.

|__|__|__| **Cuanto dura?** *(minutes)* *Usual duration* 999=Unk.,1=1 min or less

|__| **Tuvo alguna lesión como consecuencia?** *Did you have any injury caused by the event?* 0=No, 1=Yes, 2=Maybe, 9=Unk.

|__| **Cuántas veces en los últimos dos años?** *episodes in past two years* 0=No, 1=Hosp/ER, 2=Saw M.D., 9=Unk.

if yes, fill☞ _____ **Name of the Hospital** (write Unk.. if unknown)

_____ **Name of M.D.** (write Unk. if unknown)

|__| **Ha tenido algún golpe en la cabeza con pérdida de la conciencia?** *Have you had a head injury with loss of consciousness?* 0=No, 1=Yes, 2=Maybe, 9=Unk.

if yes, fill☞ |__|__| * |__|__| * |__|__|__|__| **Fecha** *Date of serious head injury with loss of consciousness* 99/99/9999=Unk.

|__| **Ha tenido alguna convulsión?** *Have you had a seizure?* 0=No, 1=Yes, 2=Maybe, 9=Unk.

if yes,fill☞ |__|__| * |__|__| * |__|__|__|__| **Fecha de la más reciente?** *Date of most recent seizure* 99/99/9999=Unk.

|__| **Lo están tratando para eso?** *Are you being treated for a seizure disorder?* 0=No, 1=Yes, 2=Maybe, 9=Unk.

Syncope First Examiner Opinion

|__| **Syncope** (0=No, 1=Yes, 2=Maybe, 3=Presyncope, 9=Unk.) *needs second opinion*

if yes, fill☞

|__| **Cardiac syncope**

|__| **Vasovagal syncope**

|__| **Other-Specify:** _____

0=No, 1=Yes, 2=Maybe, 8=No revasculation 9=Unk.

Comments_____

_____

Medical History—Cerebrovascular Diseases

Desde su último exámen o actualización medica... *Since your last exam or medical history update….*

|__|	**Debilidad muscular repentina** *Sudden muscular weakness*	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**Dificultad repentina para hablar** *Sudden speech difficulty*	
|__|	**Defecto visual repentino** *Sudden visual defect*	
|__|	**Visión doble repentina** *Sudden double vision*	
|__|	**Pérdida repentina de la vista de un ojo** *Sudden loss of vision in one eye*	
|__|	**Entumecimiento u hormigueo repentinos** *Sudden numbness, tingling*	
if yes, fill ☞	|__| **Numbness and tingling is positional**	
|__|	**Tomografía de cráneo, NO PARA NUESTRO ESTUDIO** *Head CT scan other than FHS*	0=No,1=Yes, 2= Maybe,9=Unk.
if yes, fill ☞	|__|__| * |__|__| * |__|__|__|__| **Cuándo?** *Date*	99/99/9999=Unk.
	_____ **Dónde?** *Place*	
|__|	**Resonancia de cráneo, NO PARA NUESTRO ESTUDIO** *HeadMRI other than FHS*	0=No,1=Yes, 2= Maybe,9=Unk.
if yes, fill ☞	|__|__| * |__|__| * |__|__|__|__| **Cuándo?** *Date*	99/99/9999=Unk.
	_____ **Dónde?** *Place*	
|__|	**Lo vió un neurólogo? Quién y dónde?** *Seen by neurologist? (who and when)* _____	
|__|	**Le han diagnosticado con derrame cerebral o accidente cerebral isquémico transitorio?** *Have you been told by a doctor you had a stroke or TIA* (transient ischemic attack, mini-stroke)**?**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**Ha sido diagnosticado con la enfermedad de Parkinson?** *Have you been told by a doctor you have Parkinson Disease?*	
|__|	**Le ha dicho un doctor que usted tiene problemas de memoria, demencia o Alzheimer?** *Have you been told by a doctor you have memory problems, dementia or Alzheimer's disease?*	
|__|	**Siente usted, u otras personas, que usted tiene problemas de memoria al punto que le impide hacer lo que hacía antes?** *Do you feel or do other people think that you have memory problems that prevent you from doing things you've done in the past?*	
|__|	**Siente que su memoria está empeorando?** *Do you feel like your memory is becoming worst?*	

Cerebrovascular Disease First Examiner Opinion

|__|	**TIA or stroke took place**	0=No, 1=Yes,2=Maybe, 9=Unk.
if yes or maybe fill ☞	|__|__|*|__|__|__|__| **Date** (*mo/yr*, 99/9999=Unk.) **Observed by**_____	
	|__|__|*|__|__|*|__|__| **Duration** (*use format days/hours/mins*, 99/99/99=Unk.)	
	|__| **Hospitalized or saw M.D.** (0=No, 1=Hosp.,2=Saw M.D, 9=Unk.) Name_____ Address_____	

Comments_____

MD15

Medical History--Venous and Peripheral Arterial Disease

Venous Disease

Desde su último examen o actualización médica, ha tenido… *Since your last exam or medical history update.*

|__| **Trombosis en vena profunda o coágulo en brazos o piernas?** *Deep Vein Thrombosis - DVT*

|__| **Embolia Pulmonar o coágulo en el pulmón?** *Pulmonary Embolus – PE*

0=No,1=Yes, 2=Maybe, 9=Unk.

Peripheral Arterial Disease

Desde su último examen… *Since your last exam….* (0=No, 1=Yes, 9=Unk.)

|__| **Le ha dolido alguna pierna cuando camina?** *Do you get discomfort in either leg on walking?*

if yes, fill ☞ |__| **Empieza desde que está parado o aún sentado?** *Begin still standing or sitting ?*

|__|__| **Caminando a paso normal, cuántas cuadras puede caminar antes de que aparezcan los síntomas?** *Walking at ordinary pace how many city blocks until symp. develop* (1=1 block or less, 99=Unk.) *where 10 blocks=1 mile, code as no if more than 98 blocks required to develop symptoms*

Left	Right	Claudication symptoms	0=No, 1=Yes, 9=Unk.
|__|	|__|	**Molestia en la pantorrilla cuando camina?** *Discomfort in calf while walking*
|__|	|__|	**Molestia en la pierna cuando camina?** *In lower extremity (not calf) while walking* **Write in site of discomfort**_____
	|__|	**Ocurre a a los primeros pasos?** *Occurs with first steps* **(code worse leg)**
	|__|	**Ocurre cuando camina rápido o cuesta arriba?** *Discomfort when up hill or hurry?*
	|__|	**Ha desaparecido cuando aún está caminando?** *Ever disappear while still walking?*
	|__|	**Que hace para aliviarlo cuando está caminando?** *What do you do if you get discomfort when you are walking?* (1=stop, 2=slow down, 3=continue at same pace, 9=Unk.) **1=Se detiene? 2=Camina mas lento? ó 3=Continúa igual?**
	|__|__|__|	**Cuánto tarda en aliviarse si se detiene?** *Time for discomfort to be relieved by stopping* **(minutes)** (000=No relief with stopping, 999=Unk.)
	|__|__|	**Hace cuántos días o meses tiene esta molestia?** *Number of days/month of lower limb discomfort* (1=1 day/month or less, 99=Unk.)

|__| **Desde su último examen, le ha dicho un doctor que tiene una enfermedad de las arterias periféricas o claudicación intermitente?** *Since your last exam have you been told by a doctor you have intermittent claudication or peripheral artery disease?* (0=No, 1=Yes, 9=Unk).

if yes, fill ☞ **Nombre del doctor** _____

Fecha *Date of visit* |__|__|*|__|__|*|__|__|__|__| 99/99/9999=Unk.

|__| **Desde su último examen, le ha dicho un doctor que tiene estenosis de la columna vertebral?** *Since your last exam have you been told by a doctor you have spinal stenosis?* (0=No, 1=Yes, 9=Unk).

Intermittent Claudication First Examiner Opinion

|__| **Intermittent Claudication** 0=No, 1=Yes, 2=Maybe, 9=Unk.

Comments _____

MD16

Medical History-- CVD Procedures

Desde su último examen o actualización Médica, ha tenido alguno de los siguientes procedimientos cardiovasculares?

Since your last exam or medical history update did you have any of the following cardiovascular procedures?

0=No, 1=Yes 2=Maybe, 9=Unk.	**Cardiovascular Procedures** *(if procedure was repeated code only first and provide narrative)*	**" ¿Ha tenido... "**
|__|	**Heart Valvular Surgery**	**Cirugía de válvula del corazón**
if yes fill☞	|__|__|__|__| Year done (9999=Unk)	
|__|	**Exercise Tolerance Test**	**Prueba de tolerancia de ejercicio**
if yes fill☞	|__|__|__|__| Year done (9999=Unk)	
|__|	**Coronary arteriogram**	**Arteriograma coronario**
if yes fill ☞	|__|__|__|__| Year done (9999=Unk)	
|__|	**Coronary artery angioplasty or stent**	**Angioplastia coronaria /Stent o PCI**
if yes fill☞	|__|__|__|__| Year done (9999=Unk)	
|__|	**Coronary bypass surgery**	**Baypass coronario**
if yes fill☞	|__|__|__|__| Year done (9999=Unk)	
|__|	**Permanent pacemaker insertion**	**Marcapasos permanente**
if yes fill ☞	|__|__|__|__| Year done (9999=Unk)	
|__|	**AICD**	**AICD o Defibrilador**
if yes fill ☞	|__|__|__|__| Year done (9999=Unk)	
|__|	**Carotid artery surgery or stent**	**Cirugía o stent de la carótida**
if yes fill ☞	|__|__|__|__| Year done (9999=Unk)	
|__|	**Thoracic aorta surgery**	**Cirugía de la aorta torácica**
if yes fill ☞	|__|__|__|__| Year done (9999=Unk)	
|__|	**Abdominal aorta surgery**	**Cirugía de la aorta abdominal**
if yes fill ☞	|__|__|__|__| Year done (9999=Unk)	
|__|	**Femoral or lower extremity surgery**	**Cirugía de la pierna o femoral**
if yes fill ☞	|__|__|__|__| Year done (9999=Unk)	
|__|	**Lower extremity amputation**	**Amputación de la pierna**
if yes fill ☞	|__|__|__|__| Year done (9999=Unk)	
|__|	**Other Cardiovascular Procedure**	**Otro procedimiento cardiovascular**
if yes fill ☞	|__|__|__|__| Year done (9999=Unk) Description_____	

Write in other procedures, year done, location if more than one.

Comments:_____

MD17

Physical Exam—Blood Pressure

Physician Blood Pressure Second reading	
Systolic	**BP cuff size**
|__|__|__| to nearest 2 mm Hg	|__| 0=pedi,1=reg.adult, 2=large adult, 3= thigh, 9=Unk.
Diastolic	**Protocol modification**
|__|__|__| to nearest 2 mm Hg	|__| 0=No, 1=Yes, 9=Unk.

Comments for Protocol modification_____

_____

_____

_____

Enfermedades del Riñón *History of Kidney Disease*

\|__\| **Ha tenido un cálculo renal en los últimos 10 años?** *Have you e had a kidney stone in the past 10 years?* (0=No, 1=Yes, 9=Unk.)

if yes, fill☞ \|__\| **Fue a emergencias, hospital o vio al doctor?** (0=No, 1=Hosp/ER, 2=Saw M.D., 9=Unk.)
ER/hospitalized or saw M.D

if yes, fill☞

_____ **Nombre del hospital** (write Unk.. if unknown)
Name of the Hospital

_____ **Nombre del doctor** (write Unk. if unknown)
Name of M.D

MD18

Cancer Site or Type

|__| **Desde su último examen o historial médico, ha tenido cancer o algún tumor?** *Since your last exam or medical history update have you had a cancer or a tumor?*
(0=No and skip to next page MD20; If 1=Yes, 2=Maybe, 9=Unk. please continue)

Check ALL that apply	En qué parte del cuerpo? *Site of Cancer or Tumor*	En qué año fue diagnosticado? *Year First Diagnosed*	Cancer	Maybe cancer	Benign	Qué doctor lo diagnosticó? *Name Diagnosing M.D.*	En qué ciudad y estado? *City/State of M.D.*
			Check ONE				
			1	2	3		
☐	**Esófago** *Esophagus*		☐	☐	☐		
☐	**Estómago** *Stomach*		☐	☐	☐		
☐	**Colon** *Colon*		☐	☐	☐		
☐	**Recto** *Rectum*		☐	☐	☐		
☐	**Páncreas** *Pancreas*		☐	☐	☐		
☐	**Laringe** *Larynx*		☐	☐	☐		
☐	**Trachea/Bronquio Pulmón** *lungs*		☐	☐	☐		
☐	**Leucemia** *Leukemia*		☐	☐	☐		
☐	**Piel** *Skin*		☐	☐	☐		
☐	**Seno** *Breast*		☐	☐	☐		
☐	**Matriz/Utero** *Cervix*		☐	☐	☐		
☐	**Ovario** *Ovary*		☐	☐	☐		
☐	**Próstata** *Prostate*		☐	☐	☐		
☐	**Vejiga** *Bladder*		☐	☐	☐		
☐	**Riñón** *Kidney*		☐	☐	☐		
☐	**Cerebro** *Brain*		☐	☐	☐		
☐	**Lymphoma** *Lymphoma*		☐	☐	☐		
☐	**Other/Unk.** *Otro* _____		☐	☐	☐		

|__| **Le hicieron biopsia para diganosticar?** *Diagnostic biopsy done?* (0=No, 1=Yes, 9=Unk.)

if yes fill ☞ ___ - ___ -_____ **Fecha** *Date* **Lugar de la biopsia** *location of biopsy*_____

Hosp./office name_____ **Address (city/state)**_____

Comment *(If participant has more details concerning tissue diagnosis, other hospitalization, procedures, and treatments)*

_____

_____

MD19

Physical Exam—Respiratory, Heart, Abdomen

OFFSITE VISIT – leave page BLANK

Respiratory		
|__|	**Wheezing on auscultation**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**Rales**	
|__|	**Abnormal breath sounds**	

Heart		
|__|	**S3 Gallop**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**S4 Gallop**	
|__|	**Systolic Click**	
|__|	**Neck vein distention at 90 degrees** (sitting upright)	

|__| if yes, fill below	**Systolic murmur(s)**			0=No, 1=Yes, 2=Maybe, 9=Unk.
Murmur Location	**Grade** 0=No sound 1 to 6 for grade of sound heard 9=Unk.	**Type** 0=None 1=Ejection 2=Regurgitant 3=Other 9=Unk.	**Radiation** 0=None 1=Axilla 2=Neck 3=Back 4=Rt. chest 9=Unk.	**Origin** 0=None, indet. 1=Mitral 2=Aortic 3=Tricuspid 4=Pulm 9=Ukn.
Apex	|__|	|__|	|__|	|__|
Left Sternum	|__|	|__|	|__|	|__|
Base	|__|	|__|	|__|	|__|

|__| if yes, fill ☞	**Diastolic murmur(s)**	0=No, 1=Yes, 2=Maybe, 9=Unk.
	|__| **Valve of origin for diastolic murmur(s)** (1=Mitral, 2=Aortic, 3=Both, 4=Other, 8=N/A, 9=Unk)	

Abdominal Abnormalities		
|__|	**Liver enlarged**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**Surgical scar**	
|__|	**Abdominal aneurysm**	
|__|	**Abdominal bruit**	

Comments _____

_____

_____

Physical Exam--Peripheral Vessels—Veins and Arterial pulses

OFFSITE VISIT – leave page BLANK

Left	Right	Lower Extremity Abnormalities
|__|	|__|	**Stem varicose veins** *(Do not code reticular or spider varicosities)* (0=No abnormality 1=Yes 9=Unk.)
|__|	|__|	**Ankle edema** (0=No, 1=Yes, 2=Maybe, 8=absent due to amputation 9=Unk.)
|__|	|__|	**Amputation level** (0=No, 1=Toes only, 2=Foot, 3=below Knee, 4=above Knee, 5= Other, write in_____, 9=Unk.)

Artery	Pulse (0=Normal, 1=Abnormal, 9=Unk.)		Bruit (0=Normal, 1=Abnormal, 9=Unk.)	
	Left	Right	Left	Right
Femoral	|__|	|__|	|__|	|__|
Popliteal			|__|	|__|
Post Tibial	|__|	|__|		
Dorsalis Pedis	|__|	|__|		

Comments_____

_____

_____

MD21

Physical Exam--Neurological Exam

OFFSITE VISIT – leave page BLANK

Neurological Exam			
Left	**Right**		
|__|	|__|	**Carotid Bruit**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|		**Speech disturbance**	
|__|		**Disturbance in gait**	
|__|		**Other neurological abnormalities on exam** Specify_____	

Comments _____

_____

_____

_____

MD22

Electrocardiograph--Part I

OFFSITE ONLY		
|__|__|__|	**MD Id#**	_____ **MD Name**

	Rates and Intervals	
|__|__|__|	**Ventricular rate per minute**	(999=Unk.)
|__|__|__|	**P-R Interval** (milliseconds)	(999=Fully Paced, Atrial Fib, or Unk.)
|__|__|__|	**QRS interval** (milliseconds)	(999=Fully Paced, Unk.)
|__|__|__|	**Q-T interval** (milliseconds)	(999=Fully Paced, Unk.)
|__|__|__|__|	**QRS angle** (put plus or minus as needed)	(e.g. -045 for minus 45 degrees, +090 for plus 90, 9999=Fully paced or Unk.)

	Rhythm-predominant
|__|	**0 or 1 = Normal sinus,** (including s.tach, s.brady, s arrhy, 1 degree AV block) **3 = 2nd degree AV block, Mobitz I (Wenckebach)** **4 = 2nd degree AV block, Mobitz II** **5 = 3rd degree AV block / AV dissociation** **6 = Atrial fibrillation / atrial flutter** **7 = Nodal** **8 = Paced** **9 = Other or combination of above (list)**

	Ventricular conduction abnormalities	
|__|	**IV Block**	(0=No, 1=Yes, 9=Fully paced or Unk.)
if yes, fill ☞	|__| **Pattern**	(1=Left, 2=Right, 3=Indeterminate, 9=Unk.)
	|__| **Complete (QRS interval=.12 sec or greater)**	(0=No, 1=Yes, 9=Unk.)
	|__| **Incomplete (QRS interval = .10 or .11 sec)**	(0=No, 1=Yes, 9=Unk.)
|__|	**Hemiblock**	(0=No, 1=Left Ant, 2=Left Post, 9=Fully paced or Unk.)
|__|	**WPW Syndrome**	(0=No, 1=Yes, 2=Maybe, 9=Fully paced or Unk.)

	Arrhythmias	
|__|	**Atrial premature beats**	(0=No, 1=Atr, 2=Atr Aber, 9=Unk.)
|__|	**Ventricular premature beats** (0=No, 1=Simple, 2=Multifoc, 3=Pairs, 4=Run, 5=R on T, 9=Unk.)	
|__|__|	**Number of ventricular premature beats in 10 seconds** (see 10 second rhythm strip)	

MD23

Electrocardiograph-Part II

Myocardial Infarction Location		
|__|	**Anterior**	0=No, 1=Yes, 2=Maybe, 9=Fully paced or Unk.
|__|	**Inferior**	
|__|	**True Posterior**	

Left Ventricular Hypertrophy Criteria		
|__|	**R > 20mm in any limb lead**	0=No, 1=Yes, 9=Fully paced, Complete LBBB or Unk.
|__|	**R > 11mm in AVL**	
|__|	**R in lead I plus S in lead III ≥ 25mm**	
	Measured Voltage	
*|__|__|	**R AVL in mm** (at 1 mv = 10 mm standard) **Be sure to code these voltages**	
*|__|__|	**S V3 in mm** (at 1 mv = 10 mm standard) **Be sure to code these voltages**	
	R in V5 or V6-----S in V1 or V2	
|__|	**R≥ 25mm**	0=No, 1=Yes, 9=Fully paced, Complete LBBB or Unk.
|__|	**S≥ 25mm**	
|__|	**R or S ≥ 30mm**	
|__|	**R + S ≥ 35mm**	
|__|	**Intrinsicoid deflection ≥.05 sec**	
|__|	**S-T depression (strain pattern)**	

Hypertrophy, enlargement, and other ECG Diagnoses	
|__|	**Nonspecific S-T segment abnormality** (0=No, 1=S-T depression, 2=S-T flattening, 3=Other, 9=Fully paced or Unk.)
|__|	**Nonspecific T-wave abnormality** (0=No, 1=T inversion, 2=T flattening, 3=Other, 9=Fully paced or Unk.)
|__|	**U-wave present** (0=No, 1=Yes, 2=Maybe, 9=Paced or Unk.)
|__|	
|__|	**RVH** (0=No, 1=Yes, 2=Maybe, 9=Fully paced or Unk.; **If complete RBBB OR LBBB present, RVH=9**)
|__|	**LVH** (0=No, 1=LVH with strain, 2=LVH with mild S-T Segment Abn, 3=LVH by voltage only, 9=Fully paced or Unk., **If complete LBBB present, LVH=9)**

Comments_____

_____

_____

MD24

Clinical Diagnostic Impression--Part I

Heart Diagnoses		
|__|	**Rheumatic Heart Disease**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**Aortic Valve Disease**	
|__|	**Mitral Valve Disease**	
|__|	**Arrhythmia**	
|__|	**Other Heart Disease (includes congenital)**	
		(Specify)_____	

Peripheral Vascular Disease		
|__|	**Other Peripheral Vascular Disease**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**Other Vascular Diagnosis**	
		(Specify)_____	

Neurological Disease		
|__|	**Stroke/ TIA**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**Dementia**	
|__|	**Parkinson's Disease**	
|__|	**Adult Seizure Disorder**	
|__|	**Migraine**	
|__|	**Other Neurological Disease**	
		(Specify)_____	

Comments _____

_____

_____

_____

MD25

Clinical Diagnostic Impression--Part II. Non Cardiovascular Diagnoses

Endocrine		
|__|	**Thyroid Disease**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**Diabetes Mellitus**	
|__|	**Other endocrine disorders,** specify_____	
GU/GYN		
|__|	**Renal disease,** specify_____	0=No, 1=Yes, 2=Maybe, 8=male/female 9=Unk.
|__|	**Prostate disease**	
|__|	**Gynecologic problems,** specify_____	
Pulmonary		
|__|	**Emphysema**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**Pneumonia**	
|__|	**Asthma**	
|__|	**Other pulmonary disease,** specify_____	
Rheumatologic Disorders		
|__|	**Gout**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**Degenerative joint disease**	
|__|	**Rheumatoid arthritis**	
|__|	**Other musculoskeletal or connective tissue disease,** specify_____	
GI		
|__|	**Gallbladder disease**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**GERD/ulcer disease**	
|__|	**Liver disease**	
|__|	**Other GI disease,** specify_____	
Blood		
|__|	**Hematologic disorder**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**Bleeding disorder**	
Infectious Disease		
|__|	**Infectious Disease**	0=No, 1=Yes, 2=Maybe, 9=Unk.
if yes ☞	specify_____	
Mental Health		
|__|	**Depression**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**Anxiety**	
|__|	**Psychosis**	
|__|	**Other Mental health,** specify_____	
Other		
|__|	**Eye**	0=No, 1=Yes, 2=Maybe, 9=Unk.
|__|	**ENT**	
|__|	**Skin**	
|__|	**Other,** specify_____	

Comments

_____

_____

MD26

Second Examiner Opinions

OFFSITE VISIT – leave page BLANK

|__|__|__| **2nd Examiner ID number** _____ **2nd Examiner Last Name**

Coronary Heart Disease

(Provide initiators, qualities, radiation, severity, timing, presence after procedures done)

Item requires 2nd opinion *Check ALL that apply.*	2nd opinion		
☐	|__|	**Congestive Heart Failure**	0=No, 1=Yes, 2=Maybe, 9=Unk.
☐	|__|	**Cardiac Syncope**	
☐	|__|	**Angina Pectoris**	
☐	|__|	**Coronary Insufficiency**	
☐	|__|	**Myocardial Infarct**	

Comments about heart disease _____

_____

_____

Intermittent Claudication

(Provide initiators, qualities, radiation, severity, timing, presence after procedures done)

Item requires 2nd opinion *Check ALL that apply.*	2nd opinion		
☐	|__|	**Intermittent Claudication**	0=No, 1=Yes, 2=Maybe, 9=Unk.

Comments about peripheral artery disease _____

_____

Cerebrovascular Disease

(Provide initiators, qualities, severity, timing, presence after procedures done)

Item requires 2nd opinion *Check ALL that apply.*	2nd opinion		
☐	|__|	**Stroke**	0=No, 1=Yes, 2=Maybe, 9=Unk.
☐	|__|	**TIA**	

Comments about possible cerebrovascular disease_____

_____

_____

Any Additional Comments for Second Examiner Opinions.

1 - 1234

Dear Mr. Xxxxxxx,

We thank you for participating in the Framingham Heart Study. Your clinic appointment is scheduled for Monday, January 23, 2012 at 7:30 am.

The Framingham Heart Study's new address is 73 Mt. Wayte Avenue, in the **Perini Building**. The Framingham Heart Study offices are **located in the wing at the Franklin Street side** of the building. **There is reserved parking for participants behind the Franklin Street wing.** Please see the enclosed map. The building is handicap accessible.

You should bring slippers and if you choose, bring your own robe. In order to perform certain tests, we ask that you **NOT** eat after 8:00 P.M. the previous evening. You may have **water**, **decaffeinated black coffee or tea (no creamer, milk or sugar) that evening and again in the morning** before your appointment. A urine sample will be collected when you arrive.

PLEASE TAKE ANY PRESCRIPTION MEDICATIONS AS YOU NORMALLY WOULD.

Using the enclosed **MEDICATION BAG,** please bring all prescription and nonprescription medications you currently take or have taken in the past month **in their original containers. They will be returned to you before you leave.**

ON THE BACK OF THIS SHEET, please list information regarding hospitalizations and major illnesses you have experienced in the past. **PLEASE BRING THIS LETTER WITH YOU TO YOUR APPOINTMENT.** If you need help completing this form, Clinic staff can assist you at the time of your appointment.

If you have any questions, please call [redacted], Project Coordinator at [redacted] locally and for long distance at [redacted]

Sincerely yours,

[redacted]

OVER →

[redacted]
Director
Framingham Heart Study

OMB No=0925-0216 Exp. 11/30/2013

Doctor(s)/Health Care Provider you want your report sent to:

Name	Address	Telephone

Hospitalizations, Emergency Room Visits, or Day Surgeries since 01/23/2012:

Date	Reason	Hospital Name & Address	Doctor's Name

Doctor's Office Visits:

Date	Reason	Doctor's Name

Estimado(a) _____,

Gracias por participar en el Estudio del Corazón de Framingham. Hemos reservado un lugar para usted en nuestra clínica el _____ a las _____.

La dirección del Estudio del Corazón de Framingham es: 73 Mt. Wayte Avenue (en el **Perini Building)**. Las oficinas del Estudio del Corazón de Framingham se encuentran en la parte del edificio que da a Franklin Street. **En el estacionamiento hay lugares reservados para los participantes en la parte de atrás del ala de Franklin St.** Por favor vea el mapa anexo. El edificio tiene acceso para personas incapacitadas.

Deberá traer pantuflas, y si lo desea, puede traer su propia bata. Para poder realizar ciertos exámenes, le pedimos que NO COMA nada después de las 8:00 P.M. la noche anterior. **Puede tomar agua o café o té descafeinado (<u>sin crema, ni leche ni azúcar</u>)** esa noche o en la mañana antes de su cita. Cuando llegue a la clínica se le pedirá que nos dé una muestra de orina.

Por favor no traiga nada de joyería, por la prueba de densidad ósea que le haremos.

Si toma **medicinas recetadas por un doctor**, por favor tómelas como lo haría normalmente.

En la **bolsa de plástico para medicinas** adjunta, ponga todos los medicamentos, **en sus envases originales,** que tome actualmente o que haya tomado durante el último mes antes de su cita, incluyendo medicinas no recetadas por su doctor.

EN EL REVERSO DE ESTA PAGINA, por favor escriba información respecto a hospitalizaciones y enfermedades graves que haya tenido desde su última visita o desde que le hicimos una actualización médica.

POR FAVOR TRAIGA ESTA CARTA CON USTED A LA CLINICA. Si necesita ayuda para llenar esta forma, el personal de la clínica le puede ayudar cuando venga a su cita.

Si tiene cualquier pregunta por favor comuníquese con [redacted], Coordinadora del Estudio de Omni, al: [redacted] o si llama de larga distancia, sin costo, al [redacted]

Sinceramente,

[redacted]

OVER →

OMB No=0925-0216

Nombre del Doctor(es) a quien desea que se le envíe su reporte médico:

Nombre	Dirección	Teléfono
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Hospitalizaciones, Emergencias y Cirugías saliendo el mismo día desde _____:

Fecha	Razón	Nombre y Direcc. del Hospital	Nombre del Doctor
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

Visitas al Doctor:

Fecha	Razón	Nombre del Doctor
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Letter Date_____ Exam Date_____

OMB No= 0925-0216 Exp. 11/30/2013

Dear _____,

A report of your recent examination at the Framingham Heart Study has been forwarded to your doctor or health care provider:

_____

The examination you had at the Heart Study does not take the place of a medical check-up you would get from your doctor and cannot identify all serious heart and health conditions.

Any clinical abnormalities requiring that you see your physician are listed below. Some results from tests obtained during your visit are not immediately available; any abnormalities that may have important health and treatment implications will be sent directly to your doctor.

_____

_____

_____

_____

We look forward to seeing you again and appreciate your support. Your participation in the Framingham Heart Study makes possible our efforts to identify the causes of heart disease and stroke and ways of preventing or treating them.

Thank you for your continuing support. Sincerely,

[redacted]
Medical Director
Framingham Heart Study

Examiner_____

Fecha_____

Estimado (a) _____

_____Los siguientes resultados serán enviados dentro de 6 a 8 semanas:

_____ Reporte del laboratorio

_____ Reporte de la función pulmonar

_____ Reporte de la presión arterial del tobillo

_____ A su doctor se le enviará un resumen parcial. Usted recibirá una copia del reporte del laboratorio y una tarjeta con su electrocardiograma dentro de 6 a 8 semanas.

Version # 1 1/14/05

Fecha_____ Fecha del Examen _____

OMB No=0925-0216 Exp.04/30/2011

_____

Se ha enviado un reporte del examen que tuvo en el Estudio del Corazón de Framingham a:

_____

El examen en el estudio del Corazón se enfoca en enfermedades cardiovasculares y **NO** es un examen completo. Usted debe hacer visitas a su doctor para revisiones periódicas completas. Cualquier anormalidad clínica que requiera que usted vea a su doctor está descrita en el siguiente espacio. Algunas pruebas no están disponibles inmediatamente. Cualquier anormalidad detectada será enviada directamente a su doctor.

_____

_____

_____

_____

Esperamos tener el placer de verlo por aquí otra vez y agradecemos su apoyo. Su cooperación hace posible el progreso para determinar las causas de las enfermedades del corazón y las formas de prevenirlas.

Gracias por su continuo apoyo.

Sinceramente,

[redacted]
Director Médico
Estudio del Corazón de Framingham

Examinador _____

Date of exam

_____/_____/_____

Framingham Heart Study

Summary Sheet to Personal Physician

Blood Pressure	First Reading	Second Reading
Systolic		
Diastolic		

ECG Diagnosis _____

_____

The following tests are done on a routine basis: Blood Glucose, Blood Lipids, Pulmonary Function Test (results enclosed); Echocardiogram findings will be forwarded at a later date **only if <u>abnormal.</u>**

Summary of Findings_____

|__| 1.**No history or physical exam findings to suggest cardiovascular disease.**
(check box if applicable)

_____

_____

_____

_____

_____

_____

_____

_____
Examining Physician

The Heart Study Clinic examination is not comprehensive and does not take the place of a routine physical examination.

Record Of In-Clinic Medical Encounter

(to be filed in chart)

Participant's ID#: _____ Participant's Name:_____

Date of Incident: ____/____/____

Description of Incident:

_____

_____

_____

_____

_____

_____

_____

_____

Physician:_____

Follow-Up (if any)

Date of Follow-Up: ____/____/___

_____

_____

_____

_____

_____

_____

_____

Physician/Staff:_____

Record Of Telephone Encounter

(to be filed in chart)

Participant's ID#: _____ Participant's Name: _____

Date of Incident: ____/____/____

Person Contacted:_____

_____

Regarding:_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Contact Made By:_____

_____

_____

PFT DAILY CALIBRATION

Read all prompts

- Minimize nSight (Patient Information)
- Shortcut to Plus CPLDiag
- Component = CPL (SN: SI0034)
- Balloon check: check all boxes and click on Inflate
- Deflate

LEAK TEST

Put round weight on bell

- Leak Test
- Component = CPL
- S Delay = 20
- Duration = 60
- Start
- ≤ -20 is ok. CANNOT HAVE ≥ -20. IF DO, REDO CALIBRATION (optimum = 0 to -14)

TOOLS (under nSight)

- (Follow prompts)
- Calibration
- *CPL (click on "+")
- Barometric pressure (highlight and make drop-downs visible)
- Calibrate
- Calibrate
- Temp (leave temp that is shown on screen = machine temp)
- Enter
- Humidity
- Enter
- Barometric pressure (leave barometric press that is shown on screen)
- Enter
- Continue

SPIROMETER

- Calibrate
- Calibrate (bell goes up)
- Attach syringe
- Press space bar
- Pull out syringe at constant pace
- Press space bar
- Push in at constant pace
- Press space bar
- All lines should have a green square = Valid. If not, repeat calibration
- Continue

PNEUMOTAC

- Calibrate
- Calibrate
- Continue
- Continue
- Press space bar
- Pull out syringe
- Press space bar
- Press space bar
- Push in syringe (push in before “4”)
- Space bar
- Continue
- Verify
- Close

Take off syringe

DL GAS ANALYZER

- Calibrate
- Next (all must be “Valid” in green)
- Next
- If “Failed” repeat DL Gas calibration ONLY
- If “Passed” press Finish

REPORT

- Check all boxes EXCEPT MOUTH PRESSURE
- Print
- Write initials at bottom of report
- Put printouts in white binder on low shelf in front of scale

END

- Minimize nSight
- Shortcut to Plus CPL Diag
- Component = CPL
- Close
- Enlarge Raptor

PFT TROUBLE SHOOTING INSTRUCTIONS

The first thing to check when you get an error message is to see if there is a popped balloon. Go into Check Balloons, inflate them for ~ a minute. If they are OK, then go out of program and go back in to see if it then works.

If the FVC or Diffusion does something weird, please take a screen shot of it and save it in the folder marked for the month (ie August, Sept, etc.). Instructions on saving the screen shot are attached.

Then call tech support at NSpire (in CO so 2 hours earlier than us).

You call [redacted]

-Press Option 1

-Press Option 7

You may have to leave a message and they will call you back. I usually leave the clinic number: [redacted] When they call, the float person can forward your call to the PFT room (ext. 404)—Remember to take off DND (do not disturb) on the phone in the PFT room to receive this transfer call.

You can tell [redacted] the problem and they may want you to fax the screen shots of the problem. Print the screen shots (I print 2/page) on the PFT computer and fax at [redacted]. Then call them to tell them it is faxed and to look for it.

If [redacted] can't fix the problem over the phone with you (they are very good about taking you step by step on the computer), they will put out a service call to [redacted] or, if he is not available, they will get someone else.

Note in the PFT log book if we don't do FVC, Diffusion or both.

Remember to fill out a Call Back form if the ppt needs to be called back.

We DO NOT call back just to do Diffusion!!

If a balloon pops, please remember to replace it and do a leak test on it by the end of the day or the next morning before clinic.

☺ GOOD LUCK ☺

To make and save a screen shot:

1.) Hit the Print/Scrn/SysRq Button (top right on keyboard)
2.) Go to "All Programs"
    a. "Accessories"
    b. "Paint"
    c. Hit "Ctrl" "v" button (this will copy and paste the picture)
3.) Go to "File"
    a. "Save as"
    b. "My Documents"
    c. Click on current PFT Problems with "current month" you are in.
    d. "Open"
    e. Give new file a name (ie Diffusion or FVC with current date), and "Save"

Procedures for Participants that Faint:

Do Not Use Smelling Salts

1. Use cool wet towels on the back of the neck and forehead (we have ice packs)

2. Head should be lowered between the knees

3. Always ask the patient if they had previous episodes of syncope

4. The patient should remain for 15 minutes after recovery and should not drive a car for at least 30 minutes post recovery

5. Clinic MD should be called to evaluate the participant

6. Clinic MD who sees participant should fill out the "Medical Encounter" form that is in each of the gray desks in the exam rooms. This form is placed as the first page in the participant's chart.

7. Document the incident as an Adverse Event on the Exit Interview Form

8. Copy the Exit Interview form and give copy to [redacted]

ECG CARDS

Send Date	ECG DATE	QTY SENT	RETURN DATE	COMMENTS

Protocol for ECG Cards

We will be creating templates of the ECG for Offspring Exam 9. These templates will then be sent to Sir Speedy (in a sealed envelope) in which ECG cards are made. Sir Speedy will return the new ECG cards (in a sealed envelope) to FHS. The ECG cards are then given to [redacted] to distribute to each participant. The invoice from Sir Speedy will be mailed to [redacted] (treasurer of the Friends of FHS).

How to create labels for ECG cards:

You will need Avery #5161 white mailing labels 1" x 4"
Labels are placed in printer:

- Label side down
- Top of label sheet goes into printer

1. Each ECG will have 2 white labels placed on top. The first label has the participant's first and last name, and is positioned on the top left side of the ECG (just above the red grid). The second label has the date of the ECG, and is positioned on the top right side of the ECG (just above the red grid).
2. The ECGs are placed in a large white sealed FHS envelope. You will write on the envelope the total number of cards enclosed, as well as date's listed from the ECG. Also in this envelope is a return envelope for Sir Speedy to return the ECGs and cards. Label this envelope: Clinic. Under Clinic write the name of the person this should go to (ie: Emily).
    a. Example: January 15, 2010 to January 20, 2010.
3. Write "Sir Speedy" on the front of the envelope, and call them at [redacted] Let them know that the FHS has a pick-up for them at the front desk.
4. In the ECG cards/Sir Speedy white binder you will list the date order was sent to Sir Speedy and the total quantity of ECG cards to be made.
5. Once the order has been returned to the FHS than please list in the binder the date ECG cards were returned, and any comments you may have.
6. Keep the returned ECGs (paper copy) for ~ 2 months then shred. (The ECGs may be needed to make a lost/forgotten card/name change, etc.)

TO INITIALIZE ACTICAL

- Turn on Reader (toggle switch in back)
    - Black actical goes on Reader labeled for black Actical
    - Gray actical goes on Reader labeled for gray Actical
- Put on Actical (green dot to green dot)
    - Green light on
    - Red light blinking

ON COMPUTER:

- Reader
- Write
    - Com Port: Com1 for black acticals; Com 4 for gray acticals
- Yes
- OK
- Dropdown: starting to read
    - Wait until loaded: click OK

PUT IN PARTICIPANT INFO:

- ID: under Identity
- Age
- Record Steps: click on
- HT (inches)
- WT (lbs)
- Start time: slide bar to 15:00 hours
- Epoch length: 0.50 (click on once to get to)
- Make sure days = 11 and epoch length = .50
- Send
- OK

Remove Actical First, then click OK

Put back in plastic case with participant label
Put case in Actical room
Put initials in Actical logbook under: Tech ID Initial

Battery Life:
If battery life = ≤12 days, get a new Actical from Rm 103 and write new serial number in logbook.

Weekly Set up of Float Sheet & Urine Cups

On Thursday, give [redacted] the box that has all the materials to set up the Float Station:

The box is on the desk in [redacted] office, next to the HT/WT log book. Make sure that all supplies are in the box (minus the scissors and paper clips) when you give it to her.

More urine cups can be found in the changing room on top of the table paper boxes under the mirror. More yellow float sheets can be found in the float desk top drawer, far left, in a folder. The clear plastic bags, labeled with each day of the week are in the top drawer of the float desk.

MATERIALS:

- Large yellow float sheets (5) – top drawer of clinic desk, left side
- Urine cups and tops– Clinic techs office
- Name tags – Clinic techs office
- Monthly Doctor schedule – make copy from schedule on clinic bulletin board
- Daily participant schedule (distributed by Maureen on Wed or Thurs)
- Weekly labels (from [redacted] delivered to clinic on Thursday or Friday
- Clear plastic bags labeled with each day of the week

PROCEDURE:

- Yellow float sheet (1/day)
  - Write date on top of each yellow sheet
  - Write Doctors names on top of each yellow sheet
  - Put participants (ppt) id label (taking label from the far right column) on left hand side of yellow sheet, starting at top with earliest ppt of day, ending with last ppt of day (using the daily participant schedule)
  - To left of the id labels, write time ppt is scheduled to come in

- Urine cups
  - Checking with the daily participant schedule, for each day of the week, put a ppt id label that corresponds with that day of the week on urine cup
  - Put a blue top on the urine cup
  - Place in plastic bag corresponding to that day of the week
- Name tags
  - Checking with the daily participant schedule, for each day of the week, put a ppt id label that corresponds with that day of the week on name tag
  - Put the day's name tags in a paper clip
  - Keep with yellow float sheet

- ID labels
    - Cut the remaining labels into 3 sets (again separating by day)
    - The labels with 2 name and 3 id number goes on top, then the other 2 sets, in a criss cross fashion to keep them separated. The leftover 2 labels should be papercliped with the post-it that has the day and date on it and given to the accelerometer person
    - Paper clip together with the name tags

Take yellow float sheet, daily ppt sheet, urine cup and name tag clipped with id labels and put into plastic bag corresponding with that day of the week.

Place in day order in top draw of clinic desk.