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Section IV: Physician-Administered Medical History and Physical Exam

1) Medical History
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Section V: Self-Administered Questionnaires

1) Socio-demographics
2) SF12 Health Survey
3) Sleep Questionnaire
4) Willett Food Frequency Questionnaire

Section VI: PFT-Spirometry and Diffusion Capacity (full sample)

1) Spirometry
2) Diffusion Capacity
3) Post Bronchodilator Spirometry (Sub-sample)
   a. Albuterol
4) Respiratory Disease Questionnaire

Section VII: Non-Invasive Vascular Testing**

1) Echocardiogram
2) Carotid
3) Tonometry
4) PAT

Section VIII: Exam Completeness

1) Exit Interview
2) Referral Tracking & Adverse Events
3) Participant Letter
4) MD Letter to Personal Physician

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

Offspring Exam 8 Components-Offsite

Section I: Informed Consent & Tracking Procedures

1) Informed Consent
2) Waiver of Informed Consent
3) HIPPA - Release of Health Information for Research Purposes
4) FHS Follow-up by Proxy
5) Tracking Information Form

Section II: Exam Procedures

1) Anthropometrics
   a. Weight
   b. Waist Girth
   c. Waist Girth at Iliac Crest
   d. Sagittal Abdominal Diameter
2) ECG
3) Observed Physical Performance
   a. Hand Grip Test
   b. Measured Walks

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. Living Arrangement
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4) Participant Letter
5) MD Letter to Personal Physician

Equipment For Offspring Exam 8 Procedures

1. A. Clinic:

1. Detecto Scale
Worcester Scale Co., Inc.
203 E. Daugherty
Webb City, MA 64870
h393
[redacted]
Room 100

2. Detecto Scale
Halliday Medical Inc.
25 Walpole Park South Drive
Walpole, MA 02081
h393
[redacted]
Room 101

3. Moore Medical
PO Box 1500
New Britain, CT 06050-1500
h393
[redacted]
P/N 65388
www.mooremedical.com
Room 102

B. Offsite:

SECA Portable Scale Model #841
MSI: Measurement Specialties Inc.
Fairfield, NJ 07007
h393

2. Weight to calibrate scale: 50 lbs.
Worcester Scale Co., Inc. (See above)
h393

3. SECA Stadiometer
Halliday Medical
4-694-581
Walpole, MA 02081
h399
[redacted]

4. Marquette Mac5000 (electrocardiogram cart)
Marquette Electronics
100 Marquette Drive
Jupiter, FL 33468-9100

GE Healthcare Technologies
1701 Military Trail
Suite 150
Jupiter, FL. 33458

h304- h338

Tech support: George Ryan
[redacted] ext [redacted] voice mail)
Sales Rep: [redacted]
[redacted]
Clinical **Applications**: [redacted]

5. Acquisition Module for Mac5000 h304-h338
Cam-14

6. Marquette Mac5000 – Offsite Visits h304- h338

7. Portable standard mercury column sphygmomanometer: Baumanometer, 300 model; Catalogue #0661-0320
W.A. Baum Co., Inc.
620 Oak Street
Copaigue, NY 11726-3292
[redacted]
Fax [redacted]
[redacted]

h111, h112

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

Repairs and Calibration
Welch Allyn
Arden, NC 28704
[redacted]

h233, h234

W.A Baum
9. Bauman latex free blood pressure cuffs in four sizes: regular adult, large adult, pediatric, thigh (clinic only). Inflation system is Moore medical

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

11. Tailor's plastic tape measure h403, h405

12. Ultrasonic Flow Detector and 8 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
[redacted]

Ankle-Arm Doppler
h624-h645

13. For Pulmonary Function Test (PFT), please see:
Manual of Operations: Pulmonary Function Assessment
[redacted]
Phone: [redacted]
Email: [redacted]
[redacted] NO Longer as of Sept. 07
Phone: [redacted]
Email: [redacted]

14. Spirometer: Collins CPL pf
Collins Medical
Ferraris Respiratory
KoKo Plaza, 908 Main Street. Louisville, CO
Tech Support: [redacted]
Sales Rep/Customer Service: [redacted]
Cell phone: [redacted]

PFT data set

15. Equipment for Collins CPL
a. DCII Disposable Filters and Mouthpieces (Ferraris) #K022464
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. Balloon Refills (Ferraris) #K022355
g. CO2 Absorbent Granules (Ferraris) #K022556
h. Microtach (Ferraris) #003500REV A

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
    [redacted]
    Or [redacted] VMX
    Or [redacted]
    Sales [redacted]

PFT data set

17. Albuterol Inhalers – Pro Air AS of
    Moore Medical # 52940

18. 3 Liter calibration syringe Model #021156

19. Holtain Kahn Abdominal Caliper (description: Seritex Inc. 77748)
    Seritex Inc.
    1 Madison Street
    E. Rutherford, NJ 07073
    [redacted]
    Fax: [redacted]

h407

20. Sports Stop Watch #63-5016
    Radio Shack
    314 Pond St.
    Ashland, MA 01721
    [redacted]

h614-h623

21. Heart Square, by Heartware Inc.
    purchased from: Nova Heart

h304-h338

22. Pocket Talker II
    Williams Sound Corp.
    10399 W. 70th St.
    Eden Prairie, MN 55344
    [redacted]

23. JAMAR dynamometer
Model #5030J1
Sales Address:
Lafayette Instrument Co.
P.O. Box 5729
Lafayette, IN 47903
[redacted]

h605-h612

Calibration Address:
JLW Instruments, Inc
Sammons Preston
452 N. Sangamon
Chicago, IL 60622
[redacted]
Fax [redacted]
[redacted]

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

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

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

As the FHS staff person obtaining Informed Consent for Offspring Exam 8, one must provide ample time for the participant to read the consent and answer any questions the participant may have. Each interviewer should be trained on how to administer the consent form and use the developed script for presenting the form to the participant. The script is to follow.

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 [redacted] or [redacted]

Listed below is important information that must also be documented during the consent process.

Consent Check Boxes

The introduction of the check boxes is beneficial to the participant as it gives the participant options in his/her participation. The prepared script is administered to insure a clear understanding of each statement which requires a yes or no answer. These responses are then documented for data collection. In addition, any negative responses are reported to the appropriate manager for follow up.

Visual Impaired Participants

For participants that are visually impaired, the consent form should be read to the participant. A witness must be present during the consent process. The witness must attest that the information in the consent form was accurately explained to and apparently understood by the participant. Therefore, the subject can either sign ("make their mark") and date the consent form if they can or verbally agree to participate. The consenter signs the form as the person obtaining the consent and the witness will write on the consent form "consent witnessed by" and she/he also will sign and date the form.

If the participant refuses to have the consent form read to them (i.e., asks you to stop), a detailed summary of the exam contents must be provided to the participant. After the participant is informed of what is contained in the consent and they have indicated their agreement to participate, have them sign ("make their mark") and date the consent form if they can, to indicate their willingness to participate or allow them to verbally agree. The consenter must also document on the consent the way he/she communicated this information and also have the witness sign and date.

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 consent will need to be copied and mailed to the participant after the visit.

We should not need to FAX any consent forms as we no longer will need consent by substituted judgment

Introduction to the Informed Consent

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.

Checkbox 2 allows you to agree to provide a blood sample from which DNA and other components can be extracted.

Example of "other components" is RNA. RNA is a messenger of DNA.

Checkbox 3 allows you to agree to the creation of a cell line if a cell line for you does not already exist. In your case according to our records you already gave permission and gave a blood sample and a cell line already exists By checking "yes" you give us permission to keep the cell line.

If the pt. checks no, state: "*You already have a cell line, by checking no you are telling the Heart Study not to use any existing cell line material*"

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

Checkboxes 4-6 allows you to choose to participate in the genetic studies of different health conditions.

Checkbox 4 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 5 allows you to agree to participate in genetic studies of other important diseases and health conditions such as arthritis, osteoporosis, and cancer.

Checkbox 6 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 7 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 8 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 9 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.

RESEARCH CONSENT FORM
Offspring Exam 8

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Background

You are being asked to participate in the 8th Framingham Heart Study Offspring examination. This is an observational study designed to identify the relationship between risk factors, genetics, cardiovascular disease, and other health conditions.

Purpose

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 health conditions. This examination does not take the place of a routine medical check up by your physician.

What Happens In This Research Study

You will be one of approximately 3800 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 Framingham Heart Study facility located at 73 Mount Wayte Avenue in Framingham, MA or other facility/residence.

The Framingham Heart Study Examination takes about 4 hours and includes the following:

1) History

An interview about your past and present medical status including: heart and lung illnesses; hospitalizations; reproductive history; personal and family history; and medical health habits (including diet, prescription, and non-prescription drug use).

2) Measurements and Procedures

A Framingham Heart Study physician will perform a physical examination. You will be asked to participate in standard measurements routinely done in your physician's office such as height, weight, blood pressure (including measurement in both arms and legs), electrocardiogram, and lung function. You will also be asked questions to assess your ability to perform activities of daily living, general daily functioning, and measures of memory and mood.

You will be asked to have the following procedures:

Electrocardiogram: The electrocardiogram measures the rate and regularity of your heartbeats.
Lung function test: This requires that you breathe in and out of a machine, which measures how well your lungs are working. Some participants, about 1000 or 25%, will be asked to inhale a bronchodilator medication (Albuterol) used routinely in lung functioning testing, and then to repeat some of the tests.
Echocardiogram: This is a picture of your heart using ultrasound waves instead of radiation.

3) Blood and urine specimens

A technician will draw a sample of your blood (112.5 cc or about 7.5 tablespoons) and you will be asked to give a sample of your urine. Both the blood and urine samples will be used for the testing of potential

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risk factors for the diseases and health conditions under investigation. The blood samples will also be tested for genetic studies.

Genetic Studies: You will be asked if a sample of the blood you have donated (40 cc or about 3 tablespoons) may be used for the preparation of DNA (genetic material) and for the creation of a cell line. A cell line is a frozen sample of specially processed white cells from your blood that allows us to grow more white cells and get more DNA from them in future as needed for research projects. Cell lines will be stored at a central site (repository). Neither your name nor Framingham clinic number will appear on the sample. A new security bar code number and the date the specimen is drawn will be the only information on the label. You will not be routinely informed of the results of the research performed upon your genetic blood sample, although genetic tests may be developed as a result of the combined analysis of samples in the Framingham Heart Study.

Data and DNA will be distributed to Framingham Heart Study 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 diseases and health conditions. The researchers will be given the DNA without any potentially 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.

4) Vascular function testing
You will be asked to participate in three experimental tests of vascular function, which will take about 45 minutes:
a. Carotid ultrasound takes pictures of the arteries in your neck using sound waves. This involves moving an electronic device across the surface of the neck.
b. Arterial tonometry tests blood vessel (artery) stiffness by carefully recording the blood pressure waveform. A technician will perform the arterial waveform evaluation using a tonometer (a flat pressure sensor which, when pressed lightly on the skin over the artery, records a waveform). The blood vessels in the neck (carotid), arm (brachial and radial), and groin (femoral) will be studied by tonometry.
c. Fingertip pulse test. The technician will measure the pulse at a fingertip in each hand at baseline, after blood pressure cuff inflation and after release of the blood pressure cuff.

5) Medical Records
You will be asked to sign a medical release form to allow the Framingham Heart Study Medical Records staff to obtain and review copies of your hospital, cancer registry, and medical records for the Framingham Heart Study Physician Review. This medical release will be considered valid to obtain these records and this authorization will be valid until canceled by you.

With your permission, a summary letter of routine test results from this exam will be sent to you and your physician.

In the event that you may have had a stroke, you will be examined during your hospitalization (if

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applicable) and at 3, 6, 12, and 24 months. The examination will include a neurological evaluation and assessment of your ability to perform activities of daily living. If the neurologist believes that you have had a stroke or definite memory problems, you will be asked if you would be willing to have an M.R.I. (Magnetic Resonance Imaging) scan of the brain. If you do decide at that time to undergo the test, it will be arranged by a clinic coordinator. In some instances, you may be asked to return to the clinic for further testing based on information obtained from your examination.

You will be contacted about every two years to obtain additional health information. You may also be contacted to determine your interest in participating in other FHS health-related studies. You will be asked to give your social security number for the purpose of locating you in the future, which will be up to you. It is expected that this exam will be done approximately every 4 to 8 years at which time you will be asked to sign a new consent form. If an exam is not possible, you may be asked to complete a medical history update over the phone.

You may choose to withdraw your blood samples at a future date and your samples will be destroyed at that time. If you choose to withdraw your samples, you should call the Framingham Heart Study at (508) 935-3477 and ask for the lab manager.

Any questions you have regarding your rights as a research subject can be directed to the Office of the Institutional Review Board for Boston Medical Center at [redacted] The Framingham Heart Study 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 Framingham Heart Study is documented in the Federal Register, September 26, 2002 (Vol. 67, No. 1879) pages 60776-60780.

Risks and Discomforts
Each of the test procedures and their risks and discomforts are listed below:

The Carotid Ultrasound Test: This procedure is painless. Ultrasound is widely used in clinical applications because of its low risk. Your exposure to ultrasound in this examination will be no greater than a typical clinic exam.
Fingertip pulse test: The fingertip device is made of latex and may cause a reaction if you have a latex allergy. Please tell us if you have an allergy to latex and we will not apply the fingertip device.
Echocardiogram: There may be mild discomfort where the transducer is applied.
The Lung Function Test: This involves a very low level of risk. On rare occasions a person taking a lung function test may feel lightheaded or may faint. The primary risk involved is 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).
The Blood Draw: 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.

Possible general discomforts include: headaches or feeling hungry if you have not eaten before the exam; fatigue or chill during long exam; communication limitations before, during, or after exam.

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We do not expect an unusual risk or injury to occur as a result of participation. There are no known risks if you are, or may become, pregnant. In the unlikely event that during examination procedures you should require medical care, first aid will be available.

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 precursors, etiology, and prevention of cardiovascular disease and other health conditions, including the possibility of genetic linkages.

Alternatives

Your alternative is to not participate in the study.

Subject Costs and Payments

You will not be charged for any part of the examination. If the examination uncovers any medical problems that require 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, loss of work, and transportation (gas, tolls, etc.). You will not receive payment for your participation.

Confidentiality

Any information we obtain about you during this study will be treated as strictly confidential to the full extent permitted by applicable law. To ensure confidentiality, a code number will be assigned to you and your potentially identifying information.

The code number will not be used on any blood samples you provide. A label with a new security bar code number and the date the specimen is drawn will be the only information on the label. The code numbers will only be provided to qualified investigators studying the DNA samples. Files linking names to samples will be kept locked and accessible only to Framingham Heart Study data managers. The coded samples will be stored securely, separated from files which link your name to the code numbers.

No other individuals will have access to the stored sample or information gained from your stored sample. Because no information will be provided to you or to others from the analysis of this sample, the risk in providing this sample is minimal. Your sample will be kept until it is no longer of scientific value.

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When study results are published, your name and any other potentially identifying information (i.e.code number) 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 analysis.

Information from this study and from your medical record may be reviewed and photocopied by the Food and Drug Administration (FDA) and/or 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.

Please check the appropriate box beside each statement you agree with:

1) |___|YES |___|NO I agree to participate in the Framingham Heart Study examinations described above to study the frequency of and factors contributing to heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, and other diseases and health conditions.

2) |___|YES |___|NO I agree to provide a blood sample from which DNA and other components can be extracted. The DNA will be made available to researchers studying the diseases listed above.

3) |___|YES |___|NO If a cell line has not already been collected, I agree to allow a cell line to be made from a sample of 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 get more DNA from them in the future as needed for research projects).

4) |___|YES |___|NO I agree to participate in the genetic studies of factors contributing to heart and blood vessel diseases, lung and blood diseases, stroke, and memory loss.

5) |___|YES |___|NO I agree to participate in genetic studies of other diseases and health conditions including but not limited to joint disease, bone loss, and cancer.

6) |___|YES |___|NO I agree to participate in genetic studies of reproductive conditions and mental health conditions such as alcohol use and depressive symptoms.

7) |___|YES |___|NO I agree to allow researchers from private companies to have access to my DNA and genetic data which may be used to develop diagnostic lab tests or pharmaceutical therapies that could benefit many people. (Note: You or your heirs will not benefit financially from this, nor will your DNA be sold to anyone.)

8) |___|YES |___|NO I agree to allow the Framingham Heart Study to release the findings from non-genetic tests and examinations to my physician, clinic, or hospital.

9) |___|YES |___|NO If a genetic condition is identified that may have potentially important health and treatment implications for me, I agree to allow the Framingham Heart Study to notify me and with my permission to notify my physician.

RESEARCH CONSENT FORM
Offspring Exam 8

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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] 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 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 effect 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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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

_____ _____

Person Obtaining Consent (Signature and Printed Name) Date

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Offspring Exam 8 - Offsite

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Background

You are being asked to participate in the 8th Framingham Heart Study Offspring examination. This is an observational study designed to identify the relationship between risk factors, genetics, cardiovascular disease, and other health conditions.

Purpose

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 health conditions. This examination does not take the place of a routine medical check up by your physician.

What Happens In This Research Study

You will be one of approximately 3800 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 [redacted] or other facility/residence.

The Framingham Heart Study Examination takes about 2 hours and includes the following:

1) History
An interview about your past and present medical status including: heart and lung illnesses; hospitalizations; reproductive history; personal and family history; and medical health habits (including diet, prescription, and non-prescription drug use).

2) Measurements and Procedures
You will be asked to participate in standard measurements routinely done in your physician's office such as height, weight and blood pressure. The electrocardiogram measures the rate and regularity of your heartbeats

You will be asked questions to assess your ability to perform activities of daily living, general daily functioning, and measures or memory and mood.

In the event that you may have had a stroke, you will be examined during your hospitalization (if applicable) and at 3, 6, 12, and 24 months. The examination will include a neurological evaluation and assessment of your ability to perform activities of daily living. If the neurologist believes that you have had a stroke or definite memory problems, you will be asked if you would be willing to have an M.R.I. (Magnetic Resonance Imaging) scan of the brain. If you do decide at that time to undergo the test, it will be arranged by the clinic coordinator and you will be asked to sign a separate consent form. In some instances, you may be asked to return to the clinic for further testing based on information obtained from your examination.

3) Blood urine specimens

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Genetic Studies: You will not be asked to provide a blood sample at this visit, although we will use previously frozen blood samples for testing of potential risk factors for the diseases and health conditions under investigation. Some participants may be asked to provide a small sample of blood for the creation of a cell line. A cell line is a frozen sample of specifically processed white cells from your blood that allows us to grow more white cells and get more DNA from them in the future as needed for research projects. Cell lines will be stored at a central site (repository). Neither your name nor Framingham clinic number will appear on the sample. A new security bar code number and the date the specimen is drawn will be the only information on the label. You will not be informed of the results of the research performed upon your genetic blood sample, although genetic tests may be developed as a result of the combined analysis of samples in the Framingham Heart Study.

The previous frozen blood samples will also be tested for genetic studies.

Data and DNA will be distributed to Framingham Heart Study 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 diseases and health conditions. The researchers will be given the DNA without any potentially 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.

4) Medical Records
You will be asked to sign a medical release form to allow the Framingham Heart Study Medical Records staff to obtain and review copies of your hospital, cancer registry, and medical records for the Framingham Heart Study Physician Review. This medical release will be considered valid to obtain these records and this authorization will be valid until canceled by you.

With your permission, a summary letter of routine test results from this exam will be sent to you and your physician.

You will be contacted about every two years to obtain additional health information. You may also be contacted to determine your interest in participating in other FHS health-related studies. You will be asked to give your social security number for the purpose of locating you in the future, which will be up to you. It is expected that this exam will be done approximately every 4 to 8 years at which time you will be asked to sign a new consent form. If an exam is not possible, you may be asked to complete a medical history update over the phone.

You may choose to withdraw your blood samples at a future date and your samples will be destroyed at that time. If you choose to withdraw your samples, you should call the Framingham Heart Study at [redacted] and ask for the lab manager.

Any questions you have regarding your rights as a research subject can be directed to the Office of the Institutional Review Board for Boston Medical Center at [redacted] The Framingham Heart Study

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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 Framingham Heart Study is documented in the Federal Register, September 26, 2002 (Vol. 67, No. 1879) pages 60776-60780.

Risks and Discomforts
Each of the test procedures and their risks and discomforts are listed below:

Observed Performance: this test involves a very low level of risk. The primary risk is injury from falling.

We do not expect an unusual risk or injury to occur as a result of participation. There are no known risks if you are, or may become, pregnant. In the unlikely event that during examination procedures you should require medical care, first aid will be available.

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 precursors, etiology, and prevention of cardiovascular disease and other health conditions, including the possibility of genetic linkages..

Alternatives
Your alternative is to not participate in the study.

Subject Costs and Payments
You will not be charged for any part of the examination. If the examination uncovers any medical problems that require 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, loss of work, and transportation (gas, tolls, etc.). You will not receive payment for your participation.

Confidentiality
Any information we obtain about you during this study will be treated as strictly confidential to the full extent permitted by applicable law. To ensure confidentiality, a code number will be assigned to you and any of your potentially identifying information.

The code number will not be used on any blood samples you provide. A label with a new security bar code number and the date the specimen is drawn will be the only information on the label. The code

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numbers will only be provided to qualified investigators studying the DNA samples. Files linking names to samples will be kept locked and accessible only to Framingham Heart Study data managers. The coded samples will be stored securely, separated from files which link your name to the code numbers.

No other individuals will have access to the stored sample or information gained from your stored sample. Because no information will be provided to you or to others from the analysis of this sample, the risk in providing this sample is minimal. Your sample will be kept until it is no longer of scientific value.

When study results are published, your name and any other potentially identifying information (i.e. code number) 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.

Information from this study and from your medical record may be reviewed and photocopied by the Food and Drug Administration (FDA) and/or 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.

Please check the appropriate box beside each statement you agree with:

1) |___| YES |___| NO I agree to participate in the Framingham Heart Study examinations described above to study the frequency of and factors contributing to heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, and other diseases and health conditions.

2) |___| YES |___| NO If a cell line has not already been collected, I agree to allow a cell line to be made from a sample of 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 get more DNA from them in the future as needed for research projects).

3) |___| YES |___| NO I agree to participate in the genetic studies of factors contributing to heart and blood vessel diseases, lung and blood diseases, stroke, and memory loss.

4) |___| YES |___| NO I agree to participate in genetic studies of other diseases and health conditions including but not limited to joint disease, bone loss, and cancer.

5) |___| YES |___| NO I agree to participate in genetic studies of reproductive conditions and mental health conditions such as alcohol use and depressive symptoms.

6) |___| YES |___| NO I agree to allow researchers from private companies to have access to my DNA and genetic data which may be used to develop diagnostic lab tests or pharmaceutical therapies that could benefit many people. (Note: You or your heirs will not benefit financially from this, nor will your DNA be sold to anyone.)

7) |___| YES |___| NO I agree to allow the Framingham Heart Study to release the findings from [illegible] genetic tests and examinations to my physician, clinic, or hospital.

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non-genetic tests and examinations to my physician, clinic, or hospital.

8) |___| YES |___| NO If a genetic condition is identified that may have potentially important health and treatment implications for me, I agree to allow the Framingham Heart Study to notify me and 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] 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 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 effect whether you want to continue to take part, you will be told about them as soon as possible.

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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.

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
Person Obtaining Consent (Signature and Printed Name)	Date

Waiver of Informed Consent-Offspring Cohort

On January 25, 2005 the Boston Medical Center IRB approved a new protocol for cognitively impaired offspring cohort participants allowing a Waiver of Consent. Offspring cohort participants with moderate or severe dementia as determined by the Dementia Study will sign a consent form for the sole purpose of documenting assent to the exam, providing the participant is physically able to do so. The participant will not be asked to check the consent boxes on the consent form. If the participant checks the consent boxes, those choices will not be considered the priority, rather the choices made on the last exam where their cognitive status was not an issue will be used. The Consent by Substituted Judgment form will no longer be used for the Offspring Cohort participants.

The Framingham Heart Study Health Care Proxy form information will not be collected from Offspring cohort participants with moderate or severe dementia.

Dementia is defined as having deficits in two or more cognitive domains, functional decline and evidence of cognitive decline over a 6 month period. Moderate dementia is generally performance that is greater than two standard deviations below expected (also, using clinical judgment), and severe dementia is when a subject is un-testable (or nearly so).

The Dementia Study documents moderate or severe dementia using the following criteria:

1. Dementia Review Outcome/Severity Score† = 2 or 3

and/or

2. Clinical Dementia Rating Scale (CDR)† = 2 or 3

2=Moderate Dementia
3=Severe Dementia

†Based on Dementia Review Tracking. To log in to this screen on the roster use the following command: abf heart test dem_track

Participants who have one or both of these scores will have their Consent waived and will be asked to sign a Consent at the time of their clinic exam to document assent to the exam.

If a participant does not have either of these two scores, but has a consent status of 3 or 4 determined by neuropsych testers, the participants Consent will also be waived.

The exam appointment will be arranged with a family member and/or another responsible party (i.e. POA, Healthcare Proxy). The family member/responsible party will be informed of the content of the exam but will not be required to provide verbal or written consent for the exam under the new Waiver. However, should the family member/responsible party object to a Heart Study visit, this objection will be honored.

It is important to note that the majority of these exams will be performed offsite unless family members strongly request a clinic visit. If so, the family member must accompany the participant and stay with them during their exam.

The following script should be used when placing the call to the participant's family members:

Hello, this is _____(staff name) from the Framingham Heart Study. I am calling to let you know that we will be arranging an appointment to visit with your mother/father/relative for his/her 8th Heart Study exam. As you may know, your mother/father/relative has been participating in the Heart Study over the past 30 years. The current exam includes questions regarding his/her medical history since his/her last exam, two blood pressure measurements, an ECG and personal history questionnaires (add a nursing home chart review if applicable). The exam will not involve any invasive testing or blood samples (if offsite). I'd like to visit with _____(participant name) on _____ (date). Would you like to be present at the exam?

If they want to be present, but cannot meet when suggested, arrange a date and time that works for them.

If they do not want to be present, ask *"Who should I set this appointment up with?"* and ask about a Proxy interview.

If family members refuse the exam, ask if they are willing to do a telephone health history update.

Note: At the time of the appointment if the participant refuses to have the exam his or her objections will be honored.

If the participant does not object to the exam, the staff member seeing the participant should obtain an electrocardiogram, two blood pressures, height (onsite only), weight, and self assessment questions. The technician should not ask the cognitively impaired participant the following questionnaires:

1. Nagi
2. Rosow-Breslau questions

A Proxy can be a 1st degree relative (spouse, child), other relative, friend, healthcare professional, or another appropriate person who knows the participant's history well.

The Proxy may answer all questions except:

1. Mini-Mental State Exam (MMSE)
2. CES-D
3. Self assessment questions (2)

The information regarding the Proxy should be documented on the Proxy Sheet in the exam packet. In some cases there may be more than one Proxy answering questions regarding the participant. If this is the case, document their information also.

Tricia Kelly will complete a Consent Form Waiver documentation form for all clinic participants who come in for their Offspring visit but have previously been identified as a consent waiver participant. This will go into the chart with their assent of consent.

If an Offspring participant was not known to have moderate or severe dementia as determined by the Dementia Study before having an exam the participant will sign an Informed Consent.

Consideration for use of waiver in participants not known to be impaired prior to a clinic or field visit exam should be done if during the visit a clinic staff member is concerned that a participant may be confused to a degree that he/she does not understand the consent process and thus cannot competently provide consent. If this is the case then the following steps should be followed.

1. The MMSE should be scored by [redacted]

Note: Any participant with a MMSE score at or above 26 may be presumed competent unless listed otherwise at their last evaluation. (Determined by [redacted] and [redacted] dated 3/10/01.)

2. Tricia will then determine if a participant fits into the "signed a Consent but may qualify for Waiver" category by using these additional guidelines:

A. The participant does not have the following scores on the dementia review screen:

a. Dementia Review Outcome/Severity Score=2 or 3
b. Clinical Dementia Rating Scale (CDR)=2 or 3
c. Consent Status of 3 or 4;

and

B. The Mini-Mental Score (MMSE) is:

a. below 13; unless seen by a neurologist and declared not demented*
b. between 25 and 13*.

*Determined by [redacted] and [redacted] dated 3/10/01

If the participant falls into this category, and the staff member interviewing the participant feels he or she should not continue the exam, stop the participant interview and complete a Proxy interview using the same protocol for Waiver participants. But if the staff member feels it is appropriate to continue, he or she should complete the exam and after the exam contact a family member or responsible party to explain concerns regarding the cognitive decline.

If Tricia determines that a participant's cognitive status is unclear, she will fill out a "Consent Form Waiver" to document the participant's status. This includes:

1. Date of Exam and Exam Number
2. FHS ID and Participant Name
3. Event (0=Clinic Exam, 1=Nursing Home, 2=Residence, 3=Blood draw only (clinic), 4=Other_____ (write in)).
4. Informed Consent Status (1=Informed Consent, 2= Waiver Only, 3= Consent Form signed may qualify for Waiver, 4=Other_____(write in)).
5. Clinical Dementia Rating Scale (CDR) & date evaluated
6. Dementia Review Outcome/Severity Score† & date evaluated
7. Consent Status & date evaluated
8. MMSE Score from last exam & date administered
9. MMSE Score from current exam & date administered
10. Comments

If the Informed Consent Status (#4 above) equals 3=Consent form signed may qualify for Waiver, and the chart has been reviewed by the clinic physician and Tricia has been notified, it is sent to the neuropsychology team to determine if the participants Consent should be waived.

For the neuropsychology team to be flagged that a chart will need to be reviewed [redacted] must first email the Dementia Study investigators ([redacted] and [redacted] email addresses are listed on the last page).

[redacted] will put the participant's MMSE, the MMSE handout, the Informed Consent from current exam, the Proxy Sheet and the Consent Form Waiver on the front of the chart for the neuro team to review.

Once the neuropsychology team has been notified and the chart has been given to the neuropsychologist who is available to review the chart he/she will do the following:

1. Review the Consent Form Waiver that has been completed by [redacted]
2. Review the participant's MMSE

3. Determine if the Informed Consent should be used or waived
4. Complete page two of the Waiver within 2 days and return the chart to [redacted]

The neuropsychology team member will document whether or not the Consent is waived by completing on page two:

1. The Reviewer's Neurology ID
2. Date Reviewed
3. NP (neuropsych's) disposition of Consent status, (1=Use Consent, 2=Consent Waived)
4. Comments

If the neuropsychology team determines that the Informed Consent should be waived the neuropsychology reviewer stamps, initials, and dates every page of the current Informed Consent using the Waiver Stamp. (The stamp is kept in Tricia's office and will be given to the neuro team when the chart needs to be reviewed.) The Consent will be kept only to show the participant provided assent to the FHS exam. The Data Team will use the last Consent the participant signed while still cognitively intact for DNA distribution permission.

If the Consent is not waived, comments should be written on the Waiver with the reason.

After the chart has been reviewed by the dementia team, it will be returned to
When Tricia receives the chart, if the Waiver is to be used, she will:

1. Review Waiver to ensure everything is properly documented and stamped
2. She will make sure the Consent form is stapled to the Waiver and NOT keyed
3. Key the Waiver
4. Document the Waiver Status in the roster comments, date waived and exam number
5. File the Waiver & Consent form in the chart

If the Consent is not waived, he/she will:

1. Key the Consent form & Waiver
2. Document the neuropsychology comments in the roster
3. File the Waiver with the Informed Consent

The Waiver will be keyed by [redacted] under abf heart waiver1 key and she will file the Waiver in front and stapled to the Informed Consent in the chart..
Once a month [redacted] will send a copy of all the Waivers used (tracked in an Excel spreadsheet) for Offspring Exams to .

Contact Information:

Clinic:

[redacted] [redacted] Room 228
Room 114
Room 126 [redacted]

Dementia Study/Neuropsychology:

[redacted] [redacted] Room 256
Room 256
Room 256 [redacted]

Other:

[redacted] [redacted] Room 248
Room 268
Room 204 [redacted]

Updated 10/5/05

Consent Form Waiver

On January 25, 2005 the Boston Medical Center IRB approved a new protocol for cognitively impaired offspring participants allowing a Waiver of Consent. Offspring cohorts with moderate or severe dementia as determined by the Dementia Study will sign a consent form for sole purpose of documenting assent to the exam, providing the participant is physically able to do so. If the offspring participant is not known to have moderate or severe dementia as determined by the Dementia Study and a cognitive impairment is evident, the participant will sign an informed consent form to document assent to the exam. **The Consent by Substituted Judgment form will no longer be used for Offspring Cohort participants.** The consent box answers from the last exam without cognitive impairment will be used. The exam 8 appointment will be arranged with a family member according to established protocols. The family member will be informed regarding the content of exam 8 but will not be required to provide verbal or written consent for the exam under the new waiver. However, should the family member object to a Heart Study visit, this objection will be honored. For all participants who do not sign a consent form and/or signed a consent but fall under the Waiver, this sheet will be completed by FHS staff and kept with the participant's chart.

To Be Completed by Clinic Team **Staff ID:** _____

Exam/Draw Date:___-___-___ Exam Number:_____

FHS ID:___-_____ Participant Name:_____

Event: ___ 0= Clinic Exam 1= NH 2= Residence 3=Blood draw only

4= Other:_____ (write in)

Informed Consent Status: ____ **If IC Status = 3, send to Neurology Group**

1= Informed Consent, 2= Waiver Only, 3= Consent form signed may qualify for Waiver,

4=Other_____

Clinical Dementia Rating Scale*(CDR):_____ on ___/___/___

Dementia Review Outcome/Severity Score*:____ on ___/___/___

Consent Status*:_____ on ___/___/___

MMSE Score:___ at exam ____ on ___/___/___

MMSE Score:___ at exam ____ on ___/___/___

Comments:_____

_____

*Based on Dementia Review Tracking

Send to Neurology for Review:___ 1=Yes 2=No

Date sent to Neurology: ___/___/___

Over→

To be Completed by Neurology Group Neuro ID:_____

Date Reviewed:___/___/___

NP disposition of consent status: _____ 1= Use Consent 2 = Consent Waived*
*Stamp Consent, initial and date

Comments:_____

_____

_____

_____

_____

_____

_____

_____

Keyer's initials:_____ Date Keyed:___-___-___

The Framingham Heart Study (FHS)
Waiver of Informed Consent: Offspring Cohort

The Framingham Heart Study (FHS) Offspring cohort participants have demonstrated their commitment to research by attending numerous research examinations since 1971, when the second generation known as the Offspring cohort was added to the Framingham Study. These research participants comprise of a closed cohort of 5124 individuals who enrolled in the longitudinal study to be followed for health conditions throughout their lifespan until their death. The 8th exam is scheduled to begin in 2005.

The continued participation of the Offspring cohort participants is critical to the scientific mission of the Framingham Heart Study. The participants are the best source of their health information, but with the aging of this population there may come a time when they cannot provide an informed consent due to a serious illness or dementia. In view of the fact that this is a closed cohort of participants who have continually given their informed consent to participate in the Framingham Heart Study, they are irreplaceable. We are now requesting a waiver of informed consent for this group of individuals because of their long-standing interest in being part of this research by their repeated consents in the past. Please see the information below:

45 CFR 46.116(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) the research involves no more than minimal risk to the subjects;

The FHS exam includes routine tests often performed in a physician's office such as a review of the participants' medical history since their last contact, standardized measurements of height, weight, and blood pressure, ECG, blood work (not done on offsite visits), and lifestyle interviews. The exam thus involves no more risk than going to a doctor's appointment.

2) the waiver or alteration will not adversely affect the rights and welfare of the subjects;

The waiver will not adversely affect the participants' rights and welfare because the research procedures involve no more than minimal risk. If any time before or during the examination a participant wishes to terminate the procedure or examination, this request will be honored. Established protocols for contacting family members (or other participant designated advocate) to inform them of the examination and the examination procedures will be followed.

Any scientific data obtained will be used for research purposes only and under this waiver will not be re-disclosed. When study results are published, the participants' names and/or any other potentially identifying information (i.e., code numbers) will not be revealed.

The following specific protections have been designed for this study:

1) The study has a cognitive capacity assessment protocol in the main study, which is a short 10-minute cognitive screening test. Scores that fall below cut-off points is the primary indicator that cognitive impairment may be indicated.

2) For those subjects whose cognitive status is sufficiently impaired, there is an identified advocate who is a close family member or friend as determined by phone conversations between the subject and study coordinator prior to onset of cognitive impairments.

3) The advocate will be given same information that constitutes the elements of informed consent for prospective subject to the extent that it appears one can use terms appropriate to the subject's cognitive level.

4) Dissent of the subject will be honored.

(3) the research could not be carried out without the waiver or alteration; and

Without the waiver participants may be excluded from exams. It is critical to the research goals of FHS investigators to include all Offspring cohort participants, including those with cognitive impairments, in future examinations. Therefore, without this waiver valuable information will be lost.

(4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

It has been the Framingham Heart Study's practice over the years to provide the participant and the participant's designated physician with the relevant results. Participants also receive periodic newsletters informing them of the important scientific findings of the study.

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.

For cognitively impaired participants: If the participant is cognitively impaired and have had their consent form waived, have the participants' POA sign the HIPPA form and ask for copies of the POA documentation to go along with it. The POA documentation is necessary for medical records to obtain records from covered entities.

RESEARCH SUBJECT'S AUTHORIZATION

FOR RELEASE OF HEALTH INFORMATION FOR RESEARCH PURPOSES

Name of Research Study: The Framingham Heart Study [redacted]

IRB Number: 1910G

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 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 to sign this authorization. If you choose not to sign this authorization, you will still be able to take part in the research study.

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:

- **Hospitals and physicians you have identified as providing medical care for a reported health problem**

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

- **The researchers and research staff conducting the Framingham Heart Study.**

Section B: Description of information:

(1) The researchers need 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 so we can review the health problem(s) you have reported to us. The information disclosed under this authorization will not be redisclosed to anyone but the researchers conducting this study except as required by law.

(2) I authorize _____ **to release to the**
(List name of hospital/physician or clinic)

Framingham Heart Study the following information from my medical records. Disclose the following information for the dates ranging from _____ **to** _____ **:**

Specific description of information we will collect may include:

- •Face Sheet
- •Discharge Summary
- •ER Report
- •Admission Notes
- •Progress Notes
- •Operative Report
- •Pathology report
- •Chest X-Rays
- •EKGs (All)
- •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

(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 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 the information that we obtained before you revoked your authorization but we will only use your information the way the Informed Consent Form says.

(3) Your Access to the Information:
You have the right to see your Framingham Heart Study record only after the research study has been 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:

_____

FHS Follow-up by Proxy

During each exam the cognitively intact participant will be asked to designate a health care proxy for the Framingham Heart Study. They are asked to provide a proxy in the event that the participant becomes unable to provide the details of his/her health in the future. The participant should select someone who knows them well enough to provide health information about them.

Ask the participant to read the letter entitled "Follow-up by Proxy" and complete the designation form. Examples of proxy's are: Power of Attorney's, Legal Health Care Proxy's, legal next-of-kin (spouse, son or daughter, brother or sister, or their doctor). If they have a Power of Attorney (POA) and have paperwork, a photocopy of this is necessary for the Medical Records Department to obtain records in the event the participant becomes cognitively impaired and the proxy signs a release form.

Two photocopies of the proxy packet must be given to the participant, one for them to keep, the other for them to give to their "proxy".

The Framingham Heart Study

Follow-Up by Proxy

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 not able to provide details of your health. We are asking you to provide us with the name of a person that can answer questions about your health 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 serious illness.

Why is a proxy needed?
For over 30 years you have been providing important information about your health to FHS. This information should not be lost, even if you are unable to provide it.

What does a proxy do?
We will ask your proxy to answer questions about your health, just like the questions you have been asked 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 either calling FHS 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 him/her 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!

Version #2 8/3/04

The Framingham Heart Study

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

I have named as my proxy: _____
(Name of person you choose as FHS Proxy)

Proxy Address:_____

_____

_____

Proxy Phone Number:_____

Relationship:_____

Optional: If my FHS Proxy is unwilling or unable to serve, then I appoint as my Alternate FHS Proxy:

_____
(name of person you choose as your alternate proxy)

of_____
(street) (city/town) (state) (phone)

He/she has the authority to provide medical information, consent for examinations, and/or to sign a Medical Release Form to obtain hospital records or physician records for the Framingham Heart Study.

_____ _____
Participant's Signature Date

_____ _____
Witness Date

Complete only if Participant is physically unable to sign: I have signed the Participant's name above at his/her direction in the presence of the Participant and witness.

_____ _____
(Name) (Street)

_____
(City/Town) (State)

Version #2 8/3/04

Tracking Information Form

The focus of the tracking information form is to collect tracking information. Verify all preprinted information on page 1 and 2.i.e. addresses, phone numbers etc., circling if correct and cross of and change if different. Anything that is not preprinted should be asked of the participant, i.e. place of employment.

After page two all information collected must be provided by the participant. These sections specifically ask family makeup, siblings, parents, and children. Although in some cases the information may be preprinted it still must be collected by asking the participant. Circled information always indicates the preprinted information is correct.

Used for Admin Purposes Only

«ExamName»

Keyer: _____

SECTION A - TRACKING INFORMATION (SELF)

Date this information was collected: ____/____/____ Interviewer #:_____

- **Please circle all printed information (marked with O) if accurate, otherwise correct data with red/blue ink.**
- **Please spell out first, middle, last names, address and all phone numbers to verify.**
- **Please enter "N/A" in all spaces that do not apply.**
- **All shaded areas must be updated on roster.**

1. ID Number: **«IDType»-«ID»**

O 2. Prefix: **«Prefix»**

O 3. Name: **«FName»** **«MName»** **«LName»**
(First) (MI) (Last)

O 4. Date of Birth: **«DOB»**

O 5. Sex: **«Sex»**

O 6. Address: **«Street_11»**
«Street_12»
«City_1» **«State_1»** **«Zip_1»**

O 7. Resides: **«Street_21»**
«Street_22»
«City_2» **«State_2»** **«Zip_2»**
(City) (State) (Zip Code)

O Home Phone Number: **«Hphone»**

O Work Phone Number: **«Wphone»**

Cell Phone Number: |___|___|___| - |___|___|___| - |___|___|___|___|

O 9. Email: **«Email»**

«IDType»-«ID» «LName», «FName» Used for Admin Purposes Only

SECTION A - TRACKING INFORMATION (SELF)

10. Preferred Method of Contact: Home: «HPref»
Work: «WPref»
Email: «EPref»
Cellular:

0	No
1	Yes
2	Never
8	N/A

11. Also Known As: _____

12. Maiden Name: _____

13. 2nd Address: «Str_1»
«Str_2»
«City» (City) «State» (State) «Zip» (Zip Code)

2nd Address Telephone Number: |___|___|___|-|___|___|___|-|___|___|___|___|

14. Social Security Number: |___|___|___|-|___|___|-|___|___|___|___|

DISCLOSURE STATEMENT FOR SOCIAL SECURITY NUMBER: Provision of the social security number is voluntary and unwillingness to do so will not have any effect upon the receipt of any benefits or programs of the United States Government. The information we receive will be used only for statistical purposes. Data from this study will be linked with data supplied by the National Center for Health Statistics. This information is collected under the authority of Section 421 (42USC 285b-3) of the Public Health Service Act.

15. Place of Employment: _____

Address: _____
(City) (State) (Zip Code)

Occupation: _____

«IDType»-«ID» «LName», «FName» Used for Admin Purposes Only

SECTION B – TRACKING INFORMATION (SPOUSE/PARTNER)
CURRENT SPOUSE/PARTNER

1. In FHS: ☐ **NOT IN STUDY** If Yes, Framingham ID: |__|__| - |__|__|__|__|

2. Current Spouse/Partner's Name: _____
(Prefix) (First) (MI) (Last)
(Please Circle one)
Status: Spouse / Partner / Divorce

3. Address if different: _____
(Number) (Street) (Apt. #)

_____
(City) (State) (Zip Code)

4. Telephone Number if Different: |___|___|___| - |___|___|___| - |___|___|___|___|

5. Work Telephone Number: |___|___|___| - |___|___|___| - |___|___|___|___|

SPOUSE/PARTNER ON RECORD

1. Spouse/Partner's Name: «Spprefix» «Spfname» «Spmname» «Splname»
(Please Circle one)
Status: Spouse / Partner / Divorce
2. Address: «Spstr_11», «Spstr_12»
«Spcity_1», «Spstate_1» «Spzip_1»
3. Telephone: «Sphome_ph»
4. Work Telephone : «Spwork_ph»
5. Framingham ID: «Spidtype» - «Spid»

PREVIOUS SPOUSE/PARTNER

1. In FHS: ☐ **NOT IN STUDY** If Yes, Framingham ID: |__|__| - |__|__|__|__|

2. Previous Spouse/Partner's Name: _____
(Prefix) (First) (MI) (Last) (Please Circle one)
Status: Spouse / Partner / Divorce

3. Address: _____
(Number) (Street) (Apt. #)

_____
(City) (State) (Zip Code)

4. Home Telephone Number: |___|___|___| - |___|___|___| - |___|___|___|___|

5. Work Telephone Number: |___|___|___| - |___|___|___| - |___|___|___|___|

Used for Admin Purposes Only

SECTION D – CONTACTS

RELATIVE AT DIFFERENT ADDRESS

1. In FHS: ☐ **NOT IN STUDY** If Yes, Framingham ID: |__|__| - |__|__|__|__|

2. Name: _____
(Prefix) (First) (MI) (Last)

3. Relationship: _____

4. Address: _____
(Number) (Street) (Apt. #)

_____
(City) (State) (Zip Code)

5. Telephone number: |___|___|___| - |___|___|___| - |___|___|___|___|

6. Spouse Name: _____
(Prefix) (First) (MI) (Last)

CLOSE FRIEND AT DIFFERENT ADDRESS

1. In FHS: ☐ **NOT IN STUDY** If Yes, Framingham ID: |__|__| - |__|__|__|__|

2. Name: _____
(Prefix) (First) (MI) (Last)

3. Relationship: _____

4. Address: _____
(Number) (Street) (Apt. #)

_____
(City) (State) (Zip Code)

5. Telephone number: |___|___|___| - |___|___|___| - |___|___|___|___|

6. Spouse Name: _____
(Prefix) (First) (MI) (Last)

«IDType»-«ID» «LName», «FName» Used for Admin Purposes Only

SECTION E – PHYSICIAN'S INFORMATION

1. Participant's primary physician's name: _____
(First) (Last) (Suffix)

Address: _____
(Number) (Street) (Apt. #)

_____
(City) (State) (Zip)

Telephone number: |___|___|___| - |___|___|___| - |___|___|___|___|

2. Participant's 2nd physician's name: _____
(First) (Last) (Suffix)

Address: _____
(Number) (Street) (Apt. #)

_____
(City) (State) (Zip)

Telephone number: |___|___|___| - |___|___|___| - |___|___|___|___|

3. Participant's 3rd physician's name: _____
(First) (Last) (Suffix)

Address: _____
(Number) (Street) (Apt. #)

_____
(City) (State) (Zip)

Telephone number: |___|___|___| - |___|___|___| - |___|___|___|___|

Mother: «Matfname» «Matmname» «Matlname»
«Matstr_1»
«Matstr_2» FramId: «Matid»
«Matcity» «Matstate» «Matzip»

Father: «Patfname» «Patmname» «Patlname»
«Patstr_1»
«Patstr_2» FramId: «Patid»
«Patcity» «Patstate» «Patzip»

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SECTION F – SIBLINGS (BROTHERS AND SISTERS)

List all siblings in birth order. (Oldest to youngest)

Number of Sibling(s) not including yourself: _____
(In other words, how many brothers and sisters do you have?)

SIBLING VERIFICATION
To be completed by another tech after time of admitting.

☐ Yes ☐ No Did all siblings' name and DOB match with those reported by their offspring parents?

Tech ID#:

 Used for Admin Purposes Only

SECTION F – SIBLINGS (BROTHERS AND SISTERS)

1. In FHS: ☐ **NOT IN STUDY** If Yes, Framingham ID: |__|__| - |__|__|__|__|

Name: _____
(Prefix) (First) (MI) (Last)

Address: _____
(Number) (Street) (Apt. #)

_____
(City) (State) (Zip Code)

Spouse Name: _____
(Prefix) (First) (MI) (Last)

Telephone number: |___|___|___| - |___|___|___| - |___|___|___|___|

(Please Circle one)
Relationship: Full / Half / Step / Adopted n/a

Living: Yes / No

If **NO**, Year of Death: |___|___|___|___| n/a

Cause of Death: _____n/a_____

 Used for Admin Purposes Only

SECTION F – SIBLINGS (BROTHERS AND SISTERS)

1. In FHS: ☐ **NOT IN STUDY** If Yes, Framingham ID: |__|__| - |__|__|__|__|

Name: _____
(Prefix) (First) (MI) (Last)

Address: _____
(Number) (Street) (Apt. #)

_____
(City) (State) (Zip Code)

Spouse Name: _____
(Prefix) (First) (MI) (Last)

Telephone number: |___|___|___| - |___|___|___| - |___|___|___|___|

(Please Circle one)
Relationship: Full / Half / Step / Adopted n/a

Living: Yes / No

If **NO**, Year of Death: |___|___|___|___| n/a

Cause of Death: _____n/a_____

 Used for Admin Purposes Only

SECTION F – SIBLINGS (BROTHERS AND SISTERS)

1. In FHS: ☐ **NOT IN STUDY** If Yes, Framingham ID: |__|__| - |__|__|__|__|

Name: _____
(Prefix) (First) (MI) (Last)

Address: _____
(Number) (Street) (Apt. #)

_____
(City) (State) (Zip Code)

Spouse Name: _____
(Prefix) (First) (MI) (Last)

Telephone number: |___|___|___| - |___|___|___| - |___|___|___|___|

(Please Circle one)
Relationship: Full / Half / Step / Adopted n/a

Living: Yes / No

If **NO**, Year of Death: |___|___|___|___| n/a

Cause of Death: _____n/a_____

SECTION F – SIBLINGS (BROTHERS AND SISTERS)

1. In FHS: ☐ **NOT IN STUDY** If Yes, Framingham ID: |__|__| - |__|__|__|__|

Name: _____
(Prefix) (First) (MI) (Last)

Address: _____
(Number) (Street) (Apt. #)

_____
(City) (State) (Zip Code)

Spouse Name: _____
(Prefix) (First) (MI) (Last)

Telephone number: |___|___|___| - |___|___|___| - |___|___|___|___|

(Please Circle one)
Relationship: Full / Half / Step / Adopted n/a

Living: Yes / No

If **NO**, Year of Death: |___|___|___|___| n/a

Cause of Death: _____n/a_____

 Used for Admin Purposes Only

SECTION F – SIBLINGS (BROTHERS AND SISTERS)

1. In FHS: ☐ **NOT IN STUDY** If Yes, Framingham ID: |__|__| - |__|__|__|__|

Name: _____
(Prefix) (First) (MI) (Last)

Address: _____
(Number) (Street) (Apt. #)

_____
(City) (State) (Zip Code)

Spouse Name: _____
(Prefix) (First) (MI) (Last)

Telephone number: |___|___|___| - |___|___|___| - |___|___|___|___|

(Please Circle one)
Relationship: Full / Half / Step / Adopted n/a

Living: Yes / No

If **NO**, Year of Death: |___|___|___|___| n/a

Cause of Death: _____n/a_____

SECTION F – SIBLINGS (BROTHERS AND SISTERS)

1. In FHS: ☐ **NOT IN STUDY** If Yes, Framingham ID: |__|__| - |__|__|__|__|

Name: _____
(Prefix) (First) (MI) (Last)

Address: _____
(Number) (Street) (Apt. #)

_____
(City) (State) (Zip Code)

Spouse Name: _____
(Prefix) (First) (MI) (Last)

Telephone number: |___|___|___| - |___|___|___| - |___|___|___|___|

(Please Circle one)
Relationship: Full / Half / Step / Adopted n/a

Living: Yes / No

If **NO**, Year of Death: |___|___|___|___| n/a

Cause of Death: _____n/a_____

More than 6 siblings? Yes _____ No _____

If YES, attach additional sheets!!!

SECTION G – CHILDREN

Number of Children: _____

1. In FHS: ☐ **NOT IN STUDY** If Yes, Framingham ID: |__|__| - |__|__|__|__|

Name: _____
(Prefix) (First) (MI) (Last)

Address: _____
(Number) (Street) (Apt. #)

_____
(City) (State) (Zip Code)

Spouse Name: _____
(Prefix) (First) (MI) (Last)

Telephone number: |___|___|___| - |___|___|___| - |___|___|___|___|

(Please Circle one)
Relationship: Full / Half / Step / Adopted n/a

Living: Yes / No

If **NO**, Year of Death: |___|___|___|___| n/a

Cause of Death: _____n/a_____

SECTION G – CHILDREN

2. In FHS: ☐ **NOT IN STUDY** If Yes, Framingham ID: |__|__| - |__|__|__|__|

Name: _____
(Prefix) (First) (MI) (Last)

Address: _____
(Number) (Street) (Apt. #)

_____
(City) (State) (Zip Code)

Spouse Name: _____
(Prefix) (First) (MI) (Last)

Telephone number: |___|___|___| - |___|___|___| - |___|___|___|___|

(Please Circle one)
Relationship: Full / Half / Step / Adopted n/a

Living: Yes / No

If **NO**, Year of Death: |___|___|___|___| n/a

Cause of Death: _____n/a_____

 Used for Admin Purposes Only

SECTION G – CHILDREN

3. In FHS: ☐ **NOT IN STUDY** If Yes, Framingham ID: |__|__| - |__|__|__|__|

Name: _____
(Prefix) (First) (MI) (Last)

Address: _____
(Number) (Street) (Apt. #)

_____
(City) (State) (Zip Code)

Spouse Name: _____
(Prefix) (First) (MI) (Last)

Telephone number: |___|___|___| - |___|___|___| - |___|___|___|___|

(Please Circle one)
Relationship: Full / Half / Step / Adopted n/a

Living: Yes / No

If **NO**, Year of Death: |___|___|___|___| n/a

Cause of Death: _____n/a_____

SECTION G – CHILDREN

4. In FHS: ☐ **NOT IN STUDY** If Yes, Framingham ID: |__|__| - |__|__|__|__|

Name: _____
(Prefix) (First) (MI) (Last)

Address: _____
(Number) (Street) (Apt. #)

_____
(City) (State) (Zip Code)

Spouse Name: _____
(Prefix) (First) (MI) (Last)

Telephone number: |___|___|___| - |___|___|___| - |___|___|___|___|

(Please Circle one)
Relationship: Full / Half / Step / Adopted n/a

Living: Yes / No

If **NO**, Year of Death: |___|___|___|___| n/a

Cause of Death: _____n/a_____

SECTION G – CHILDREN

5. In FHS: ☐ **NOT IN STUDY** If Yes, Framingham ID: |__|__| - |__|__|__|__|

Name: _____
(Prefix) (First) (MI) (Last)

Address: _____
(Number) (Street) (Apt. #)

_____
(City) (State) (Zip Code)

Spouse Name: _____
(Prefix) (First) (MI) (Last)

Telephone number: |___|___|___| - |___|___|___| - |___|___|___|___|

(Please Circle one)
Relationship: Full / Half / Step / Adopted n/a

Living: Yes / No

If **NO**, Year of Death: |___|___|___|___| n/a

Cause of Death: _____n/a_____

Used for Admin Purposes Only

SECTION G – CHILDREN

6. In FHS: ☐ **NOT IN STUDY** If Yes, Framingham ID: |__|__| - |__|__|__|__|

Name: _____
(Prefix) (First) (MI) (Last)

Address: _____
(Number) (Street) (Apt. #)

_____
(City) (State) (Zip Code)

Spouse Name: _____
(Prefix) (First) (MI) (Last)

Telephone number: |___|___|___| - |___|___|___| - |___|___|___|___|

(Please Circle one)
Relationship: Full / Half / Step / Adopted n/a

Living: Yes / No

If **NO**, Year of Death: |___|___|___|___| n/a

Cause of Death: _____n/a_____

For Participants Wish to Complete Their Exam on a Second Visit

OMB NO=0925-0216 12/31/2007

h436 -h437- h438	**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.*

Exam 8 Procedures Sheet

h439	☐☐	**MD Questionaire.**	
h440	☐☐	**Anthropometry**	
h441	☐☐	**Sociodemographic Questions**	
h442	☐☐	**SF-12 Health Survey**	
h443	☐☐	**CES-D Scale**	0=No,
h444	☐☐	**Exercise Questionnaire**	
h445	☐☐	**Mini-Mental Status Exam**	
h446	☐☐	**Urine Specimen**	1=Yes,
h447	☐☐	**Blood Draw**	
h448	☐☐	**ECG**	
h449	☐☐	**Observed performance** (Timed walk hand grip)	
h450	☐☐	**Tonometry /ECHO/Carotid**	8=Offsite visit
h451	☐☐	**Ankle-brachial blood pressure by Doppler.**	
h452	☐☐	**Spirometry**	
h453	☐☐	**Post bronchodilator Spirometry**	
h454	☐☐	**Diffusion Capacity**	
h455	☐☐	**Reason Spirometry not done**	1=Major Surgery, 2=Heart Attack,
h456	☐☐	**Reason post bronchodilator test not done**	3=Stroke, 4=Aneurysm, 5=BP>210/110,
h457	☐☐	**Reason Diffusion not done**	6=Refused, 7=Test Aborted, 8=Other, 10=equipment problems

TECH02a

Offspring Exam 8 Table of Contents: 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) Waiver of Informed Consent
3) HIPPA - Release of Health Information for Research Purposes
4) FHS Follow-up by Proxy
5) Tracking Information Form

II. Clinical Measurements & Procedures

1) Lab
   a. Blood
   b. Urine
2) Anthropometrics
   a. Weight
   b. Height
   c. Waist Girth
   d. Waist Girth at Iliac Crest
   e. Sagittal Abdominal Diameter
3) ECG

III. Physician-Administered Medical History and Physical Exam

1) Medical History
2) Resting Blood Pressure
3) Physical Exam

IV. Non-invasive Vascular Testing

1) Echocardiogram

V. Questionnaires

If time permits for a short exam, the participant will undergo PFT & other measures of vascular function (Carotid ultrasound, Ankle-brachial blood pressure measurements, or arterial tonometry).

If participants choose 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 8

Participant Name/Id

Exam Date:

Check Box to indicate which test(s) needs to be completed on second visit.

	TEST:	Approx Time:	Fasting:
___	MD Questionnaire/Physical Exam	30 min	No
___	Measurements (Ht, Wt, Waists)	10 min	No
___	Self Administered Questionnaires		No
___	Tech Administered Questionnaires	15-20min	No
___	Urine		No
___	Lab	5-10 min	Yes
___	ECG	10 min	No
___	Observed Performance	10 min	No
___	ECHO	50min-1 hr	Yes
___	Carotid	15-20 min	No
___	Ankle/Arm Doppler	15 min	No
___	PFT	20-40* min	No

*Maximum Time is with albuterols testing

Why did this participant leave early?

Which Tech did the participant work most with?

Second Appointment Date and Time:

Recruiters Initials:

Phlebotomy Protocol
Offspring Exam 8

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 15 ml red top (serum)
1 x 10 ml red top (serum)
2 x 4.5 ml blue tops (citrate)
3 x 8.5 ml yellow tops (ACD [acid citrate dextrose])
1 x 2.5 ml PAXgene tube

Total volume of blood drawn is 112 ml (3.8 ounces).

If participant needs a cell line, add: 2 x 8 ml Blue tiger tops (CPT)
Total volume of blood drawn is 128 ml (4.3 ounces).

EDTA

1. EDTA plasma used for cholesterol, HDL cholesterol, triglycerides, glucose and HBA1c measured fresh at the Heart Study.
2. Buffy coat samples collected from all 5 EDTA Vacutainers; split into two aliquots, one sent to Framingham Genetics Laboratory at Boston Medical Center for extraction of DNA, one sent to MGH for analysis of endothelial progenitor cells.
3. EDTA plasma and red cells saved in several aliquots for future measurements; stored at –80 C.

Serum

1. Serum used for creatinine, measured fresh at the Heart Study.
2. Serum saved in several aliquots for future measurements; stored at –80 C.

Citrate

1. RNA will be extracted from lymphocytes and platelets in citrate anticoagulated whole blood. Platelet poor plasma from these citrate tubes will be split. One aliquot to be sent to MGH for analysis of endothelial microparticles, one saved for future measurements; stored at -80 C.
2. Citrate plasma saved in several aliquots for future measurements; stored at –80 C.

PAXgene

Whole blood drawn into a PAXgene tube will be saved for future extraction of RNA; stored at -80C.

CPT

CPT whole blood shipped on the day of draw to Fairview University Medical Center in Minneapolis, Minnesota. Lymphocytes are cryopreserved in preparation for future immortalization.

Urine

As part of the Offspring Exam 8 clinic visit, participants are asked to provide a random urine sample.

1. Samples are tested qualitatively for pH, protein, glucose, ketone and blood with reagent test strips.
2. Urine is saved in several aliquots for future measurements; stored at –80 C.

Note: Blood and urine samples are not done during offsite visits.

The Framingham Heart Study
LABORATORY

LABORATORY TEST REQUEST

PARTICIPANT INFORMATION:

TESTS REQUESTED:

TOTAL CHOLESTEROL
HDL CHOLESTEROL
TRIGLYCERIDES
GLUCOSE

[redacted]

Director, Framingham Heart Study

Please be advised that laboratory testing at the Framingham Heart Study is done for research purposes only. Blood test results provide a guide to participants and their physicians. Framingham Heart Study laboratory results should not be used in place of regular clinical care and should be repeated for confirmation.

Weight Measurement h393

Clinic

1. Ask participant to wear FHS gown for measurement if he/she brought a heavy gown from home. The participant should remove slippers or shoes.

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, and 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**.

h393

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

h399

Standing Height Measurement
(Clinic only)

Clinic

1. 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.

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.

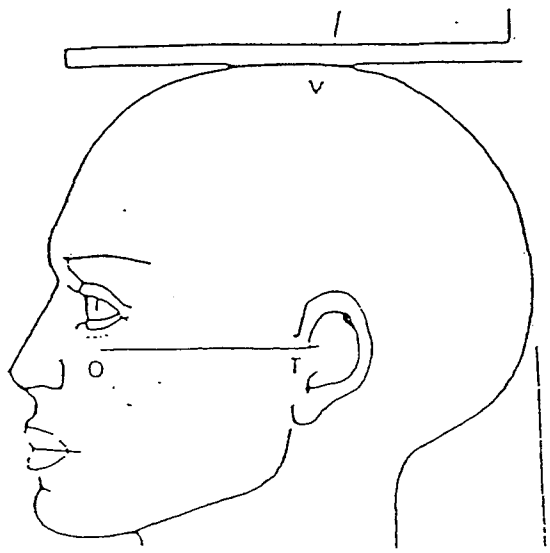
6. Record measurement to the **nearest 1/4 inch, rounding down.**

Note: Measurement is not taken during offsite visits.

h399

Standing Height Measurement

FRANFORT PLANE FOR MEASURING BODY HEIGHT



ORBITALE: Lower margin of eye socket
TRAGION: Notch above tragus of ear or at upper margin of zygomatic bone at that point
FRANFORT PLANE: Orbitale-tragion horizontal line

h403

Waist Girth: FHS Protocol

1. Participant stands erect, arms hanging loosely at sides, weight equally distributed on both feet, head facing straight ahead.

2. Apply anthropometric tape at the level of the umbilicus, underneath the gown

3. Apply tape snugly but not tightly.

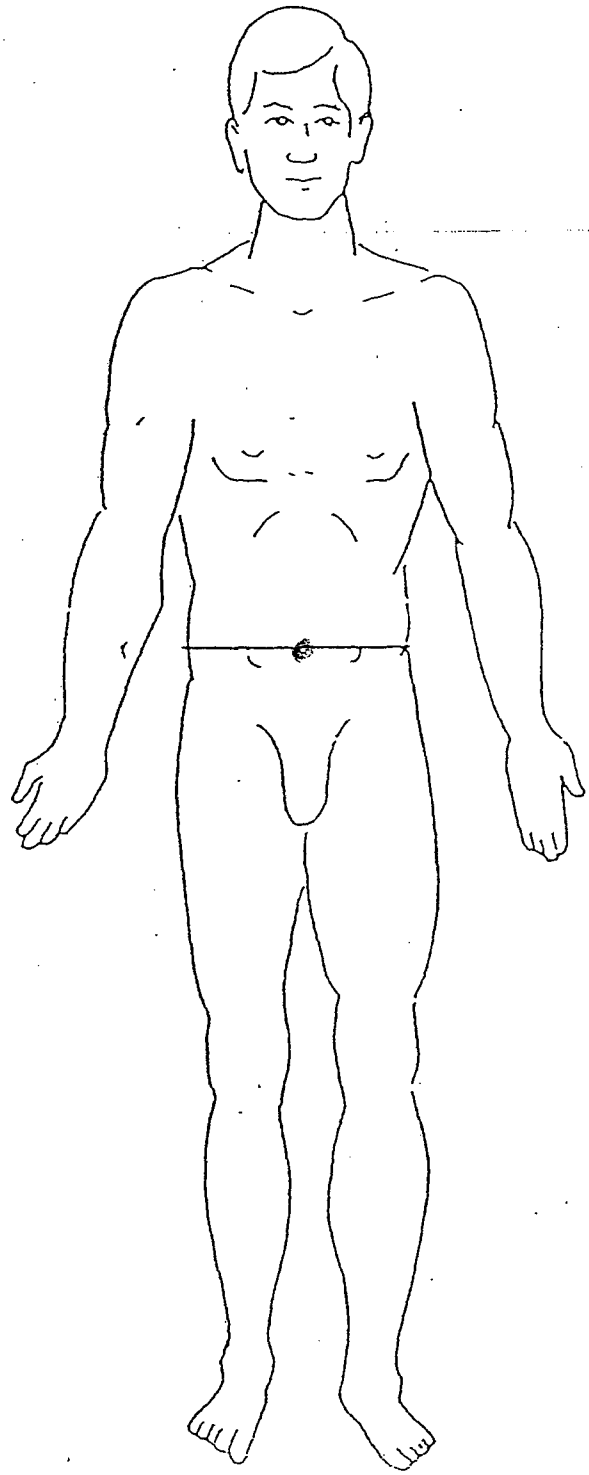
4. Make sure the tape is horizontal and not twisted, checking from both the front and back by using 2 mirrors mounted to the wall.

5. Record measurement **to the nearest 1/4 inch, rounding down.**

For offsite visits the waist measurement will be done without using a mirror. Code 8 should be entered as a protocol modification to capture this.

Waist Girth

h403



Waist Girth at level of umbilicus.

78

h405

Waist Girth at Iliac Crest: NHANES Protocol

1. To define the level at which waist circumference is measured, a bony landmark is first located and marked.

2. The subject stands and the examiner, positioned at the right of the subject, palpates the upper hip bone to locate the right iliac crest.

3. If the right iliac crest cannot be located, stand behind the participant and ask him/her to bend to the left while palpating the iliac crest. Once located, the participant should stand erect before proceeding to number 4.

4. Just above the uppermost lateral border of the right iliac crest, a horizontal mark is drawn, then crossed with a vertical mark on the midaxillary line.

5. The measuring tape is placed in a horizontal plane around the abdomen at the level of this marked point on the right side of the trunk.

6. The plane of the tape is parallel to the floor and the tape is snug, but does not compress the skin.

7. The measurement is made at a normal minimal respiration.

For offsite visits the waist at iliac crest measurement will be done. Code 8 should be entered as a protocol modification to capture this.

centered on the horizontal plane.

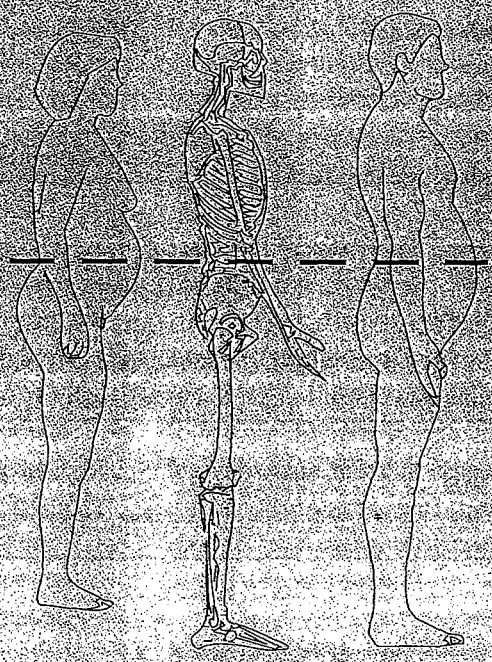
Ref: U.S. Department of Health and Human Services, PHS. NHANES III Anthropometric Procedures Video. U.S. Government Printing Office Stock Number 017-022-01335-5. Washington, D.C. : U.S. GPO, Public Health Service; 1996. 538

n405

Figure 3

Waist Circumference Measurement

To measure waist circumference, locate the upper hip bone and the top of the right iliac crest. Place a measuring tape in a horizontal plane around the abdomen at the level of the iliac crest. Before reading the tape measure, ensure that the tape is snug, but does not compress the skin, and is parallel to the floor. The measurement is made at the end of a normal expiration.



Measuring-Tape Position for Waist (Abdominal) Circumference in Adults

Clinical judgment must be used in interpreting BMI in situations that may affect its accuracy as an indicator of total body fat. Examples of these situations include the presence of edema, high muscularity, muscle wasting, and individuals who are limited in stature. The relationship between BMI and body fat content varies somewhat with age, gender, and possibly ethnicity because of differences in the composition of lean tissue, sitting height, and hydration state.[23,24] For example, older persons often have lost muscle mass; thus, they have more fat for a given BMI than younger persons. Women may have more body fat for a given BMI than men, whereas patients with clinical edema may have less fat for a given BMI compared with those without edema. Nevertheless, these circumstances do not markedly influence the validity of BMI for classifying individuals into broad categories of overweight and obesity in order to monitor the weight status of individuals in clinical settings.[23]

It should be noted that the risk levels for disease depicted in Table 2 are relative risks; in other words, they are relative to the risk at normal body weight. There are no randomized, controlled trials that support a specific classification system to establish the degree of disease risk for patients during weight loss or weight maintenance.

Although waist circumference and BMI are interrelated, waist circumference provides an independent prediction of risk over and above that of BMI. The waist circumference measurement is particularly useful in patients who are categorized as normal or overweight in terms of BMI. For individuals with a BMI ≥ 35, waist circumference adds little to the predictive power of the disease risk classification of BMI. A high waist circumference is associated with an increased risk for type 2 diabetes, dyslipidemia, hypertension, and CVD in patients with a BMI between 25 and 34.9 kg/m.[2,25]

In addition to measuring BMI, monitoring changes in waist circumference over time may be helpful; it can provide an estimate of increases or decreases in abdominal fat, even in the absence of changes in BMI. Furthermore, in obese patients with metabolic complications, changes in waist circumfer-

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predictor when the BMI is not markedly increased. [537] Therefore, waist or abdominal circumference, as well as BMI, should be measured not only for the initial assessment of obesity, but also as a guide to the efficacy of weight loss treatment.

The waist-to-hip ratio (WHR) also has been used in a number of epidemiologic studies to show increased risk for diabetes, coronary artery disease, and hypertension. [500] However, waist circumference has been found to be a better marker of abdominal fat content than is WHR. [85] Whether WHR imparts any independent information about disease risk beyond waist circumference is uncertain, but between the two, the waist circumference appears to carry greater prognostic significance. Therefore, in clinical practice, abdominal fat content should be assessed and followed by measuring waist circumference.

RECOMMENDATION: *The waist circumference should be used to assess abdominal fat content. Evidence Category C.*

Instructions for Measuring Waist Circumference, According to NHANES III Protocol

To define the level at which waist circumference is measured, a bony landmark is first located and marked. The subject stands and the examiner, positioned at the right of the subject, palpates the upper hip bone to locate the right iliac crest. Just above the uppermost lateral border of the right iliac crest, a horizontal mark is drawn, then crossed with a vertical mark on the midaxillary line. The measuring tape is placed in a horizontal plane around the abdomen at the level of this marked point on the right side of the trunk. The plane of the tape is parallel to the floor and the tape is snug, but does not compress the skin. The measurement is made at a normal minimal respiration (see Figure 5).

Ref.: U.S. Department of Health and Human Services, PHS. NHANES III Anthropometric Procedures Video. U.S. Government Printing Office Stock Number 017-022-01335-5. Washington, D.C.: U.S. GPO, Public Health Service, 1996. [538]

2. Classification of Overweight and Obesity

- *According to BMI.* The primary classification of obesity is based on the measurement of BMI. This classification is designed to relate BMI to risk of disease. It should be noted that the relation between BMI and disease risk varies among individuals and among different populations. Therefore, the classification must be viewed as a broad generalization. Individuals who are very muscular may have a BMI placing them in an overweight category when they are not overly fat. Also, very short persons (under 5 feet) may have high BMIs that may not reflect overweight or fatness. In addition, susceptibility to risk factors at a given weight varies among individuals. Some individuals may have multiple risk factors

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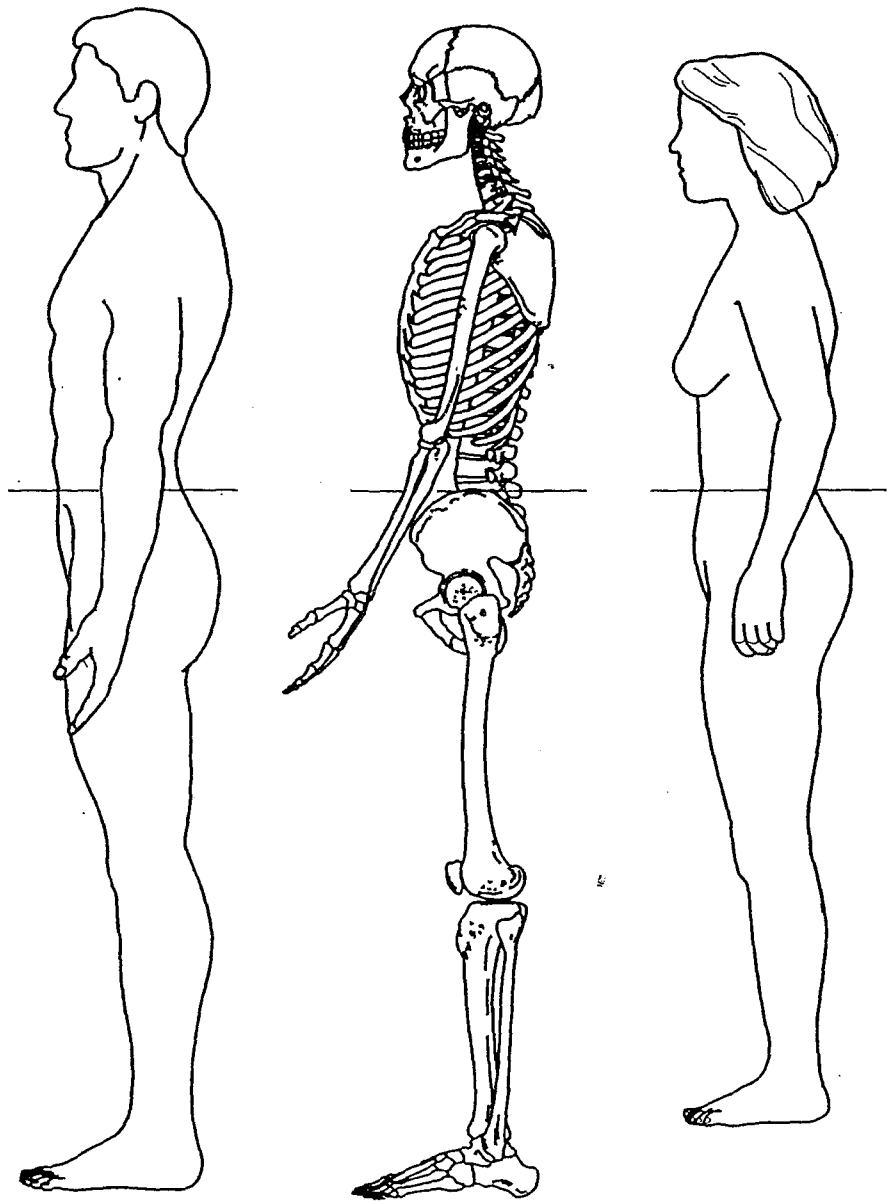
with mild obesity, whereas others may have fewer risk factors with more severe obesity. It should also be noted that the risk levels shown for each increment in risk are relative risks; that is, relative to risk at normal weight. They should not be equated with absolute risk which is determined by a summation of risk factors. No randomized controlled trial studies exist that support a specific system for classification that establishes the degree of disease risk for patients during weight loss or weight maintenance. The classification is based on observational and prospective epidemiological studies.

Figure 5. Measuring tape position for waist (abdominal) circumference



35.75

82

h407

Sagittal Abdominal Diameter

Purpose

The Holtain Kahn Abdominal Caliper is designed for the bedside measurement of the sagittal abdominal diameter in supine subjects. This sagittal (i.e. antero-posterior) dimension has been shown to be highly correlated with the volume of visceral (intra-abdominal) fat as determined by multi-scan, computed tomography [see Kvist H et al. *American Journal of Clinical Nutrition* 1988; 48 : 1351-61 and Sjostrom L. *International Journal of Obesity* 1991 ; 15 (Suppl 2) : 19-30]. The caliper allows a direct reading of the distance between its lower arm touching the subject's back and its sliding, upper arm (touching the front of the subject's abdomen).

Measurement Conditions

The subject should be supine on a flat, comfortable bed or examination table. The subject's trunk should be horizontal, but it is acceptable for the head to be supported with a pillow. There should be no clothing around the middle of the back or abdomen. Wherever possible, invite the subject to urinate and defecate before attempting this measurement.

Equipment

1. Bed or examination table
2. Soft, small cushion or folded towel
3. Caliper

Instructions

1. If the subject is to be examined on a firm exam table rather than a soft bed, there might be a visible gap between the lower arm of the caliper and the subject's back. In this situation it will help to have a soft, small cushion or folded towel; this can be used to elevate the caliper's lower arm just enough to make contact with the subject's back.

2. Supine subject viewed from the right side.

3. Slide the caliper's upper arm to its fullest height. Have the subject raise their hips briefly and insert the caliper's lower arm underneath the small of the back.

4. Position the caliper with the vertical line at the iliac crest. The vertical line should center the caliper.

5. Adjust the caliper's location and slide its upper arm down until it is about 2 centimetres directly over the mid-abdomen. Check the bubble in the spirit level to be sure that the caliper's shaft is vertical; if it is not, adjust the caliper's location accordingly.

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6. Ask the subject to inhale gently, then exhale gently, then relax at rest.

7. Promptly slide down the caliper's upper arm so it is just touching, but not compressing the abdomen. Check that the bubble in the spirit level confirms a vertical orientation. DOES NOT HAVE TO BE PER [redacted]

8. Read the distance from the top of the caliper on the centimetre scale to the nearest 0.1 centimetre

9. Record the measurement on the data form.

For offsite visits the waist measurement will be done. Code 8 should be entered as a protocol modification to capture this.

Additional information :

Williamson DF, Kahn HS, Worthman CM, Burnette JC, Russell CM. Precision of recumbent anthropometry. **American Journal of Human Biology** 1993 ; 15 : 159-67.

Kahn HS. Choosing an index for abdominal obesity : an opportunity for epidemiologic clarification. **Journal of Clinical Epidemiology** 1993 ; 46 (5) : 491-4.

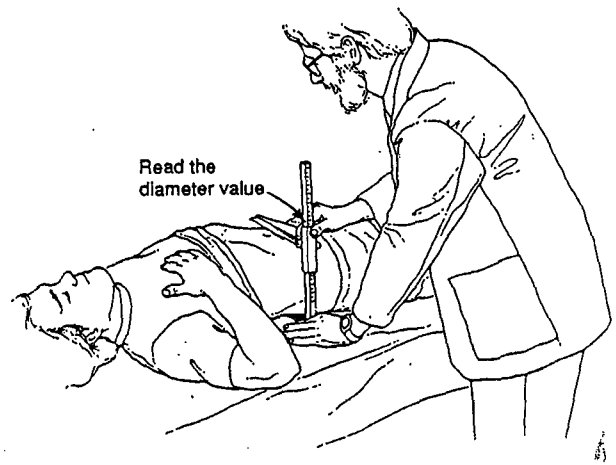
Kahn HS, Austin H, Williamson DF, Arensberg D. An association between the sagittal abdominal diameter and ischemic heart disease incidence. Presentation at Third International Conference on Preventive Cardiology, June 1993, Oslo, Norway.

HOLTAIN KAHN ABDOMINAL CALIPER

✧✧✧✧✧✧

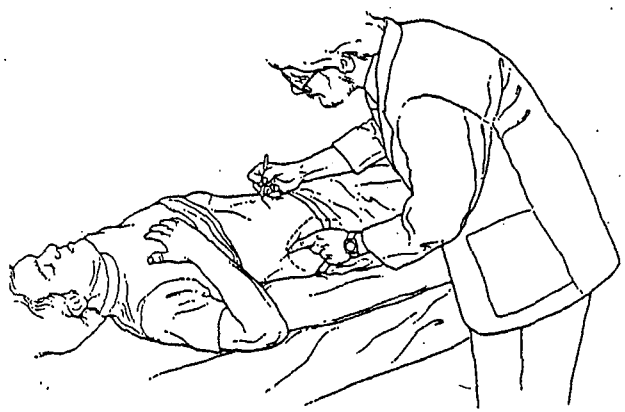
Purpose

The Holtain Kahn Abdominal Caliper is designed for the bedside measurement of the sagittal abdominal diameter in supine subjects. This sagittal (i.e. antero-posterior) dimension has been shown to be highly correlated with the volume of visceral (intra-abdominal) fat as determined by multi-scan, computed tomography [see Kvist H et al. *American Journal of Clinical Nutrition* 1988 ; 48 : 1351-61 and Sjostrom L. *International Journal of Obesity* 1991 ; 15 (Suppl 2) : 19-30]. The caliper allows a direct reading of the distance between its lower arm (touching the subject's back) and its sliding, upper arm (touching the front of the subject's abdomen).



(Figure 2)

Supine subject, same view. Caliper is in reading position as examiner looks from above at the spirit level. An arrow points to the lower edge of upper arm at the cetimeter scale ("Read the diameter value").



(Figure 1)

Supine subject viewed from the right side. Examiner's left finger demonstrates palpation of right iliac crest; right hand is making a mark on the mid-abdomen.

Measurement Conditions

The subject should be supine on a flat, comfortable bed or examination table. The subject's trunk should be horizontal, but it is acceptable for the head to be supported with a pillow. There should be no clothing around the middle of the back or abdomen. Wherever possible, invite the subject to urinate and defecate before attempting this measurement.

✧✧✧✧✧✧✧

Additional equipment

A **cosmetic pencil** or similar writing instrument is necessary for making a small, temporary mark on the abdomen. This mark should be easily removable with water or skin-cleansing lotion.

If the subject is to be examined on a firm exam table rather than a soft bed, there might be a visible gap between the lower arm of the caliper and the subject's back. In this situation it will help to have a **soft, small cushion or folded towel**; this can be used to elevate the caliper's lower arm just enough to make contact with the patient's back.

Instructions

After the subject is supine and comfortable, make a mark on the anterior abdomen that is midway between the left and right iliac crests. The iliac crest can be easily palpated at either side of the abdomen (Figure 1).

[Note that the iliac crests are not the same as the anterior superior iliac spines.]

Slide the caliper's upper arm to its fullest height. Have the subject raise the hips briefly and insert the caliper's lower arm underneath the small of the back.

Adjust the caliper's location and slide its upper arm down until it is about 2 centimetres directly over the mid-abdominal mark. Check the bubble in the spirit level to be sure that the caliper's shaft is vertical; if it is not, adjust the caliper's location accordingly.

Ask the subject to inhale gently, then exhale gently, then relax at rest. Promptly slide down the caliper's upper arm so it is just touching, but not compressing the abdomen. Check that the bubble in the spirit level confirms a vertical orientation (figure 2).

Read the distance on the centimetre scale to the nearest 0.1 centimetre.

ORIGINAL ARTICLE

h407

Sagittal Abdominal Diameter Is a Strong Anthropometric Marker of Insulin Resistance and Hyperproinsulinemia in Obese Men

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JOHAN ÄRNLÖV, MD, PHD[1]
KERSTIN BRISMAR, MD, PHD[2]
BJÖRN ZETHELIUS, MD, PHD[1]
LARS BERGLUND, BSC[3]
BENGT VESSBY, MD, PHD[1]

OBJECTIVE — It is clinically important to find noninvasive markers of insulin resistance and hyperproinsulinemia because they both predict cardiovascular and diabetes risk. Sagittal abdominal diameter (SAD) or "supine abdominal height" is a simple anthropometric measure previously shown to predict mortality in men, but its association with insulin resistance and hyperproinsulinemia is unknown.

RESEARCH DESIGN AND METHODS — In a common high-risk group of 59 moderately obese men (aged 35–65 years, BMI 32.6 ± 2.3 kg/m^2), we determined anthropometry (SAD, BMI, waist girth, and waist-to-hip ratio [WHR]); insulin sensitivity (euglycemic-hyperinsulinemic clamp); and plasma concentrations of intact proinsulin, specific insulin, C-peptide, glucose, and serum IGF binding protein-1 (IGFBP-1). To compare SAD with other anthropometric measures, univariate and multiple regression analyses were used to determine correlations between anthropometric and metabolic variables.

RESULTS — SAD showed stronger correlations to all measured metabolic variables, including insulin sensitivity, than BMI, waist girth, and WHR. SAD explained the largest degree of variation in insulin sensitivity ($R^2 = 0.38$, $P < 0.0001$) compared with other anthropometric measures. In multiple regression analyses, including all anthropometric measures, SAD was the only independent anthropometric predictor of insulin resistance ($P < 0.001$) and hyperproinsulinemia ($P < 0.001$).

CONCLUSIONS — In obese men, SAD seems to be a better correlate of insulin resistance and hyperproinsulinemia (i.e., cardiovascular risk) than other anthropometric measures. In overweight and obese individuals, SAD could represent a simple, cheap, and noninvasive tool that could identify the most insulin resistant in both the clinic and clinical trials evaluating insulin sensitizers. These results need confirmation in larger studies that also include women and lean subjects.

Diabetes Care 27:2041–2046, 2004

More than half of adult Americans are overweight or obese (1). Many, but far from all of those subjects, will suffer from obesity-related diseases. Insulin resistance may be the key factor in obesity that contributes to increased health risk, as the more insulin resistant an individual, the more likely they are to develop diabetes and cardiovascular disease (2–4). Therefore, identification of insulin resistance also is important in moderately obese subjects.

Recently, elevated intact proinsulin, reflecting both insulin resistance and β-cell dysfunction (5), has emerged as an independent predictor of type 2 diabetes (5–7) and cardiovascular mortality (8,9). However, a simple clinical surrogate marker for hyperproinsulinemia is still to be found.

McLaughlin and Reaven (10) recently highlighted the need for a useful tool to identify insulin resistance, as direct measures of insulin resistance are unfeasible for clinical use. While fasting insulin has shown to be a useful estimate of insulin resistance, it is invasive and the lack of standardized assays limits its use (11). Alternatively, triglycerides (>1.47 mmol/l) could function as a good marker (11).

Anthropometric measures have served as noninvasive markers because obesity, particularly abdominal obesity (12), is closely associated with insulin resistance. However, studies using direct methods revealed that only ~25–50% of all obese nondiabetic and normotensive subjects are clinically significantly insulin resistant (11,13) and that waist girth or waist-to-hip ratio (WHR) was not better than BMI in identifying insulin resistance (13). More recently, "abdominal height" or sagittal abdominal diameter (SAD) has shown to be strongly associated with glucose intolerance (14), cardiovascular risk (14–18), and mortality (19,20) (SAD was divided by thigh girth in the study by Kahn et al. [19]) independently of other anthropometric measures. SAD is also an excellent estimate of visceral fat (21–23), implying that SAD might be a particularly good marker of insulin resistance (12,24). Despite these compelling data, the role of SAD has been overlooked, whereas waist girth has received more attention (14,25,26). Given that insulin resistance is a major health culprit (4), there are sur-

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Abbreviations: ELISA, enzyme-linked immunosorbent assay; IGFBP-1, IGF binding protein-1; SAD, sagittal abdominal diameter; WHR, waist-to-hip ratio.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

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Table 1—*Baseline characteristics*

	Mean ± SD (range)
Age (years)	53 ± 8.2 (35–65)
SAD (cm)	28.5 ± 2.05 (25.5–34.3)
BMI (kg/m^2)	30.6 ± 2.30 (27.7–39)
Waist girth (cm)	113.9 ± 7.70 (100–139)
WHR	1.01 ± 0.04 (0.95–1.12)
Triglycerides	2.04 ± 1.2 (1.7–8.3)
HDL cholesterol	0.98 ± 0.2 (0.7–1.4)
M (mg · kg^{-1} · min^{-1})*	4.07 ± 1.56 (1.06–7.0)
Proinsulin (pmol/l)	16.2 ± 10.6 (3.9–47)
Insulin (pmol/l)	11.4 ± 4.3 (5.7–21.9)
Glucose (mmol/l)	5.7 ± 0.64 (4.8–7.0)
C-peptide (pmol/l)	879.1 ± 306.3 (402–1832)
IGFBP-1 (μg/l)	14.3 ± 7.40 (4–34)

*Data from the euglycemic clamp (i.e., insulin sensitivity) were available in 59 men, whereas all other variables were available in 60 men.

prisingly little data comparing different anthropometric measures as correlates to insulin resistance determined by gold standard techniques.

Hence, the aim of this study was to identify the best noninvasive marker of insulin resistance that would be suitable for both clinical and research use. In a common high-risk group of obese men, we compared anthropometric measures (BMI, waist girth, WHR, and SAD) in relation to insulin sensitivity, as determined directly using a euglycemic clamp. We also measured the related, clinically relevant variables, including proinsulin, insulin, C-peptide and glucose concentrations, and serum insulin and IGF binding protein-1 (IGFBP-1), that also reflect cardiovascular risk (27,28).

RESEARCH DESIGN AND METHODS

— A total of 60 adult Caucasian moderately obese men (Table 1) were recruited in Uppsala, Sweden, through local advertisements to initially take part in an intervention study (29). The inclusion criteria were waist girth >102 cm, WHR >0.94, BMI 27–39 kg/m^2, triglycerides >1.7 mmol/l, and/or HDL cholesterol <0.9 mmol/l. In addition, all men had an SAD >25 cm, a cutoff point corresponding to a waist girth >100 cm (14). No one had heart, liver, or renal disease or diabetes.

Anthropometry

All anthropometric measurements were performed by one investigator. Body weight was measured using an electronic scale to the nearest 0.1 kg, with the subjects wearing light clothing and no shoes. Height was measured to the nearest 0.5 cm without shoes, and BMI was calculated as weight (in kilograms) divided by the square of height (in meters). SAD (anteroposterior) or "abdominal height" was measured to the nearest 0.1 cm after a normal expiration while in the supine position with bent knees on a firm examination table and without clothes in the measurement area (Fig. 1). At the level of iliac crest (L_{4-5}), SAD was measured (using a sliding-beam caliper) as the distance between the examination table up to the horizontal level, allowing the caliper arm to touch the abdomen slightly but without compression. Waist girth was measured in underwear with a stretchless tape in standing position after normal expiration, midway between the caudal part of the lateral costal arch and the iliac crest (World Health Organization standard), and hip girth was measured at the symphysis trochanter level.

Euglycemic-hyperinsulinemic clamp

A 2-h euglycemic-hyperinsulinemic clamp was performed to determine whole-body insulin sensitivity as previously described (29). Insulin (Actrapid Human; Novo Nordisk, Copenhagen, Denmark) was infused (336 pmol/l · m^{-2} · min^{-1}), resulting in a mean steady state with insulin levels of 624 pmol/l. The target plasma glucose level was 5.1 mmol/l, which was maintained by determining glucose levels every 5 min. During the last hour of the clamp, the range of the glucose levels was between 4.8 and 5.2 mmol/l. Insulin sensitivity (M) was calculated as the glucose infusion rate adjusted for body weight during the last hour of the clamp (mg · kg body wt^{-1} · min^{-1}). Plasma glucose levels were assayed in a Beckman Glucose Analyzer II (Beckman Instruments, Fullerton, CA), using an enzymatic method.

Biochemical analyses

Venous blood was drawn into vacuum tubes, coagulated, and centrifuged at room temperature. All plasma and serum samples used for analyses were stored at −70°C (storage time <2 years).

Insulin peptides, including proinsulin, have been shown to be stable at −70°C for 27 years (8). Specific plasma insulin (intra-assay and interassay coefficient of variation [CV] 2.8%), was measured by using an enzyme-linked immunosorbent assay (ELISA) kit (Mercodia, Uppsala, Sweden). Plasma intact proinsulin (intra-assay CV 3.2% and interassay CV 5.2%) was measured by an ELISA kit (Mercodia). Cross-reactivity with insulin and C-peptide was <0.03

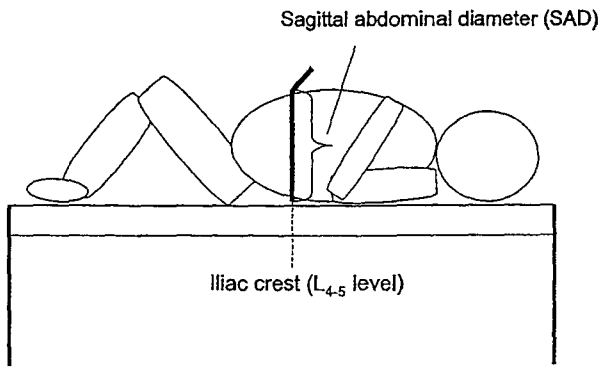

Figure 1—*Measurement of the SAD in a supine subject.*

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Table 2—*Correlation coefficients between anthropometric and metabolic variables*

	SAD	BMI	Waist	WHR
SAD (cm)	—	0.81†	0.84†	0.38‡
M (mg · kg^{-1} · min^{-1})*	−0.61†	−0.48§	−0.43§	−0.40‖
Proinsulin (pmol/l)	0.47†	0.28‖	0.25	0.19
Insulin (pmol/l)	0.41‡	0.29‖	0.28‖	0.24‖
Glucose (mmol/l)	0.32‡	0.09	0.10	0.06
C-peptide (pmol/l)	0.44§	0.30‖	0.27‖	0.35‡
IGFBP-1 (μg/l)	−0.32‖	−0.19	−0.22	−0.09

*Data from the euglycemic clamp (i.e., insulin sensitivity) were available in 59 men, whereas all other variables were available in 60 men. †$P < 0.0001$; ‡$P < 0.01$; §$P < 0.001$; ‖$P < 0.05$.

and 0.006%, respectively. Plasma C-peptide (intra-assay CV 3.1% and interassay CV 4.4%) was measured using a specific ELISA kit (Mercodia). All insulin-like peptides were measured in a Bio-Rad Coda automated EIA analyzer (Bio-Rad Laboratories, Hercules, CA). Serum samples were acid-ethanol extracted to partially separate IGFBP-1 from IGF-1. IGFBP-1 was determined by radioimmunoassay as previously described (intra-assay CV 3% and interassay CV 10%) (30).

Statistics

All anthropometric measures were skewed (Shapiro-Wilk W test) and logarithmically transformed before a statistical analysis was performed, but all metabolic and anthropometric variables were normally distributed after transformation. Pearson's correlation coefficients were used to investigate the associations between anthropometric and metabolic variables. To evaluate possible independent relationships between anthropometric and metabolic variables, multiple linear regression analyses were used, with the four anthropometric measures and age as independent variables and insulin sensitivity as a dependent variable. R^2 was determined for each anthropometric variable to evaluate the proportion of the variability that can be explained by its univariate relationship to each metabolic variable. Differences between the anthropometric correlations to insulin sensitivity were tested for statistical significance using the method described by Morrison (31). $P < 0.05$ was regarded as significant. A JMP software package was used for statistics (SAS Institute, Cary, NC).

RESULTS— A total of 60 men were included in the analysis with complete data for all variables except for insulin sensitivity data (clamp), which was determined in 59 subjects (Table 1).

All anthropometric measures were significantly inversely correlated to insulin sensitivity (Table 2). SAD was more strongly correlated to insulin sensitivity (M) and to all other metabolic variables than to other anthropometric measures (Table 2). The correlation between insulin sensitivity and SAD was significantly stronger than to waist girth and BMI ($P < 0.01$) but not WHR. The correlations between SAD and insulin sensitivity also remained significant when analyzing subjects with BMI <30 kg/m^2 ($r = -0.54$, $n = 26$) and BMI >30 kg/m^2 ($r = -0.59$, $n = 34$) separately (both P values <0.01). Dividing SAD or waist girth for height did not improve the associations with insulin sensitivity or other metabolic variables (data not shown). For proinsulin, SAD and BMI were the only significant anthropometric predictors, but SAD was a much stronger correlate than BMI. Furthermore, SAD was the only significant predictor of fasting glucose and IGFBP-1 concentrations. In multiple analyses (including SAD, BMI, waist girth, and WHR), SAD remained the sole significant predictor of insulin sensitivity, proinsulin, and all other metabolic variables (all P values <0.01). Adjusting for age did not alter these associations. Using the regression line (slope), it was predicted that for every 1-cm increase in SAD, there is a decrease in the M value by 0.75 mg · kg^{-1} · min^{-1} (SE 0.14, $P < 0.001$). This decrease in insulin sensitivity corresponded to a mean decrease in insulin action by 18%. SAD consistently explained a greater proportion of the variation in all metabolic variables than did other anthropometric measures, and for fasting glucose and IGFBP-1, only SAD showed a significant R^2 (Fig. 2).

CONCLUSIONS— As insulin resistance predicts type 2 diabetes (2) and cardiovascular disease (3,4), we sought to

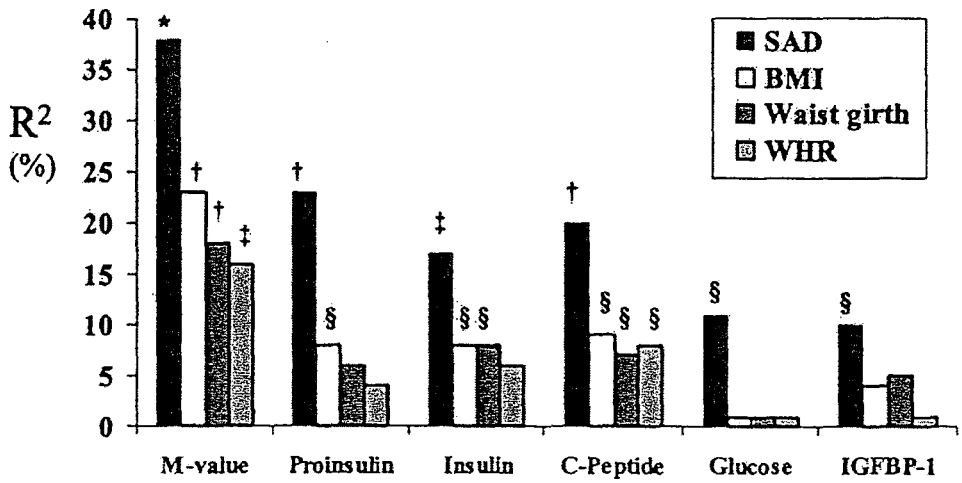

Figure 2—*Bars are R^2 coefficients (%) for different anthropometric measures with regard to metabolic variables. *$P < 0.0001$; †$P < 0.001$; ‡$P < 0.01$; §$P < 0.05$.*

identify the best anthropometric predictor of insulin resistance in obese men.

SAD was surprisingly strong in predicting insulin resistance and hyperproinsulinemia compared with other classic anthropometric measures. In fact, SAD exhibited the highest degree of association with all the signs of disturbed glucose metabolism, including increased concentrations of proinsulin, glucose, insulin, C-peptide, and lower levels of IGFBP-1.

The close correlation between SAD and hyperproinsulinemia is also novel and of clinical importance, as elevated proinsulin concentrations independently predict cardiovascular mortality (8,9) and type 2 diabetes (5–7). The correlations between SAD and proinsulin and C-peptide concentrations may also indicate that SAD is a good marker of elevated insulin secretion in nondiabetic obese men.

In line with our results, previous data on men and women have shown that SAD is more closely related to hyperlipidemia (16) and cardiovascular risk (16–18,32), including the Framingham risk index (33), than BMI, waist girth, and WHR. Recent results also showed that SAD was the best correlate to hypertension (16,32) and plasminogen activating inhibitor-1 (16). Furthermore, in the large Swedish Obese Subjects (SOS) study, the change in SAD was most closely related to change in the metabolic syndrome (34). However, in a Chinese population in whom insulin sensitivity was measured indirectly using the homeostasis model assessment index, SAD was a better marker than WHR but comparable to waist girth and BMI (35). Also, in a study of nonobese subjects, SAD and waist girth showed the same correlation coefficient (−0.57) in men, but not in women, and both were the best markers of insulin resistance (minimal model) in men (36). These latter inconsistencies might be due to ethnicity, sex, phenotype, or methodological differences. Notably, in this and a previous larger study, we measured SAD with the legs bent. This procedure improves reliability compared with the measurement of SAD with straight legs (37). This slightly altered technique may contribute to the strong correlations between SAD and the metabolic variables found in both these studies.

For all metabolic variables, SAD showed an R^2 value that was about twofold higher than BMI, waist girth, and WHR. In addition, SAD was the sole anthropometric variable that explained the variations in fasting glucose and IGFBP-1 concentrations. The latter accords well with our results, as low IGFBP-1 reflects peripheral insulin resistance (38) and perhaps also hepatic insulin resistance (39). However, of more clinical relevance, low IGFBP-1 is a risk marker of cardiovascular disease (27,28).

Interestingly, SAD was the only anthropometric measure that remained a significant marker of insulin resistance in multiple analyses. The fact that SAD was associated with all metabolic disorders, even independently of age, BMI, waist girth, and WHR, indicates that SAD carries unique information beyond that given by other anthropometric measures. Similar to our results, in a large clamp study, waist girth or WHR did not add any information on insulin sensitivity beyond BMI (13). Unfortunately, SAD was not measured in that study.

The most likely explanation for the high predictive capacity of SAD is the higher measurement reliability of SAD compared with other anthropometric measures (37,40). SAD may also be the only measure with high reliability in both lean and obese subjects (37). In our study, SAD significantly predicted insulin resistance when analyzing overweight and obese men separately. Previous data in normal-weight Caucasian men indicated that SAD was the best anthropometric predictor of an adverse metabolic risk profile independent of BMI (15). In that study, SAD/height was a slightly better predictor than SAD alone, but adjusting SAD or waist girth for height did not improve the correlations in our study. However, it remains to be determined whether the current results can be confirmed in lean subjects, women, and other ethnic populations. Another limitation of this study could be the limited sample size.

These results were not only explained by a lower measurement error of SAD, but the strong relationship with insulin resistance may also be partly explained by SAD closely reflecting visceral adiposity (21–23,41). A detrimental effect of visceral fat on insulin sensitivity has been suggested. In obese boys, visceral adipose tissue area and SAD were the best diagnostic criteria of metabolic abnormalities, and SAD was the best anthropmetric estimate of visceral adipose tissue area (42). However, as both visceral and subcutaneous fat are linked to insulin resistance (43–45), it is relevant that SAD is also a valid measure of total abdominal fat (23). Because abdominal obesity seems to be an early sign of insulin resistance (46) that is more genetically determined than generalized obesity (47), high SAD values might, to a larger extent than increments in other measures, reflect such a genetic component (48) as well as reflect a sedentary lifestyle (48).

Despite the rather homogenous group with central obesity, the current associations between SAD and metabolic disorders were quite strong. Interestingly, even among men classified as abdominally obese (waist girth >102 cm), insulin sensitivity varied sixfold in this study. A large waist girth is a useful tool to detect metabolic disorders (14,25,26), including insulin resistance (49). In one study, SAD and waist girth were equally good markers of various metabolic disorders (14). However, no previous studies have compared waist girth with SAD with respect to hyperproinsulinemia or insulin resistance determined directly.

Because 47 million people in the U.S. are obese and over one-third of the adult population is abdominally obese (50), our results are motivational for the use of SAD as a single, easy (takes ~20 s to measure), and cheap marker to identify the most insulin-resistant overweight subjects who would especially benefit from intensive lifestyle therapy (51). SAD may also be a useful screening tool in clinical trials evaluating insulin sensitizers (i.e., thiazolidinediones). Thus, a subject with a large SAD may prove to be an optimal target for intervention. An SAD >25 cm is most likely associated with metabolic disorders (14). Notably, in our study, all subjects had a relatively large SAD above that cutoff limit.

In summary, among the anthropometric measures studied, SAD was the best marker of insulin resistance and elevated proinsulin concentrations (i.e., cardiovascular risk) in overweight and obese men. If ongoing prospective studies will show that SAD predicts mortality, as already indicated in men (19,20), and our results can be confirmed in women, SAD might be worth including in future obesity guidelines.

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h304 → h338

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**.

h304-h338

7. **V5:** Exactly halfway between **V4** and **V6**.

8. Before electrodes are placed on the participant, ask if he/she is known to be allergic to alcohol wipes. If yes, 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)~~. 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.

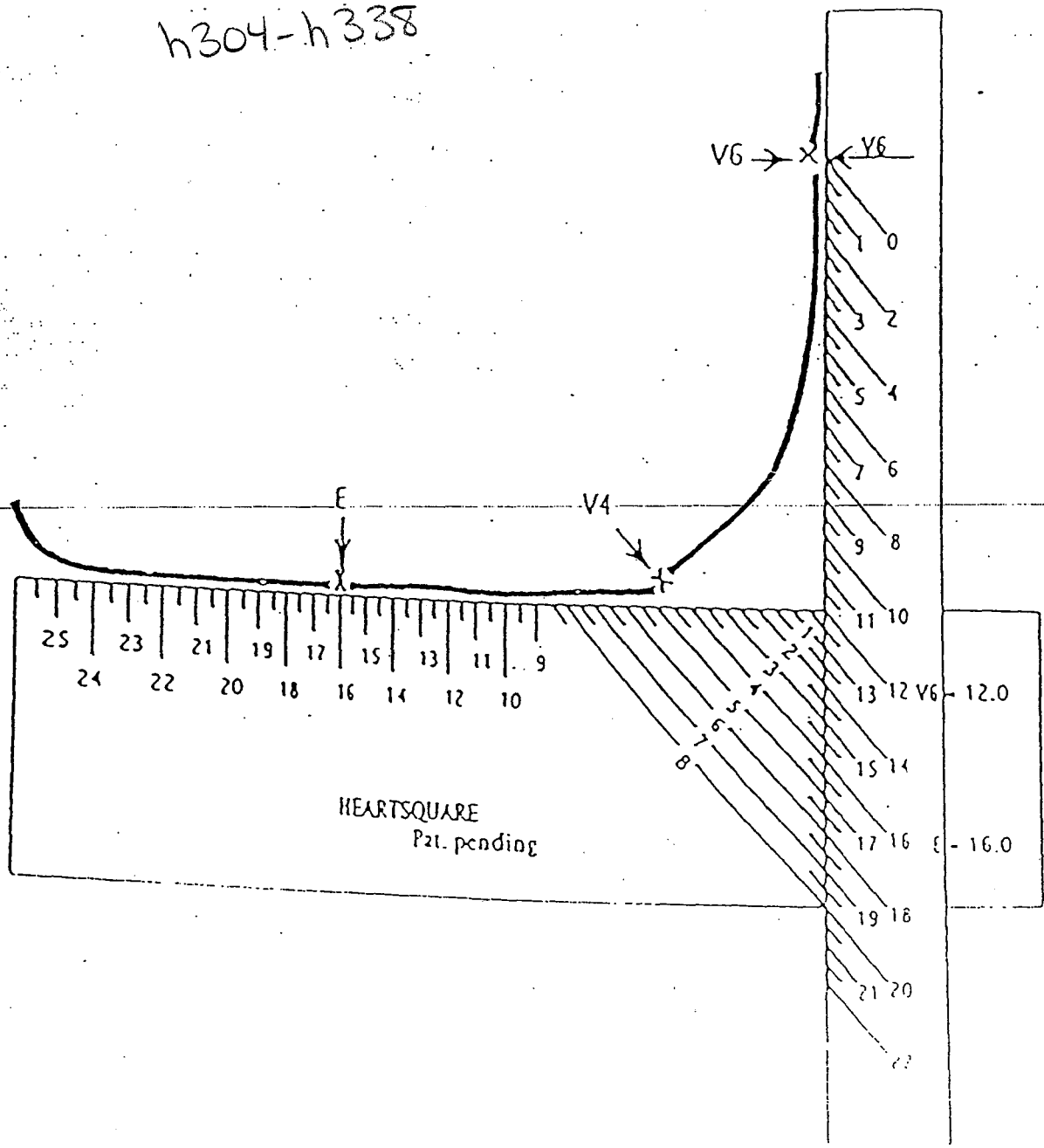
12. The ECG is printed and reviewed for errors. If ECG needs to be run at **5 mmHg** because of high voltage (if the standard **10 mmHg** is beyond the lines of the ECG paper), highlight (yellow or orange highlighter) the **5 mmHg** on the bottom of the printed ECG. On the top margin of the tracing write " *1/2 **STANDARD***" using a bold magic marker.

13. Leads are checked again for proper placement and disconnected. Electrodes are carefully removed.

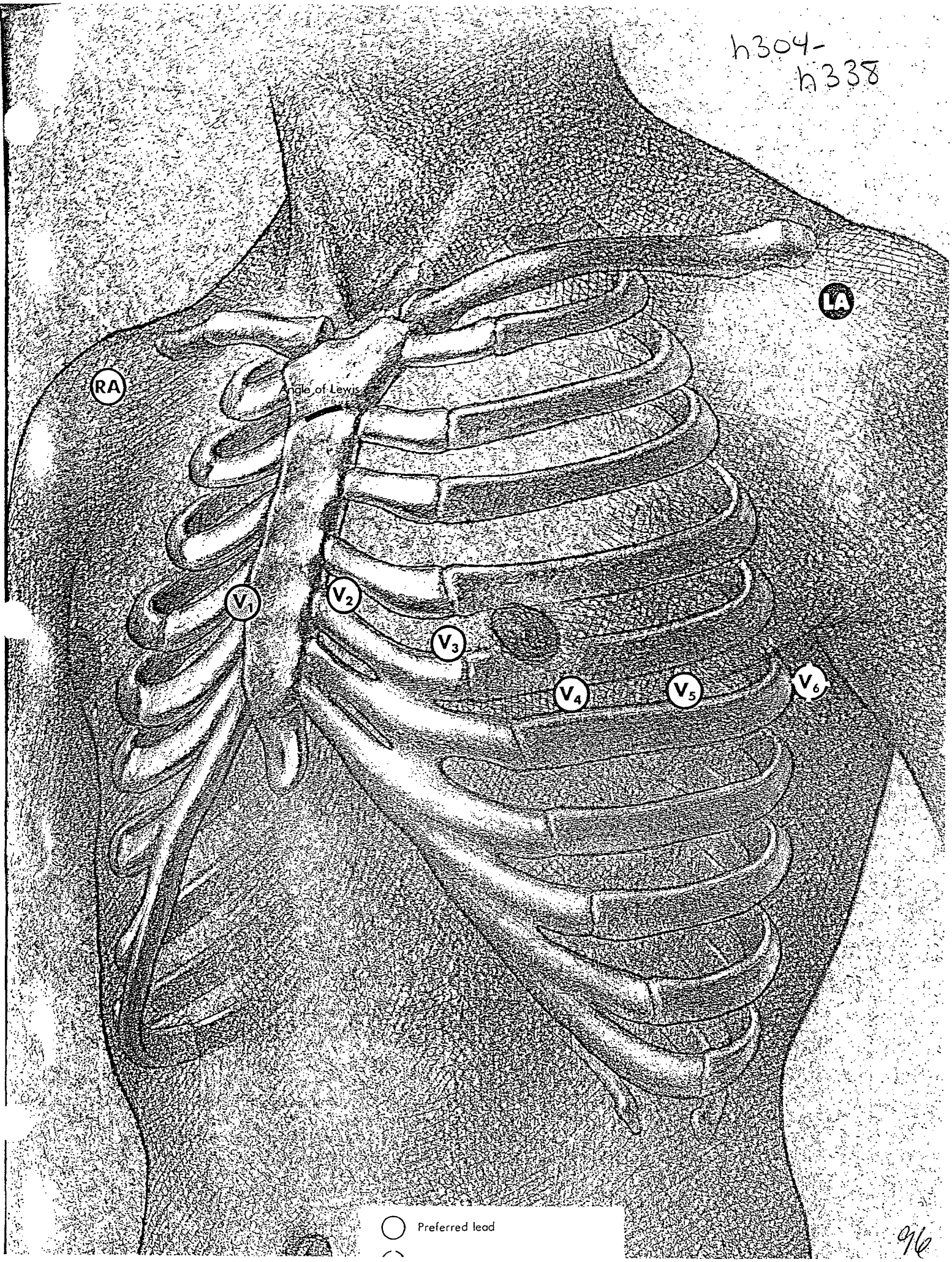
14. After each use, wash the Heart Square gently with soap and water (1 part detergent to at least 20 parts water, approximately 3 drops of detergent to one cup of water) and gently wipe dry with a soft cloth.

ADDENDUM: The tech will go to the directory after printing out the first copy of the ECG. In the directory the participant's name is located and chosen. The tech then clicks on display. Once the same ECG is displayed the tech clicks on the print and save key. This ensures the ECG just performed is recorded to the disk since the MAC 5000 has no hard drive. The second printed copy of the ECG is sent out and a laminated card of the ECG is made and given to the participant by mail 4-6 weeks later.

h304-h338


V6
V6
E
V4
25
24
23
22
21
20
19
18
17
16
15
14
13
12
11
10
9
HEARTSQUARE
Pat. pending
V6 - 12.0
E - 16.0

h304-
h338



96

h625 → h645

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. 8 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 three sizes:
   - 4 large adult cuffs
   - 4 pediatric cuffs
   - 4 regular adult cuffs
   - 2 thigh cuffs
6. Washcloths to remove conducting jelly

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 bilateral amputations of legs.

   Code as 2

3. Persons with rigid arteries such that an occlusion pressure cannot be reached

   Code as 3= Other

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.

h625-h645

C. **Set-up Procedure:**

1. Ask participant to remove shoes and stockings so that the ankles are bare to mid-calf.
2. Lay participant supine on the examining table.
3. Keep participant supine for at least five minutes before measuring BP.
4. Place four BP cuffs on the participant (be sure to check for appropriate cuff size):

    a. Right arm
    b. Right ankle
    c. Left ankle
    d. Left arm

5. Apply ankle cuffs with midpoint of bladder over posterior tibial artery, with lower end of bladder approximately 3 cm above medial malleolus.

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 sphygmomanometer.
2. Palpate the brachial artery pulse for the right arm
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.

h625-h645

E. Right Arm Systolic Blood Pressure Measurement:

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. Right Ankle Systolic Blood Pressure Measurement:

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.

G. Repeat Section F for Left Ankle

H. Repeat Section E for Left Arm

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.

h625-h645

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.

J. **For Ankle Measurements record which sites the measurement was taken from**

0= posterior tibial (ankle)
1=dorsalis pedis (foot)

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.

Ankle-Brachial Blood Pressure is not done on Offsite Visits

Doppler Ankle Brachial Blood Pressure Measurements. Tech- Obtained

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SYSTOLIC BLOOD PRESSURES BY DOPPLER (to be taken in the following order with participant supine after 5 minutes of rest)

h624 |_|_|_|	**Examiner's Number** for Doppler Ankle Brachial Blood Pressure	
h625 |_|_|	**Cuff size, arm**	0= pediatric, 1= regular adult 2= large adult, 3= thigh
h626 |_|_|	**Cuff size, ankle**	

h627 |_|_|_|	**Right arm**	300=≥300
h628 |_|_|_|	**Right ankle**	999= Unknown or not done
h629 |_|_|_|	**Left ankle**	
h630 |_|_|_|	**Left arm**	

REPEAT SYSTOLIC BLOOD PRESSURE MEASUREMENTS (reverse order)

h631 |_|_|_|	**Left arm**	300=≥300
h632 |_|_|_|	**Left ankle**	999= Unknown or not done
h633 |_|_|_|	**Right ankle**	
h634 |_|_|_|	**Right arm**	

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

h635 |_|_|_|	**Left arm**	300=≥300
h636 |_|_|_|	**Left ankle**	999= Unknown or not done
h637 |_|_|_|	**Right ankle**	
h638 |_|_|_|	**Right arm**	

h639 |_|_|	**Right Ankle blood pressure site**	0= posterior tibial (ankle) 1= dorsalis pedis (foot)
h640 |_|_|	**Left Ankle blood pressure site**	

EXCLUSIONS:

Right	Left	
h641/h642 |_|_|	|_|_|	**Lower Extremity Exclusions** 0= None, 1= venous stasis ulceration, 2= amputation, 3= other_____
h643/h644 |_|_|	|_|_|	**Upper Extremity Exclusions** 0= None, 1=Mastectomy, 3= Other_____

h645 |_|_|	**Protocol modification,** write in_____	0= No,1= Yes 2=Incomplete/ refused

TECH13

h605 → h612 h614 → h623

Observed Physical Performance Measures

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.

Definitions

Impairment: Dysfunctional and structural abnormalities in specific body systems, such as the musculoskeletal system or the cardiovascular system.

Functional limitations: Restrictions in basic physical and mental actions, including things such as ambulation reaching, and grasping.

Disability: Difficulty doing activities of daily life, including not only personal care, but household management, jobs, and hobbies.

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. 5 Meter Chain
5. 1" Masking tape
6. JAMAR Dynamometer

h605-h612
h614-h623

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 together. I will ask you to walk for me and then I will ask to test your grip strength.

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. Measured Walks

JAMAR Hand Grip Strength Test: h605-h612

1. 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.***

2. Participant is seated in chair with arms, forearm resting on chair arm, elbow at about a 90 degree angle.

3. Participant should hold JAMAR in upright position, wrist in neutral position, JAMAR facing the technician.

4. Make sure that red peak-hold needle is set to zero.

5. Tell participant to squeeze as hard as s/he can, and squeeze until you tell s/he to stop. Hold squeeze for a 3 to 5-1000 second count.

6. 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.

7. Repeat steps until three measurements are recorded with the right hand.

8. Repeat steps for three trials with the left hand.

Measured Walks: h614-h623

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 a normal walking pace while being observed and timed. Next, he or she will repeat this usual pace while being timed. The examiner will then demonstrate the rapid pace walk and the participant will be asked to walk the course at a rapid pace while being timed.

A cane or walker may be used during the walk, but if people 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 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	**3** = Wheelchair	**9** = Unknown

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.

1. Walk #1:

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.

h614-h623

2. Walk #2:

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.

3. Walk #3:

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.

Training Note: we do not do time walks for participant in a wheelchair.

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.

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

Observed performance. Part 1

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h604

|__|__|__|	**Examiner's Number**

HAND GRIP TEST Measured to the nearest kilogram

Right hand

h605 **Trial 1** 99=Unknown |__|__|

h606 **Trial 2** 99=Unknown |__|__|

h607 **Trial 3** 99=Unknown |__|__|

Left hand

h608 **Trial 1** 99=Unknown |__|__|

h609 **Trial 2** 99=Unknown |__|__|

h610 **Trial 3** 99=Unknown |__|__|

h611 **Was this test completed?** (0=No, 1=Yes, 8=Not attempted, 9=Unknown) |__|

If not attempted or completed, why not?

h612 1=Physical limitation 3=Other _____ write in |__|

2=Refused 9=Unknown

TECH11

Observed performance. Part 2

OMB NO=0925-0216 12/31/2007

h613	___	**Examiner's Number**

MEASURED WALKS

h614 **Walking aid used:** 0=No aid, 1=Cane, 2=Walker, 3=Wheelchair, 4=Other, 9=Unknown __

First Walk

h615 **Was this test completed?** (0=No, 1=Yes, 8=Not attempted, 9=Unknown) __

If not attempted or completed, why not?
1=Physical limitation 3=Other _____ write in
2=Refused 9=Unknown

h616 __

h617 **Walk time** (in seconds, 99.99=Unknown) ___*___

Second Walk

h618 **Was this test completed?** (0=No, 1=Yes, 8=Not attempted, 9=Unknown) __

If not attempted or completed, why not?
1=Physical limitation 3=Other _____ write in
2=Refused 9=Unknown

h619 __

h620 **Walk time** (in seconds, 99.99=Unknown) ___*___

Quick Walk

h621 **Was this test completed?** (0=No, 1=Yes, 8=Not attempted, 9=Unknown) __

If not attempted or completed, why not?
1=Physical limitation 3=Other _____ write in
2=Refused 9=Unknown

h622 __

h623 **Walk time** (in seconds, 99.99=Unknown) __*___

h582-> h603

Mini-Mental State Exam (MMSE)

Tech-Administered

A. 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.

B. Definitions:

1. **Alert Level**: In general participant scoring below education-adjusted cut-off scores* on the MMSE may be cognitively impaired.

MMSE-EDUCATION ADJUSTED CUT-OFF SCORES

a. Subjects whose education levels are **7th grade or lower**, a score on the **MMSE of 22 or below**

b. Subjects whose education attainment level is **8th grade or some high school** (but not a graduate of), a score on the **MMSE of 24 or below**

c. Subjects whose education attainment level is **high school graduate**, a score on **the MMSE of 25 or below**

d. Subjects whose education attainment level is **some college or higher**, a score on the **MMSE of 26 or below.**

***Note: The Education Adjusted Cut-off Scores are calculated by data management.**

2. **Mini-Mental State Exam Scoring**:

The official total score for the MMSE (i.e. the scores used for statistical analyses) are computer generated. Examiners record individual test item scores on the MMSE test form. The one exception is "WORLD" where examiners record the response of subjects in the exact order that it is given by the subject.

For **referral purposes**, any participant with a drop of 3 points in score since their last exam should be referred to neurology group. A preliminary score can be calculated by [redacted] to determine if the participant should be referred. A referral form should be completed and given to the Neuro Project Coordinator, [redacted], after the exam. Referral forms can be found in the appendices.

If a participant is referred they may also qualify for a consent form Waiver.

3. **Consent Form Waiver:**
   Guidelines dated 3/10/01 verified 3/25/04:

   Any subject with MMSE at or above 26 may be presumed competent unless listed otherwise at last evaluation

   Any subject with MMSE below 13 requires use of a Waiver unless seen by a neurologist and declared not demented

   MMSEs between 25 and 13 would trigger a decision process. The participants in this category will sign a consent but they may qualify for a waiver. The neurology team will review each case and decide which category to be in (Consent or Waiver).

Refer to Waiver of Informed Consent Section of manual for full protocol.

C. 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 (i.e. [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).

h582-h603

D. Expanded Scoring Instructions for Mini-Mental Exam:

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.)

> **9** = When test item was not administered (refused or inability because of physical limitations) or subject's response is uninterpretable (response could be correct, but tester is unable to discern the response).

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:

1. Incorrect response
2. *I don't know*
3. Unintelligible response in context of other intelligible responses (see scoring of **9** as well).
4. Participants attempted to respond but responds incorrectly (i.e. they are demonstrating that they heard the question and are making an attempt to respond to it).

h582-h603

E. 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.

Month	Correct Response
January	Winter
February	Winter
March	Winter or Spring
April	Spring
May	Spring
June	Spring or Summer
July	Summer
August	Summer
September	Summer or Fall
October	Fall
November	Fall
December	Fall or Winter

3. *What day of the week is it?*

4. *What town, county, and state are we in?*

    a. Ask the participant what town, county, and state we are in.
    b. For offsite visits, refer to the section of the manual titled "New England Counties" for a complete list of all counties.

h582-h603

5. *What is the name of this place?*

    a. 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?*

6. *What floor of the building are we on?*

7. *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.*

    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. For tabulating a total MMSE score for screening purposes, please determine a total score between 0-5 for this item).

    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.

9. *What are the 3 objects I asked you to remember a few moments ago?*

    a. Items may be repeated in any order.

h582-h603

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 *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.
    c. Code **1** = correct when the participant correctly repeated the phrase.
    d. Code **0** = incorrect when the participant did not repeat the phrase exactly.

    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.

h582-h603

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.)

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).
d. Score: **1** for <u>each</u> correctly performed act (code **6** if low vision).

h582-h603

F. Factors Potentially Affecting Mental Status Testing

The examiner's impression for Cohort Cycle 28 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	Paralysis
0	1	2	9	Depression/Possible Depression
0	1	2	9	Aphasia
0	1	2	9	Coma
0	1	2	9	Parkinsonism or neurological impairment
0	1	2	9	Other

Note: Questions cannot be answered by a proxy.

h594

PLEASE CLOSE YOUR EYES

Cognitive Function--Part I

OMB NO=0925-0216 12/31/2007

I'm going to start by asking questions that require concentration and memory. Some questions are more difficult that others and some will be asked more than one time.

h581 |__|__|__| **Examiner's Number** for Cognitive Function -- Part I+II

	SCORE CORRECT No Try=6 Unknown=9	Write all responses on exam form (score 1 point for each correct response)
h582	0 1 2 3 6 9	**What Is the Date Today?** (Month, day, year, correct score=3)
h583	0 1 6 9	**What Is the Season?**
h584	0 1 6 9	**What Day of the Week Is it?**
h585	0 1 2 3 6 9	**What Town, County and State Are We in?**
h586	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)
h587	0 1 6 9	**What Floor of the Building Are We on?**
h588	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. Remember what they are because I will ask you to name them again in a few minutes: Apple, Table, Penny**
h589	|__|__|__|__|__|	**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 Scored Later) Score as: 66666=Not administered for reason unrelated to cognitive status; 00000=Administered, but couldn't do; 99999=Unknown
h590	0 1 2 3 6 9	**What are the 3 objects I asked you to remember a few moments ago?**

Cognitive Function --Part II

OMB NO=0925-0216 12/31/2007

	SCORE CORRECT No Try=6 Unknown=9	Write all responses on exam form.
h591	0 1 6 9	**What Is this Called?** (Watch)
h592	0 1 6 9	**What Is this Called?** (Pencil)
h593	0 1 6 9	**Please Repeat the Following: "No Ifs, Ands, or Buts."** (Perfect=1)
h594	0 1 6 9	**Please Read the Following & Do What it Says** (performed=1, code 6 if low vision)
h595	0 1 6 9	**Please Write a Sentence** (code 6 if low vision)
h596	0 1 6 9	**Please Copy this Drawing** (code 6 if low vision)
h597	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 below)	Factor Potentially Affecting Mental Status Testing
h598	0 1 2 9	Illiterate or low education
h599	0 1 2 9	Not fluent in English
h600	0 1 2 9	Poor eyesight
h601	0 1 2 9	Poor hearing
h602	0 1 2 9	Depression / possible depression
h603	0 1 2 9	Other, write in _____

TECH10

OMB NO=0925-0216 12/31/2007

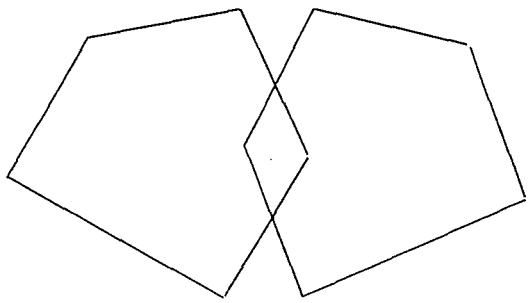
Sentence and Design Handout for Participant

PLEASE WRITE A SENTENCE

h595

PLEASE COPY THIS DESIGN

h596



h474 -> h478

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:

- General level of physical functioning and mobility
- Ability to carry out instrumental activities of daily living
- Ability to carry out activities of daily living
- Framingham Disability Index

B. Activities of Daily Living

The activities & examples of each ADL include:

1. Dressing
   - Undressing and redressing
   - Picking out clothes, dress oneself including buttoning, fastening, etc.
   - Devices such as: velcro, elastic laces.
2. Bathing
   - Including getting in and out of tub or shower
   - Getting water, soap, towel and other necessary items and wash oneself
   - Devices such as: bath chair, long handled sponge, hand held shower, safety bars.
3. Eating
   - Able to eat from a dish and drink from a cup
   - Devices such as: rocking knife, spork, long straw, plate guard.
4. Transferring
   - Getting in and out of a chair
   - Arising from a sitting position to a standing position and back
   - 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.

Katz Activities of Daily Living Scale

OMB NO=0925-0216 12/31/2007

h473	|_|_|	**Examiner's Number** for Activities of Daily Living
	During the Course of a Normal Day, Can you do the following activities independently or do you need human assistance or the use of a device? Coding: 0=No help needed, independent, 1=Uses device, independent, 2=Human assistance needed, minimally dependent, 3=Dependent, 4=Do not do during a normal day, 9=Unknown	
h474	|_|	**Dressing** (undressing and redressing) Devices such as: velcro, elastic laces;
h475	|_|	**Bathing** (including getting in and out of tub or shower) Devices such as: bath chair, long handled sponge, hand held shower, safety bars;
h476	|_|	**Eating** Devices such as: rocking knife, spork, long straw, plate guard.
h477	|_|	**Transferring** (getting in and out of a chair) Devices such as: sliding board, grab bars, special seat;
h478	|_|	**Toileting Activities** (using bathroom facilities and handle clothing) Devices such as: special toilet seat, commode;

TECH04

h459 → h470

Rosow-Breslau Questions

Rationale & Background

Respondents' self-assessments of health may raise questions about the validity of such judgments. However, we are not interested in the literal details of people's medical condition as much as in the behavioral consequences, their physical capacity for role fulfillment and social participation. We are primarily concerned with the *functional* health which old 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**. The questions assess the degree of difficulty that a person has performing a specific activity. This form has several important purposes:

1. These data will enable us to assess the level of independence and function in the study population.
2. It is hypothesized that impairments of physical function may be a risk factor for cardiovascular end points and progression of disease.
3. It will measure loss of physical functioning as a consequence of cardiovascular disease.

*Note: Do not ask the Rosow-Breslau questions of cognitively impaired participants; their proxy **can** answer these questions.*

Rosow-Breslau Scale

OMB NO=0925-0216 12/31/2007

h458 |__|__|__| **Examiner's Number** for Socio-demographics

Socio-demographics

h459 |__| **Where do you live?** (0=Private residence, 1=Nursing home, 2=Other institution, such as: assisted living, retirement community, 9=Unknown

h460 |__| **Does anyone live with you?** (0=No, 1=Yes, 9=Unknown)
Code Nursing Home Residents as NO to these questions

If Yes ☞

If 0 or 9, skip down

		0=No 1=Yes, less than 3 months per year 2=Yes, more than 3 months per year 9=Unknown
h461	|__| Spouse	
h462	|__| Significant Other	
h463	|__| Children	
h464	|__| Friends	
h465	|__| Relatives	

Use of Nursing and Community Services

h466 |__| **Have you been admitted to a nursing home (or skilled facility) in the past year)**

h467 |__| **In the past year, have you been visited by a nursing service, or used home, community, or outpatient programs?**

0=No
1=Yes
9=Unknown

Rosow-Breslau Questions

h468 |__| **Are you able to do heavy work around the house, like shoveling snow or washing windows, walls, or floors without help?**

h469 |__| **Are you able to walk half a mile without help?** (About 4-6 blocks)

h470 |__| **Are you able to walk up and down one flight of stairs without help?**

0=No
1=Yes
9=Unknown

CES-D Scale (Self-administered)

The questions below ask about your feelings.

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)
h471 1. I felt that everything I did was an effort.	0	1	2	3
h472 2. I could not "get going"	0	1	2	3

TECH03

Katz Activities of Daily Living Scale

OMB NO=0925-0216 12/31/2007

h473

⌊_⌋⌊_⌋⌊_⌋	**Examiner's Number** for Activities of Daily Living

During the Course of a Normal Day, Can you do the following activities independently or do you need human assistance or the use of a device? Coding: 0=No help needed, independent, 1=Uses device, independent, 2=Human assistance needed, minimally dependent, 3=Dependent, 4=Do not do during a normal day, 9=Unknown

h474 ⌊_⌋	**Dressing** (undressing and redressing) Devices such as: velcro, elastic laces;
h475 ⌊_⌋	**Bathing** (including getting in and out of tub or shower) Devices such as: bath chair, long handled sponge, hand held shower, safety bars;
h476 ⌊_⌋	**Eating** Devices such as: rocking knife, spork, long straw, plate guard.
h477 ⌊_⌋	**Transferring**(getting in and out of a chair) Devices such as: sliding board, grab bars, special seat;
h478 ⌊_⌋	**Toileting Activities** (using bathroom facilities and handle clothing) Devices such as: special toilet seat, commode;

TECH04

h569 → h577

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:

No Difficulty
A Little Difficulty
Some Difficulty
A Lot of Difficulty
Unable to Do
Don't Do on MD Orders
Unable to Assess Difficulty Because Not Done as Part of Daily Activities

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 MD Orders or Institutional Orders, or if you are Unable to Assess Difficulty Because the activity is not done as part of your daily activities.*

3. Read each activity separately, and go through the level of difficulty for each one until the participant understands the response choices.

Notes:

"Institutional Orders" is any facility that assists a person with their daily activities, (ex. Nursing homes, assisted living facilities, etc.)

Do not ask these questions if the participant is cognitively impaired; proxy may answer these questions.

h569-h577

No Difficulty

A Little Difficulty

Some Difficulty

A Lot of Difficulty

Unable to Do

Don't Do on MD Orders or Institutional Orders

Unable to Assess Difficulty Because Not Done as Part of Daily Activities

Nagi Questions

OMB NO=0925-0216 12/31/2007

h568

|_|_|_|	**Examiner's Number** for Activities - Part B

Nagi Questions

For each thing 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 MD Orders
(6) Unable to Assess Difficulty Because not Done as Part of Daily Activities
(9) Unknown

h569	|_|	**Pulling or pushing large objects like a living room chair**
h570	|_|	**Either stooping, crouching, or kneeling**
h571	|_|	**Reaching or extending arms below shoulder level**
h572	|_|	**Reaching or extending arms above shoulder level**
h573	|_|	**Either writing, or handling, or fingering small objects**
h574	|_|	**Standing in one place for long periods, say 15 minutes**
h575	|_|	**Sitting for long periods, say 1 hour**
h576	|_|	**Lifting or carrying weights under 10 pounds** (like a bag of potatoes)
h577	|_|	**Lifting or carrying weights over 10 pounds** (like a very heavy bag of groceries)

TECH07

Falls/Fractures

OMB NO=0925-0216 12/31/2007

h577 |__|__|__| **Examiner's Number** for Activities - Part C

Fractures

h579 |__| **Since Your Last Clinic Visit Have You Broken Any Bones?**
(Code: 0=No, 1=Yes, 2=Unsure, 9=Unknown)

h580 h580A h580B **If Yes, fill** ☞ |__|__| **Location of fracture:**

Location (code unknown 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)_____

TECH08

h471, h472

CES-D

The depression questions used in the HANES I survey were the 20-item set of the CES-D developed and validated by the Center for Epidemiologic Studies, National Institute of Mental Health (NIMH). The FHS is using only two questions to assess the participant's feelings during the past week.

Tech Administered

Script

The questions below ask about your feelings, please say if you felt this way during the past week.

1. *During the past week, I felt that everything I did was an effort.*
2. *During the past week, I could not "get going"*

Instructions for Scale Scoring of the CES-D:

Each item have a range of four response options which indicated how often the survey examinee had 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)

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

Note: Questions may not be answered by a proxy.

Rosow-Breslau Scale

OMB NO=0925-0216 12/31/2007

h458 |__|__|__| **Examiner's Number** for Socio-demographics

Socio-demographics

h459 |__| **Where do you live?** (0=Private residence, 1=Nursing home, 2=Other institution, such as: assisted living, retirement community, 9=Unknown

h460 |__| **Does anyone live with you?** (0=No, 1=Yes, 9=Unknown) Code Nursing Home Residents as NO to these questions

If Yes ☞

If 0 or 9, skip down

h461	|__| Spouse	0=No 1=Yes, less than 3 months per year 2=Yes, more than 3 months per year 9=Unknown
h462	|__| Significant Other	
h463	|__| Children	
h464	|__| Friends	
h465	|__| Relatives	

Use of Nursing and Community Services

h466 |__| **Have you been admitted to a nursing home (or skilled facility) in the past year)**

h467 |__| **In the past year, have you been visited by a nursing service, or used home, community, or outpatient programs?**

0=No
1=Yes
9=Unknown

Rosow-Breslau Questions

h468 |__| **Are you able to do heavy work around the house, like shoveling snow or washing windows, walls, or floors without help?**

h469 |__| **Are you able to walk half a mile without help?** (About 4-6 blocks)

h470 |__| **Are you able to walk up and down one flight of stairs without help?**

0=No
1=Yes
9=Unknown

CES-D Scale (Self-administered)

The questions below ask about your feelings.

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)
h471 1. I felt that everything I did was an effort.	0	1	2	3
h472 2. I could not "get going"	0	1	2	3

TECH03

h480 → h567

Physical Activity Questionnaire-Exercise

Tech-Administered

1. Explain that the first section is Rest and Activity for a Typical Day (24 hours).

2. Read through each activity and explain that the total number of hours for a typical day must equal 24 hours.

    - Sleep
    - Sedentary
    - Slight Activity
    - Moderate Activity
    - Heavy Activity

3. Make adjustments according to participant until the total number of hours equals 24. Do not ask the participant any leading questions.

4. The second section of physical activity questions was adapted from the Cardiovascular Health Study (CHS). http://128.208.129.3/chs/forms/4pl.htm These questions cover physical activity over the past year.

Note for Offsite visits: If the participant is cognitively impaired, do not ask the questions of the participant or their proxy.

Physical Activity Questionnaire--Framingham Heart Study
Tech-administered

OMB NO=0925-0216 12/31/2007

h479 |_|_|_| **Examiner ID**

	Rest and Activity for a Typical Day (Activities must equal 24 hours)	**Number of hours**
h480	**Sleep**--Number of hours that you typically sleep?	____
h481	**Sedentary**--Number of hours typically sitting?	____
h482	**Slight Activity**--Number of hours with activities such as standing, walking?	____
h483	**Moderate Activity**--Number of hours with activities such as housework (vacuum, dust, yard chores, climbing stairs; light sports such as bowling, golf)?	____
h484	**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**

h485 |_| **What is your normal walking pace outdoors?**

0 = Unable to walk
1 = Easy, casual, slow (less than 2 miles per hour)
2 = Normal, average (2 to 2.9 miles per hour)
3 = Brisk pace (3 to 3.9 miles per hour)
4 = Very brisk pace (4 to 4.9 miles per hour)
9 = Unknown

h486 |_| **How many flights of stairs (not steps) do you climb daily?** (10 stairs per flight)

0 = No flights
1 = 1-2 flights
2 = 3-4 flights
3 = 5-9 flights
4 = 10-14 flights
5 = >15 flights
9 = Unknown

TECH05

Physical Activity Questionnaire--Framingham Heart Study
Tech-administered

OMB NO=0925-0216 12/31/2007

I am going to read a list of activities. Please tell me which activities you have done in the <u>past year</u>.

h487 |__|__|__| **Examiner ID**

During past year	0=No, 1=Yes, 8=Refused, 9=Unknown	In a typical 2 week period of time, how often do you (name of activity)	Average time/session: hours	Average time/session: minutes	Number months/year 0-12
h488	Walking for exercise	h489	h490	h491	h492
h493	Calisthenics/general exercise	h494	h495	h496	h497
h498	Moderate strenuous household chores	h499	h500	h501	h502
h503	Mowing the lawn	h504	h505	h506	h507
h508	Gardening	h509	h510	h511	h512
h513	Hiking	h514	h515	h516	h517
h518	Jogging	h519	h520	h521	h522
h523	Biking	h524	h525	h526	h527
h528	Exercise cycle, ski or stair machine	h529	h530	h531	h532
h533	Dancing	h534	h535	h536	h537
h538	Aerobics	h539	h540	h541	h542
h542	Golf	h543	h544	h545	h546
h547	Swimming	h548	h549	h550	h551
h552	Weight training (free weights, machines)	h553	h554	h555	h557
h558	Other, write in_____	h559	h560	h561	h562
h563	Other, write in_____	h564	h565	h566	h567

TECH06

h688 → h698

Exam 8 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.

Proxy form

OMB NO=0925-0216 12/31/2007

h688	|__|	**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** _____
h689	|__|	**Relationship** (1=1st Degree Relative(spouse, child), 2=Other Relative, 3=Friend, 4=Health Care Professional, 5=Other, 9=Unknown
h690-h691	|__|__|*|__|__|	**How long have you known the participant?** (Years, months; 99.99=Unk) example: 3m=00*03
h692	|__|	**Are you currently living in the same household with the participant?** (0=No, 1=Yes, 9=Unk)
h693	|__|	**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=Unknown)
		Proxy Name _____
h694	|__|	**Relationship** (1=1st Degree Relative(spouse, child), 2=Other Relative, 3=Friend, 4=Health Care Professional, 5=Other, 9=Unknown
h695-h696	|__|__|*|__|__|	**How long have you known the participant?** (Years, months; 99.99=Unk) example: 3 m=00*03
h697	|__|	**Are you currently living in the same household with the participant?** (0=No, 1=Yes, 9=Unk)
h698	|__|	**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=Unknown)

TECH016

EXIT INTERVIEW PROCEDURES FOR OFFSPRING EXAM 8

h430-h435

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 and the Referral Tracking Form sticking sideways out of the chart in the correct order and obtain a button.
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. 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, Questionnaire packet & 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. Make sure the participant leaves the clinic area with all of their belongings; **ESPECIALLY THEIR MEDICATION BAG WITH MEDICATIONS.**
9. Thank the participant for their time and willingness to participate
10. 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. Will you be calling my grandchildren to come in?
A. *We have no plans for a Generation 4 Study at this time.*

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 400 of this group still living, of which we saw 300 for their Cycle 28. We plan to see about 3200 Offspring during Cycle 8 and we saw 4100 Generation 3 participants.*

OFFSPRING Exam 8
Chart Order:
(Inside Orange Folder)

Consent Form
Summary Sheet
ECG
Summary of Findings (beige)
Main Exam Form
Health Status Update

Numerical Data Sheet
Second Visit Sheet

Stapled:
Rosow-Breslau Scale
Physical Activity
Nagi
Cognitive Function/Sentence & Design

Observed Performance
Ankle Arm Doppler

Respiratory Disease Questionnaire
PFT (green sheet) (or white if not done)
Proxy

Stapled:
Sociodemographic
SF-12
Sleep Questionnaire

Referral Tracking
Admitting Form (inside green; Personal Family History form)

FHS Proxy

Participant Letter (Letter from Dr. to Partcipant)
HIPPA (Research Release form)
Appointment Letter
Lab Test Request

All other information gathered since last exam
All Summary Sheets including Exam 7

(Inside Purple Folder)
Exam 7
Orange Folder

OMB NO=0925-0216 12/31/2007

Exam 8 Procedures Sheet

h410	☐	**Informed Consent Signed**	0=No, 1=Yes, 2=Consent signed, may qualify for waiver 3=Waiver used, 4=Other
h411	☐	**Anthropometry**	
h412	☐	**Sociodemographic Questions**	
h413	☐	**SF-12 Health Survey**	
h414	☐	**CES-D Scale**	
h415	☐	**Exercise Questionnaire**	0=No,
h416	☐	**Mini-Mental Status Exam**	
h417	☐	**Urine Specimen**	
h418	☐	**Blood Draw**	1=Yes,
h419	☐	**ECG**	
h420	☐	**Observed performance** (Timed walk hand grip)	
h421	☐	**Tonometry /ECHO/Carotid**	
h422	☐	**Ankle-brachial blood pressure by Doppler.**	8=Offsite visit
h423	☐	**Spirometry**	
h424	☐	**Post bronchodilator Spirometry**	
h425	☐	**Diffusion Capacity**	
h426	☐☐	**Reason Spirometry not done**	1=Major Surgery, 2=Heart Attack 3=Stroke, 4=Aneurysm, 5=BP>210/110 6=Refused, 7=Test Aborted, 8=Other, 10=equipment problems
h427	☐☐	**Reason post bronchodilator test not done**	
h428	☐☐	**Reason Diffusion not done**	

Exit Interview

h429 ☐☐☐ **Examiner ID**

h430	☐	Procedure sheet reviewed
h431	☐	Referral sheet reviewed
h432	☐	Willett dietary questionnaire provided (if not completed in clinic)
h433	☐	Left clinic w/ belongings
h434	☐	Feedback 0=No feedback, 1=Positive feedback, 2=Negative feedback, 3=Other

0=No
1=Yes
8=Offsite

h435 Comments _____

_____

_____

_____

TECH02

Medical History h001-h008

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.

h001-h008

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.

h018 - h023

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 8 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 MD12)

When the participant states that they have not experienced any chest discomfort, clarify further using the terms *chest pain, chest tightness, chest pressure.* h115

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. h127

Alcohol Consumption (screen MD08) h071-h079

Code number of alcoholic beverages as EITHER weekly **OR** monthly as appropriate.

Cerebrovascular, Neurological and Venous Diseases (screen MD14)

It is important to stress that these CVA symptoms are **sudden**, not a gradual progression of a symptom.

1. Sudden Muscular Weakness h161
   *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 h162
   *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 h163
   *Since (date of last FHS exam) until today, have you experienced any **sudden** visual defect?*

4. Sudden Double Vision h164
Since (date of last FHS exam) until today, have you experienced any double vision?

5. Sudden Loss of Vision in One Eye h165
*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 h166
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? h167

CVD Procedures
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 h206, h207
Have you had surgery on your heart valves?

Exercise tolerance test h208, h209
Have you had an exercise stress test or a treadmill test of your heart?

Coronary Arteriogram h210, h211
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 h212-h214
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 h215, h216
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 h217, h218
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 h219, h220
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 h221, h222
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 h223, h224
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 h225, h226
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 h227, h228
Have you had any surgery to improve the circulation in your legs such as bypass surgery or angioplasty?

Lower extremity amputation h229, h230
Have you had an amputation of part of your leg or foot?

Other cardiovascular procedures (write in) h231, h232
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. h110, h132-h135, h157-h160, h205
2. Code the ECG. The MD ECG reading should be added to the letter to the personal physician. h303-h338
3. Complete the "clinical diagnostic impression" h339-h379
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.

ECG CODING FOR FRAMINGHAM HEART STUDY EXAMINATIONS h304-h338

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 hundredths of a second based upon examination of the ECG recording. (Lead II should be used when possible for these measurements). A QRS of 0.08 seconds is coded as 08.

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 .12 sec or greater. When the QRS is prolonged, but the pattern is not that of right or left BBB, then indeterminate IV block is coded as follows: 1=QRS .12 or greater, 2=QRS of .11 or .10. 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 .09 sec or greater it represents incomplete RBBB.

HEMIBLOCK

h304-h338

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 two 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 and 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 in 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 h304-h338

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 T 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 10.5 mm.

ARRHYTHMIAS

The presence of rhythm disturbances should be made on the basis of examination of the 1/2 speed rhythm strip which accompanies each ECG. This represents a simultaneous 3 lead recording of the entire 12-lead ECG.

NAME= idtype= id= EXAM= EXDATE= DATE COMPLETED=

NTH	DAY	YEAR	TYPE	REASON
.	.	.	-----	-----

Medical History—Hospitalizations, ER Visits, MD Visits

Offspring EXAM 8

DATE _____

OMB NO=0925-0216 12/31/2007
Last exam on: «LExam»
Last Health History Update on: «LUpdate»

		Health Care
h001	|0|	**1st Examiner Prefix** (0=MD, 1=Tech. for OFFSITE visit)
h002	|__|__|__|	**1st Examiner ID** _____ 1st Examiner Name
h003	|__|	**Hospitalization** (not just E.R.) **since your last exam** (0=No; 1=yes, hospitalization, 2=yes, more than 1 hospitalization, 9=Unknown)
h004	|__|	**E.R. Visit since your last exam** (0=No; 1=Yes, 1 or more E. Room visit, 9=Unk)
h005	|__|	**Day Surgery** (0=No, 1=Yes, 9=Unknown)
h006	|__|	**Major illness with visit to doctor** (0=No, 1=Yes, 1 visit; 2=Yes, more than 1 visit; 9=Unk)
h007	|__|	**Have you had a fever or infection in past two weeks?** (0=No, 1=Yes, 9=Unknown)
h008	|__|	**Check up** by doctor in past 5 years (0=No, 1=Yes, 9=Unknown)
h009	MM DD YYYY	**Date** of this FHS exam (Today's date - See above)

Note: if FHS needs outside hospital record, please obtain details: mo/yr, hospital site.

Medical Encounter	Month/Year (of last visit)	Site of Hospital or Office	Doctor

MD01

Medical History—Medications

OMB NO=0925-0216 12/31/2007

h010	|__| **Take aspirin regularly?** (0=No, 1=Yes, 9=Unk)
h011	If yes, fill ☞ |__|__| **Number aspirins taken regularly** (99=Unknown)
h012	|__| **Frequency per** (1=Day, 2=Week 3=Month, 4=Year, 9=Unk)
h013	|__|__|__| **Usual dose (** 081=baby,160=half dose, 325=nl, 500=extra or larger,999=unk)

h014 |__| **Since your last exam have you taken medication for hypertension/high blood pressure?** (0=no, 1=yes,now, 2=yes,not now, 9=unk)
h015 |__| **Since your last exam have you taken medication for high blood cholesterol or high triglycerides?** (0=no, 1=yes, now, 2=yes,not now, 9=unk)
h016 |__| **Since your last exam have you been told by a doctor you have high blood sugar or diabetes?** (0=no, 1=yes,now, 2=yes,not now, 9=unk)
h017 |__| **Since your last exam have you taken medication for cardiovascular disease**(for example angina/chest pain,heart failure, atrial fibrillation/heart rhythm abnormality, stroke, leg pain when walking? (0=no, 1=yes,now, 2=yes,not now, 9=unk)

MD02

Medical History – Prescription and Non-Prescription Medications

OMB NO=0925-0216 12/31/2007

Copy the name of medicine, 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.

h018 |__| **Medication bottles/packs used by examiner to record medications?** 0=No, 1=Yes

*****List medications taken regularly in past month/ongoing medications*****

Medication Name (Print first 20 letters)	Strength (include mg, IU, etc)	Number per (day/week/month) (circle one)		Prn (0=no, 1=yes, 9=unkn)
EXAMPLE: SAMPLE DRUG NAME	100 mg	1	(D) W M	0
h019	h020	h021	D W M h022	h023
			D W M	
			D W M	
			D W M	
			D W M	
			D W M	
			D W M	
			D W M	
			D W M	
			D W M	
			D W M	
			D W M	
			D W M	
			D W M	
			D W M	

Continue on the next page→

Medical History—Prescription and Non-Prescription Medications

Continue from screen 3.

OMB NO=0925-0216 12/31/2007

Copy the name of medicine, 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.

*****List medications taken regularly in past month/ongoing medications*****

Medication Name (Print first 20 letters)	Strength (include mg, IU, etc)	Number per (day/week/month) (circle one)		Prn (0=no, 1=yes, 9=unkn)
EXAMPLE DRUG NAME	100 mg	1	(D) W M	9
			D W M	
			D W M	
			D W M	
			D W M	
			D W M	
			D W M	
			D W M	
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			D W M	
			D W M	
			D W M	
			D W M	
			D W M	
			D W M	

MD04

Medical History–Female Reproductive History. Part 1.

| OMB NO=0925-0216 12/31/2007

If participant is male, leave questions blank

h024 |__| **1. Since your last exam have you taken or used oral contraceptive 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=unknown)

If yes, fill☞ What is the name of the **current or most recent** oral contraceptive, shot or implant used?

h025 _____ Name

h026 _____ Strength

h027 |__| Form (1=pill, 2=shot, 3=patch, 4=implant)

h028 __/h029 h030 h031 Duration of use (mo/yr began, mo/yr ended, year –4 digits) 99/9999=Unknown, **88/8888=current user**

h032 |__| **2. Have you had a hysterectomy (uterus/womb removed)since your last exam?** (0=no, 1=yes, 9=unknown)

If yes, fill☞

h033 |__|__| Age at hysterectomy?

h034 __/__h035 Date of surgery (mo/yr) Use 4 digits for year 99/9999=Unknown

h036 |__| **3. Since your last exam have you had an operation to remove one or both of your ovaries?** (0=no, 1=yes, one ovary removed, 2=yes, two ovaries removed, 3=yes, unknown number of ovaries removed, 4=yes, part of an ovary removed, 9=unknown)

If yes, fill☞

h037 |__|__| Age when ovaries removed? If more than one surgery, **use age at last surgery**

MD05

Medical History–Female Reproductive History. Part 2.

OMB NO=0925-0216 12/31/2007

h038 |__| **4. Have your periods stopped (for one year or more)? (Have you reached menopause?)** (0=not stopped, pregnant, breast feeding, 1=stopped but now have periods induced by hormones, 2=yes stopped>1 year, 3=yes stopped<1 year, 9=unknown)

*Please fill in **only** one of the boxes below, **not both!***

IF PERIODS NOT STOPPED (pre-menopausal, pregnant, breast feeding!)

h039 h040 h041 __/__/____ **When was the first day of your last menstrual period?**(Use 4 digits for year, 99/9999=Unknown)

h042 |__|__| **How many periods have you had in past 12 months?**

IF PERIODS STOPPED (post-menopausal, post-menopausal on hormone replacement, or peri-menopausal on horm repl.)

h043 |__|__| **a) Age when periods stopped** (00=not stopped, 99=unknown) ! If periods now induced by hormones, code age when periods naturally stopped.

h044 |__| **b) Was your menopause natural or the result of surgery, chemotherapy, or radiation?** (1=natural, 2=surgical, 3=chemo/radiation, 4=other, 9=unknown)

h045 |__| **c) Since your last exam have you taken hormone replacement therapy?** (estrogen/progesterone) (0=no, 1=yes, now, 2=yes, not now, 9=unknown)

If yes, fill ☞

h046 |__|__| **What age did you begin hormone replacement therapy?** 99=unknown

h047 |__|__| years

h048 |__|__| months **For how long did you take hormones?** 99/99=unknown

h049 |__| **Estrogen use?** (0=no, 1=yes, now, 2=yes, not now, 9=unknown)

If yes, fill ☞

h050 _____ Name of most recent estrogen preparation

h051 |__|__|.|__|__|__| Strength

h052 |__|__| Number of days per month taken

h053 |__| **Progesterone use?** (0=no, 1=yes, now, 2=yes, not now, 9=unknown)

If yes, fill ☞

h054 _____ Name of most recent progesterone preparation

h055 |__|__|.|__|__| Strength

h056 |__|__| Number of days per month taken

h057 |__| **d) Have you used Evista (raloxifene) or Nolvadex (tamoxifen) or other selective estrogen receptor Modulator (SERM)?** (0=no, 1=yes, now, 2=yes, not now, 9=unknown)

If yes, fill ☞

h059 |__|__|__| **Number of months used?**

h060 | | **Current use?** (0=no, 1=yes, raloxifene, 2=yes, tamoxifen, 3=yes, other, 9=unknown)

Medical History--Smoking

OMB NO=0925-0216 12/31/2007

Cigarettes

h060 |__| **Since your last exam have you smoked cigarettes regularly?** (No means less than 1 cigarette a day for 1 year.) (0=no, 1=yes, 9=unk)

If yes, fill☞

h061 |__| Have you smoked cigarettes regularly in the last year?

h062 |__| Do you now smoke cigarettes (as of 1 month ago)?

h063 |__|__|__| How many cigarettes do you smoke per day now?

h064 |__|__| On average, since your last exam, how many cigarettes did you smoke per day?

h065 |__|__| How old were you when you first started regular cigarette smoking? (99=Unk.)

h066 |__|__| If you have stopped smoking cigarettes completely, how old were you when you stopped?
(Age stopped, 00=not stopped, 99=Unk)

h067 |__| During the time you were smoking since your last exam, did you ever stop smoking for >6 months?

If yes, fill☞

h068 |__|__| During the time since your last exam, for how many years in total did you stop smoking cigarettes (00=never stopped)

Other

h069 |__| **Since your last exam, have you regularly smoked a pipe or cigar?**

0=No
1=Yes
9=Unknown

If yes, fill☞

h070 |__| Do you smoke a pipe or cigar now

Medical History –Alcohol Consumption.

OMB NO=0925-0216 12/31/2007

In the interim did you drink any of the following beverages at least once a month?

	Drink? 0=No, 1=Yes, 9=Ukn	Beverage	If yes, complete for number of drinks in a typical week/month over past year. *Code EITHER per week OR per month as appropriate.*	Number of drinks: Per week **OR** Per month (999=Unk)	
h071	|__|	Beer	12oz bottle, glass, can	|__|__|__| h072	|__|__|__| h073
h074	|__|	Wine	4oz glass	|__|__|__| h075	|__|__|__| h076
h077	|__|	Liquor/spirits	1 ¼ oz jigger	|__|__|__| h078	|__|__|__| h079

h080	|__|__|	**At what age did you stop drinking alcohol?** (00= not stopped, 888=never drink99=Unknown)
h081	|__|	**Over the past year, on average on how many days per week did you drink an alcoholic beverage of any type?** (1=1or less, 9=Unknown)
h082	|__|__|	**Over the past year, on a typical day when you drink, how many drinks do you have?** (99=Unknown)
h083	|__|__|	**What was the maximum number of drinks you had in 24 hr. period during the past month?** (99=Unknown)
h084	|__|	**Has there ever been a time in your life when you drank 5 or more alcoholic drinks of any kind almost daily?** (0=no, 1=yes, 9=unknown)

MD08

Medical History—Respiratory Symptoms. Part I

OMB NO=0925-0216 12/31/2007

Cough

h085 |__| **Do you usually have a cough?** (Exclude clearing of the throat) 0=No 1=Yes 9=Don't know

h086 |__| **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:

h087 |__| Do you cough like this on most days for three consecutive months or more during the past year? 0=No 1=Yes 9=Don't know

h088 |__|__| How many years have you had this cough? (99=Unk.) # of years

Phlegm

h089 |__| **Do you usually bring up phlegm from your chest ?** 0=No 1=Yes 9=Don't know

h090 |__| **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:

h091 |__| Do you bring up phlegm from your chest on most days (4 or more days/week) for three consecutive months or more during the year? 0=No 1=Yes 9=Don't know

h092 |__|__| How many years have you had trouble with phlegm? (99=Unk.) # of years

Wheeze

h093 |__| **In the last 12 months, have you had wheezing or whistling in your chest at any time?** 0=No 1=Yes 9=Don't know

h094 if yes, fill all ☞ |__| **In the last 12 months, 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=Unknown

h095 |__| **In the past 12 months, have you had this wheezing or whistling in the chest when you had a cold?** 0=No 1=Yes 9=Don't know

h096 |__| **In the past 12 months, have you had this wheezing or whistling in the chest apart from colds?**

h097 |__| **In the last 12 months, have you had an attack of wheezing or whistling in the chest that had made you feel short of breath?**

Medical History—Respiratory Symptoms. Part II

OMB NO=0925-0216 12/31/2007

Nocturnal chest symptoms

h098 ☐ **In the last 12 months, have you been awakened by shortness of breath?**

h099 ☐ **In the last 12 months, have you been awakened by a wheezing/whistling in your chest?**

h100 ☐ **In the last 12 months, have you been awakened by coughing?**

h101 **if yes, fill all☞** ☐ In the last 12 months, how often have you been awakened by coughing?

0=No
1=Yes
9=Don't know

0=Not at all 9=Unknown
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

Shortness of breath

h102 ☐ **Are you troubled by shortness of breath when hurrying on level ground or walking up a slight hill?**

h103 **if yes, fill all☞** ☐ Do you have to walk slower than people of your age on level ground because of shortness of breath?

h104 ☐ Do you ever have to stop for breath when walking at your own pace on level ground?

h105 ☐ Do you ever have to stop for breath after walking 100 yards (or after a few minutes) on level ground?

h106 ☐ **Do you/have you needed to sleep on two or more pillows to help you breath?** (Orthopnea)

h107 ☐ **Since your last exam have you had swelling in both your ankles (ankle edema)?**

h108 ☐ **Since your last exam have you been told you had heart failure or congestive heart failure?**

h109 ☐ **Since your last exam have you been hospitalized for heart failure?**

0=No
1=Yes
9=Don't know

Examiner's opinion:

h110 ☐ **First examiner believes CHF**

0=No,1=Yes
2=Maybe,9=Unkn

Comments_____

OMB NO=0925-0216 12/31/2007

Physician Blood Pressure (first reading)			
Systolic	**Diastolic**	**BP cuff size**	**Protocol modification**
h111 ⌊_⌋⌊_⌋⌊_⌋	h112 ⌊_⌋⌊_⌋⌊_⌋	h113 ⌊_⌋	h114 ⌊_⌋
to nearest 2 mm Hg	to nearest 2 mm Hg	0=pedi, 1=reg adult, 2=large adult, 3= thigh, 9=unknown	0=No, 1=Yes, 9=Unknown
Comments on protocol modification_____			

MD11

Medical History—Chest pain

OMB NO=0925-0216 12/31/2007

h115 |__| **Any chest discomfort** (0=No, 1=Yes, 2=Maybe, 9=Unknown)
(please provide narrative comments in addition to checking the appropriate boxes)

if yes, fill ☞ and below

h116 |__| Chest discomfort with exertion or excitement (0=No, 1=Yes, 2=Maybe, 9=Unknown)

h117 |__| Chest discomfort when quiet or resting

Chest Discomfort Characteristics (must have checked box at top of table)

h118-h119	|__|__|*|__|__|__|__| Date of onset	(mo/yr, Use 4 digits for year, 99/9999=Unknown)
h120	|__|__|__| Usual duration	(minutes: 1=1 min or less, 900=15 hrs or more, 999=Unknown)
h121	|__|__|__| Longest duration	(minutes: 1=1 min or less, 900=15 hrs or more, 999=Unknown)
h122	|__| 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=Unknown)
h123	|__| 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=Unknown)
h124	|__|__|__| Frequency (number in past month)	999=Unknown
h125	|__|__|__| Frequency (number in past year)	999=Unknown
h126	|__| Type	(1=Pressure, heavy, vise, 2=Sharp, 3=Dull, 4=Other, 9=Unk)
h127	|__| Relief by Nitroglycerine in <15 minutes	0=No
h128	|__| Relief by Rest in <15 minutes	1=Yes,
h129	|__| Relief Spontaneously in <15 minutes	8=Not tried
h130	|__| Relief by Other cause in <15 minutes	9=Unknown

h131 |__| **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=Unknown

CHD First Opinions

h132	|__| **Angina pectoris**	(0=No, 1=Yes, 2=Maybe, 9=Unknown)
h133	|__| **Angina pectoris since revascularization procedure**	
h134	|__| **Coronary insufficiency**	
h135	|__| **Myocardial infarct**	

Comments_____

_____

_____

_____

MD12

Medical History—Atrial Fibrillation/Syncope

OMB NO=0925-0216 12/31/2007

h136 |__| **Have you been told you have/had a heart rhythm problem called atrial fibrillation?** (0=No, 1=Yes, 2=Maybe,, 9=Unknown)

if yes, fill ☞ h137 |__|__|*h138 |__|__|*h139 |__|__|__|__| mm dd yyyy — Date of first episode (99/99/9999=unk) code year as 4 digits, example: Year 1999=1999

h140 |__| ER/hospitalized or saw M.D. (0=No, 1=Hosp/ER, 2=Saw M.D., 9=Unkn)

Hospitalized at: _____

M.D. seen: _____

h141 |__| **Since your last exam have you fainted or lost consciousness?** If event immediately preceded by head injury or accident code 0=No) — Code: 0=No, 1=Yes, 2=Maybe, 9=Unknown

h142 if yes, fill all ☞ |__|__|__| Number of episodes in the past two years (999=Unknown)

h143 |__|__|*h144 |__|__|__|__| Date of first episode (use 4 digits for year, i.e. 1998) (mo/yr, 99/9999=Unknown)

h145 |__|__|__| Usual duration of loss of consciousness (minutes, 999=Unkn) 1=1 min or less

h146 |__| **Did you have any injury caused by the event?** (0=No,1=Yes, 2=Maybe,9=Unkn)

h147 |__| **ER/hospitalized or saw M.D.** (0=No, 1=Hosp/ER, 2=Saw M.D., 9=Unkn)

Hospitalized at: _____

M.D. seen: _____

h148 |__| **History (since your last exam) of having a head injury with loss of consciousness** (0=No, 1=Yes, 2=Maybe, 9=Unknown)

if yes, fill ☞ h149 |__|__|*h150 |__|__|*h151 |__|__|__|__| mm dd yyyy — Date of serious head injury with loss of consciousness (00/00/0000 =none, 99/99/9999=unk, Use 4 digits for year)

h152 |__| **History of a seizure disorder.** Since your last exam have you had a seizure? (0=No, 1=Yes, 2=Maybe,, 9=Unknown)

if yes, fill ☞ h153 |__|__|*h154 |__|__|*h155 |__|__|__|__| mm dd yyyy — Date of most recent seizure (99/99/9999=unk) code four digit year

h156 |__| Are you being treated for a seizure disorder? (0=No, 1=Yes, 2=Maybe, 9=Unknown)

Syncope First Opinions

h157 |__| **Syncope** (0=No, 1=Yes, 2=Maybe, 3=Presyncope, 9=Unknown) needs second opinion

h158 |__| **Cardiac syncope**

h159 |__| **Vasovagal syncope**

h160 |__| **Other-Specify:** _____

(0=No, 1=Yes, 2=Maybe, 9=Unknown)

Comments: _____

_____

_____

Medical History—Cerebrovascular, Neurological and Venous Diseases

OMB NO=0925-0216 12/31/2007

Cerebrovascular Episodes Since Your Last Exam

Code: 0=No, 1=Yes, 2=Maybe, 9=Unknown

h161 ☐ **Sudden muscular weakness**

h162 ☐ **Sudden speech difficulty**

h163 ☐ **Sudden visual defect**

h164 ☐ **Sudden double vision**

h165 ☐ **Sudden loss of vision in one eye**

h166 ☐ **Sudden numbness, tingling**

h167 **if yes, fill** ☞ ☐ Numbness and tingling is positional

h168 ☐ **Head CT or MRI scan** date ___-___-_____ 0=No,1=Yes, 2=both,9=Unkn.
place _____

h169 ☐ **Seen by neurologist**(write in who and when below)

Code: 0=No, 1=Yes, 2=Maybe, 9=Unknown

h170 ☐ **Have you been told by a doctor you had a stroke or TIA (transient ischemic attack, mini-stroke)?**

h171 ☐ **Have you been told by a doctor you have Parkinson Disease?**

h172 ☐ **Have you been told by a doctor you have memory problems, dementia or Alzheimer's disease?**

h173 ☐ **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?**

Cerebrovascular Disease First Opinions

h174 ☐ **TIA or stroke took place** 0=No, 1=Yes, 2=Maybe, 9=Unkn

h175·h176 **if yes or maybe fill** ☞ ☐☐*☐☐☐☐ **Date** (mo/yr, Use 4 digits for year, 99/9999=Unkn)
Observed by_____

h177·h178·h179 ☐☐*☐☐*☐☐ **Duration** (use format days/hours/mins, 99/99/99=Unknown)

h180 ☐ **Hospitalized or saw M.D.** (0=No, 1=Hosp,2=Saw M.D, 9=Unk)
Name_____
Address_____

Neurology Comments_____

_____

Venous Disease

h181 ☐ **Since your last exam have you had a Deep Vein Thrombosis** (blood clots in legs or arms) 0=No, 1=Yes, 2=Maybe, 9=Unknown

h182 ☐ **Since your last exam have you had a Pulmonary Embolus** (blood clot in lungs)

Medical History--Peripheral Arterial Disease

OMB NO=0925-0216 12/31/2007

Peripheral Arterial Disease

h183 |__| **Do you have discomfort in your legs while walking?** (0=No, 1=Yes, 9=Unkn)

if yes, fill ☞ h184 |__|__| **If walking on level ground, how many city blocks until symptoms develop** (00=no, 99=unknown) where 10 blocks=1 mile, code as no if more than 98 blocks required to develop symptoms

h185 |__|__|__|__| **Year symptoms started** (Use 4 digits for year ,00=no, 9999=unkn)

Left	Right	Claudication symptoms (0=No, 1=Yes, 9=Unkn)
h186 · h187 |__| |__|	Discomfort in calf while walking
h188 · h189 |__| |__|	Discomfort in lower extremity (not calf) while walking
h190 |__|	Occurs with first steps (code worse leg)
h191 |__|	After walking a while (code worse leg)
h192 |__|	Related to rapidity of walking or steepness
h193 |__|	Forced to stop walking
h194 |__|__|	Time for discomfort to be relieved by stopping (minutes) (00=No relief with stopping, 88=Not Applicable, 99=Unknown)
h195 |__|__|	Number of days/month of lower limb discomfort (00=No,88=N/A,99=Unk.)

h196 |__| **Have you had back pain in the past 12 month?** 0=No, 1=all days, 2=most of the days, 3=some days, 4=a few days

if yes, fill ☞ h197 |__| **What happens to back and any leg pain that goes with it when you walk?**

h198 |__| **What happens to back and any pain that goes with it when you sit?**

0=no change, 1=gets worse, 2=gets better, 9=Unknown

h199 |__| **Have you ever been told by a doctor you have intermittent claudication or peripheral arterial disease ?** 0=No, 1=Yes, 9=Unknown

h200 |__| **Has a doctor ever told you you had spinal stenosis?**

if yes, fill ☞ h201 |__| **Have you had a CT or MRI of your spine?**
Date__-__-____ **Location** _____
h202 h203 h204

PAD First Opinion

|__| h205 **Intermittent Claudication** 0=No, 1=Yes, 2=Maybe,9=Unkn.

Comments Peripheral Vascular Disease / Venous Disease_____

_____

MD15

Medical History-- CVD Procedures

OMB NO=0925-0216 12/31/2007

Coding: 0=No, 1=Yes 2=Maybe, 9=Unkn	Cardiovascular Procedures (if procedure was repeated code only first and provide narrative) (write 4 digits for year, i.e. 1998, 1999, 2000)
h206 |__| if yes h207 fill ☞	**Heart Valvular Surgery** |__|__|__|__| Year done (9999-Unk) Location and description_____
h208 |__| if yes h209 fill ☞	**Exercise Tolerance Test** |__|__|__|__| Year done (9999-Unk) Location_____
h210 |__| if yes h211 fill ☞	**Coronary arteriogram** |__|__|__|__| Year done (9999-Unk)
h212 |__| h213 if yes h214 fill ☞	**Coronary artery angioplasty/stent/PCI** |__|__|__|__| Year done (9999-Unk) |__| Type of procedure (0=none, 1=balloon, 2=stent, 3=other, 9=unkn)
h215 |__| if yes h216 fill ☞	**Coronary bypass surgery** |__|__|__|__| Year done (9999-Unk)
h217 |__| if yes h218 fill ☞	**Permanent pacemaker insertion** |__|__|__|__| Year done (9999-Unk)
h219 |__| if yes h220 fill ☞	**AICD** |__|__|__|__| Year done (9999-Unk)
h221 |__| if yes h222 fill ☞	**Carotid artery surgery/stent** |__|__|__|__| Year done (9999-Unk)
h223 |__| if yes h224 fill ☞	**Thoracic aorta surgery** |__|__|__|__| Year done (9999-Unk)
h225 |__| if yes h226 fill ☞	**Abdominal aorta surgery/stent** |__|__|__|__| Year done (9999-Unk)
h227 |__| if yes h228 fill ☞	**Femoral or lower extremity surgery/stent/angioplasty** |__|__|__|__| Year done (9999-Unk)
h229 |__| if yes h230 fill ☞	**Lower extremity amputation** |__|__|__|__| Year done (9999-Unk)
h231 |__| if yes h232 fill ☞	**Other Cardiovascular Procedure (write in below)** |__|__|__|__| Year done (9999-Unk) Description_____

Write in other procedures, year done, location if more than one.

Comments:_____

_____

_____

OMB NO=0925-0216 12/31/2007

Physician Blood Pressure
(second reading)

Systolic	Diastolic	BP cuff size	Protocol modification
h233 ⌊_⌊_⌊_⌊_	h234 ⌊_⌊_⌊_	h235 ⌊_	h236 ⌊_
to nearest 2 mm Hg 999=Unknown	to nearest 2 mm Hg 999=Unknwon	0=pedi,1=reg.adult, 2=large adult, 3= thigh, 9=Unknown	0=No, 1=Yes, 9=Unknown

Write in protocol modification: _____

Cancer Site or Type

h237 ⌊_⌊

Since your last exam have you had cancer or a tumor?
(0=No and skip to next screen; If 1=Yes, 2=Maybe, 9=Unknown please continue)

Code for table:
0=No, 1=Yes, Cancerous, 2=Maybe, Possible Cancer, 3=Benign, 9=Unknown

	Code	Site of Cancer or Tumor	Year First Diagnosed	Name Diagnosing M.D.	City of M.D.
h238	⌊_⌊	Esophagus			
h239	⌊_⌊	Stomach			
h240	⌊_⌊	Colon			
h241	⌊_⌊	Rectum			
h242	⌊_⌊	Pancreas			
h243	⌊_⌊	Larynx			
h244	⌊_⌊	Trachea/Bronchus/Lung			
h245	⌊_⌊	Leukemia			
h246	⌊_⌊	Skin			
h247	⌊_⌊	Breast			
h248	⌊_⌊	Cervix/Uterus			
h249	⌊_⌊	Ovary			
h250	⌊_⌊	Prostate			
h251	⌊_⌊	Bladder			
h252	⌊_⌊	Kidney			
h253	⌊_⌊	Brain			
h254	⌊_⌊	Lymphoma			
h255	⌊_⌊	Other/Unknown _____			

Comment (If participant has more details concerning tissue diagnosis, other hospitalization, procedures, treatments)

_____

Physical Exam—Respiratory, Heart, Abdomen

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OMB NO=0925-0216 12/31/2007

Respiratory

h256 ☐	Wheezing on auscultation	0=No, 1=Yes, 2=Maybe, 9=Unknown
h257 ☐	Rales	
h258 ☐	Abnormal breath sounds	

Heart

h259 ☐	S3 Gallop	0=No 1=Yes 9=Unknown
h260 ☐	S4 Gallop	
h261 ☐	Systolic Click	0=No, 1=Yes 2=Maybe 9=Unknown
h262 ☐	Neck vein distention at 90 degrees (sitting upright)	
h263 ☐ if yes, fill out below	Systolic murmur(s) (0=No, 1=Yes, 2=Maybe, 9=Unknown)	

Murmur Location	Grade (0=No sound; 1 to 6 for grade of sound heard; 9=Unknown)	Type (0=None; 1=Ejection; 2=Regurgitant; 3=Other; 9=Unknown)	Radiation (0=None; 1=Axilla; 2=Neck; 3=Back; 4=Rt. chest; 9=Unknown)	Origin (0=None, indet.; 1=Mitral; 2=Aortic; 3=Tricuspid; 4=Pulm; 9=Unknown)
Apex	h264	h265	h266	h267
Left Sternum	h268	h269	h270	h271
Base	h272	h273	h274	h275

h276 ☐ Diastolic murmur(s) (0=No, 1=Yes, 2=Maybe, 9=Unknown)

if yes, fill ☞ h277 ☐ Valve of origin for diastolic murmur(s) (0=No, 1=Mitral, 2=Aortic, 3=Both, 4=Other, 8=N/A, 9=Unk)

Abdominal Abnormalities

h278 ☐	Liver enlarged	0=No 1=Yes 2=Maybe 9=Unknown
h279 ☐	Surgical scar	
h280 ☐	Abdominal aneurysm	
h281 ☐	Abdominal bruit	

Comments about respiratory, heart, and abdominal abnormalities

_____

_____

_____

Physical Exam--Peripheral Vessels—Veins and Arterial pulses

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OMB NO=0925-0216 12/31/2007

Left	Right	Varicosities	
|__| h282	|__| h283	**Stem varicose veins** (Do not code reticular or spider varicosities)	0=No abnormality 1=Yes 9=Unknown
Left	**Right**	**Lower Extremity Abnormalities**	
|__| h284	|__| h285	**Ankle edema**	(0=No, 1=Yes, 2=Maybe, 8=absent due to amputation 9=Unknown)
|__| h286	|__| h287	**Amputation level**	(0=No, 1=Toes only, 2=Ankle, 3=Knee, 4=Hip, 8=Not applicable, 9=Unknown)

Comments_____

_____

Artery	Pulse (0=Normal, 1=Abnormal, 9=Unknown)		Bruit (0=Normal, 1=Abnormal, 9=Unknown)	
	Left	Right	Left	Right
Femoral	|__| h288	|__| h289	|__| h290	|__| h291
Popliteal			|__| h292	|__| h293
Post Tibial	|__| h294	|__| h295		
Dorsalis Pedis	|__| h296	|__| h297		

Comments_____

_____

_____

MD19

Physical Exam--Neurological Exam

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OMB NO=0925-0216 12/31/2007

Neurological Exam			
Left	Right		
☐ h298	☐ h299	**Carotid Bruit**	Coding (0=No, 1=Yes, 2=Maybe, 9=Unknown)
h300 ☐		**Speech disturbance**	
h301 ☐		**Disturbance in gait**	
h302 ☐		**Other neurological abnormalities on exam** Specify	

MD20

Electrocardiograph--Part I

OMB NO=0925-0216 12/31/2007

h303 |__|__|__|__| **MD Id#** **OFFSITE ONLY MD Name**

Rates and Intervals

h304 |__|__|__| **Ventricular rate per minute** (999=Unknown)

h305 |__|__| **P-R Interval (hundreths of a second)** (99=Fully Paced, Atrial Fib, or Unknown)

h306 |__|__| **QRS interval (hundreths of second)** (99=Fully Paced, Unknown)

h307 |__|__| **Q-T interval (hundreths of second)** (99=Fully Paced, Unknown)

h308 |__|__|__|__| **QRS angle (put plus or minus as needed)** (e.g. -045 for minus 45 degrees, +090 for plus 90, 9999=Fully paced or Unknown)

Rhythm--predominant

h309 |__|

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

h310 |__| **IV Block** (0=No, 1=Yes, 9=Fully paced or Unknown)

h311 **if yes, fill** ☞ |__| **Pattern** (1=Left, 2=Right, 3=Indeterminate, 9=Unknown)

h312 |__| **Complete (QRS interval=.12 sec or greater)**(0=No, 1=Yes, 9=Unknown)

h313 |__| **Incomplete (QRS interval = .10 or .11 sec)** (0=No, 1=Yes, 9=Unknown)

h314 |__| **Hemiblock** (0=No, 1=Left Ant, 2=Left Post, 9=Fully paced or Unknown)

h315 |__| **WPW Syndrome** (0=No, 1=Yes, 2=Maybe, 9=Fully paced or Unknown)

Arrhythmias

h316 |__| **Atrial premature beats** (0=No, 1=Atr, 2=Atr Aber, 9=Unknown)

h317 |__| **Ventricular premature beats** (0=No, 1=Simple, 2=Multifoc, 3=Pairs, 4=Run, 5=R on T, 9=Unk)

h318 |__|__| **Number of ventricular premature beats in 10 seconds** (see 10 second rhythm strip)

MD21

Electrocardiograph-Part II

OMB NO=0925-0216 12/31/2007

Myocardial Infarction Location

h319 |__| Anterior
h320 |__| Inferior
h321 |__| True Posterior

(0=No, 1=Yes, 2=Maybe, 9=Fully paced or Unknown)

Left Ventricular Hypertrophy Criteria

h322 |__| R > 20mm in any limb lead
h323 |__| R > 11mm in AVL
h324 |__| R in lead I plus S in lead III ≥ 25mm

(0=No, 1=Yes, 9=Fully paced, Complete LBBB or Unk)

Measured Voltage

h325 *|__|__| **R AVL in mm** (at 1 mv = 10 mm standard) Be sure to code these voltages
h326 *|__|__| **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

h327 |__| R≥ 25mm
h328 |__| S≥ 25mm
h329 |__| R or S ≥ 30mm
h330 |__| R + S ≥ 35mm
h331 |__| Intrinsicoid deflection ≥ .05 sec
h332 |__| S-T depression (strain pattern)

(0=No, 1=Yes, 9=Fully paced, Complete LBBB or Unk)

Hypertrophy, enlargement, and other ECG Diagnoses

h333 |__| Nonspecific S-T segment abnormality (0=No, 1=S-T depression, 2=S-T flattening, 3=Other, 9=Fully paced or unknown)
h334 |__| Nonspecific T-wave abnormality (0=No, 1=T inversion, 2=T flattening, 3=Other, 9=Fully paced or unknown)
h335 |__| U-wave present (0=No, 1=Yes, 2=Maybe, 9=Paced or Unknown)
h336 |__| Atrial enlargement (0=None, 1=Left, 2=Right, 3=Both, 9=Atrial fib. or Unknown)
h337 |__| RVH (0=No, 1=Yes, 2=Maybe, 9=Fully paced or Unknown; If complete RBBB present, RVH=9)
h338 |__| LVH (0=No, 1=LVH with strain, 2=LVH with mild S-T Segment Abn, 3=LVH by voltage only, 9=Fully paced or Unkn, If complete LBBB present, LVH=9)

Comments and Diagnosis_____

Clinical Diagnostic Impression--Part I

)MB NO=0925-0216 12/31/2007

		Heart Diagnoses First Examiner Opinions	
h339	☐	Rheumatic Heart Disease	
h340	☐	Aortic Valve Disease	
h341	☐	Mitral Valve Disease	0=No, 1=Yes, 2=Maybe, 9=Unknown
h342	☐	Other Heart Disease (includes congenital)	
h343	☐	Arrhythmia	

		Peripheral Vascular Disease First Examiner Opinions	
h344	☐	Other Peripheral Vascular Disease	0=No, 1=Yes, 2=Maybe, 9=Unknown
h345	☐	Other Vascular Diagnosis (Specify)_____	

		Neurologic Disease First Examiner Opinions	
h346	☐	Stroke/ TIA	
h347	☐	Dementia	
h348	☐	Parkinson's Disease	0=No, 1=Yes, 2=Maybe, 9=Unknown
h349	☐	Adult Seizure Disorder	
h350	☐	Other Neurological Disease (Specify)_____	

Comments CDI

Clinical Diagnostic Impression--Part II

Non Cardiovascular Diagnoses First Examiner Opinions

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		Endocrine	
h351	☐	**Thyroid Disease**	0=No, 1=Yes, 2=Maybe, 9=Unknown
h352	☐	**Diabetes Mellitus**	
h353	☐	**Other endocrine disorders,** specify_____	
		GU/GYN	
h354	☐	**Renal disease,** specify_____	0=No, 1=Yes, 2=Maybe, 9=Unknown
h355	☐	**Prostate disease**	
h356	☐	**Gynecologic problems,** specify_____	
		Pulmonary	
h357	☐	**Emphysema**	0=No, 1=Yes, 2=Maybe, 9=Unknown
h358	☐	**Pneumonia**	
h359	☐	**Asthma**	
h360	☐	**Other pulmonary disease,** specify_____	
		Rheumatologic Disorders	
h361	☐	**Gout**	0=No, 1=Yes, 2=Maybe, 9=Unknown
h362	☐	**Degenerative joint disease**	
h363	☐	**Rheumatoid arthritis**	
h364	☐	**Other musculoskeletal or connective tissue disease,**specify_____	
		GI	
h365	☐	**Gallbladder disease**	0=No, 1=Yes, 2=Maybe, 9=Unknown
h366	☐	**GERD/ulcer disease**	
h367	☐	**Liver disease**	
h368	☐	**Other GI disease,** specify_____	
		Blood	
h369	☐	**Hematologic disorder**	0=No, 1=Yes, 2=Maybe, 9=Unk
h370	☐	**Bleeding disorder**	
		Other	
h371	☐	**Eye**	0=No, 1=Yes, 2=Maybe, 9=Unknown
h372	☐	**ENT**	
h373	☐	**Skin**	
h374	☐	**Other,** specify_____	
		Infectious Disease	
h375	☐	If Yes, specify_____ _____	0=No, 1=Yes, 2=Maybe, 9=Unknown
		Mental Health	
h376	☐	**Depression**	0=No, 1=Yes, 2=Maybe, 9=Unknown
h377	☐	**Anxiety**	
h378	☐	**Psychosis**	
h379	☐	**Other,** specify_____	

Comments CDI Diagnoses_____

_____

_____

Second Examiner Opinions

OFFSITE VISIT – leave page BLANK

)MB NO=0925-0216 12/31/2007

h380 |__|__|__| **2nd Examiner ID Number** _____ **2nd Examiner Last Name**

Coronary Heart Disease Second Examiner Opinions
(Provide initiators, qualities, radiation, severity, timing, presence after procedures done)

h381	|__|	**Congestive Heart Failure**	0=No, 1=Yes, 2=Maybe, 9=Unknown
h382	|__|	**Cardiac Syncope**	
h383	|__|	**Angina Pectoris**	
h384	|__|	**Coronary Insufficiency**	
h385	|__|	**Myocardial Infarct**	

Comments about chest and heart disease

Intermittent Claudication Second Examiner Opinions
(Provide initiators, qualities, radiation, severity, timing, presence after procedures done)

h386	|__|	**Intermittent Claudication**	0=No, 1=Yes, 2=Maybe, 9=Unknown

Comments about peripheral vascular disease

Cerebrovascular Disease Second Examiner Opinions
(Provide initiators, qualities, severity, timing, presence after procedures done)

h387	|__|	**Stroke**	0=No, 1=Yes, 2=Maybe, 9=Unknown
h388	|__|	**TIA**	

Comments about possible Cerebrovascular Disease

Date of exam

____/____/____

Framingham Heart Study
Offspring Exam 8

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 hx 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.

The Framingham Heart Study

A Project of the National Heart, Lung, and Blood Institute and Boston University

Letter Date_____ Exam Date_____

OMB No = 0925-0216 Exp 12/31/2007

_____

A report of your recent examination at the Framingham Heart Study has been forwarded to :

_____

The examination at the Heart Study focuses on cardiovascular disease and is **NOT** a full exam. You need to see your own doctor for periodic complete check-ups. Any clinical abnormalities requiring that you see your physician are written in the following space. Some test results are not immediately available; any abnormalities detected will be sent directly to your doctor.

_____

_____

_____

_____

We look forward to seeing you again and appreciate your support. Your participation makes possible further progress in the determination of causes and ways of preventing heart disease.

Thank you for your continuing support.

Sincerely,

[redacted]

Medical Director
Framingham Heart Study

Examiner_____

73 Mt. Wayte Avenue • Framingham, MA 01702 • 508.872.6562 tel • 508.626.1262 fax

Referral Tracking

OMB NO=0925-0216 12/31/2007

h747 |__| if yes fill below — Was further medical evaluation recommended for this participant? 0=No, 1=Yes, 9=Unknown

RESULT **Reason for further evaluation:** 0=No, 1=Yes, 9=Unknown

h748 |__| **Blood Pressure** result ____/____ mmHg
Phone call > 200/110
Expedite ≥ 180/100
Elevated > 140/90

h749 |__| **Abnormal Urine** result _____
Write in abnormality

h750 |__| **ECG abnormality** _____

h751 |__| **Clinic Physician** _____

identified medical problem

h752 |__| **Other** _____

_____

h753 |__|__|__| **Technician ID#**

h754 |__| **Was there an adverse event in clinic/offsite that does not require further medical evaluation?** (0=No, 1=Yes, 9=Unkown)
Comments: _____

h771 _____

offcite inly
h755 if yes fill ☞ |__|__|__| **Technician ID# (OFFSITE visits only)**

h756 |__| **Was a FHS physician contacted during the examination due to adverse exam finding?** (0=No, 1=Yes, 9=Unknown)
Comments: _____

h772 _____

TECH23

OMB NO=0925-0216 12/31/2007

	Method used to inform participant of need for further medical evaluation (circle ALL that apply)	
h757	1	Face-to-face in clinic
h758	2	Phone call
h759	3	Result letter
h760	4	Other

	Method used to inform participant's personal physician of need for further medical evaluation (circle ALL that apply)	
h761	1	Phone call
h762	2	Result letter mailed
h763	3	Result letter FAX'd
h764	4	Other

Date referral made: h765 __/__/ h767 (h766) Use 4 digits for year

ID number of person completing the referral: _____ h768

Notes documenting conversation with participant or participant's personal physician:_____

_____

_____

TECH24

h111 → h114
h233 → h236

Blood Pressure Measurement

Note: No tech blood pressure measurement for exam 8 only MD

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 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

h111-h114
h233-h236

at the start of the reading exceeds the systolic blood pressure and thus allows the first Korotkoff 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~~ 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 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).

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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.

h111-h114, h233-h236

BRIEF REPORT: How Well Do Clinic-Based Blood Pressure Measurements Agree with the Mercury Standard?

Jennifer W. Kim, BA,[1] Hayden B. Bosworth, PhD,[2,3] Corrine I. Voils, PhD,[3] Maren Olsen, PhD,[3,4] Tara Dudley, MStat,[4] Matthew Gribbin, MS,[5] Martha Adams, MD,[2] Eugene Z. Oddone, MD, MHSC[2,3]

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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.

Poster presentation at Society of General Internal Medicine Annual Meeting on May 13, 2004.
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.

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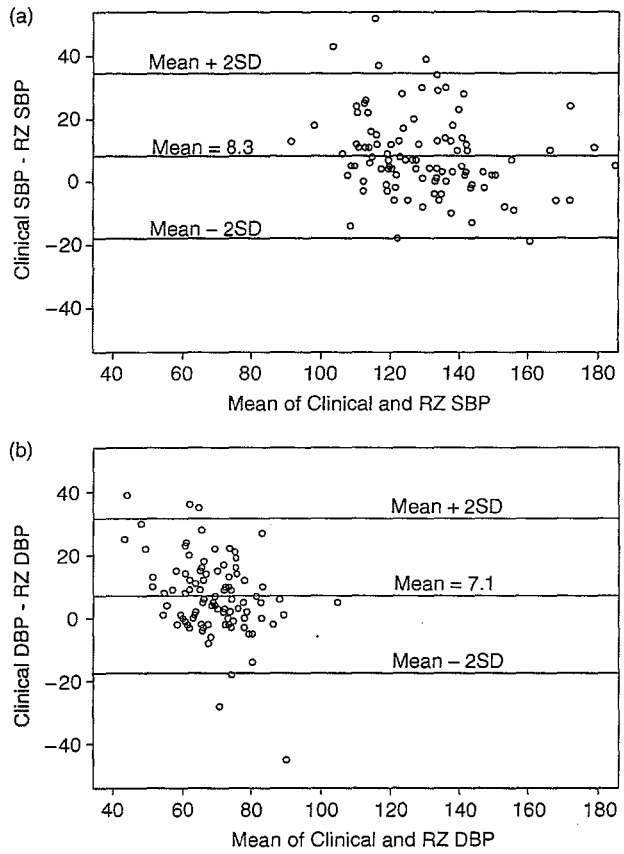

FIGURE 1. Bland–Altman graphs comparing blood pressure values obtained by the random-zero mercury sphygmomanometer versus the clinic-based method: (A) systolic blood pressures; (B) diastolic blood pressures.

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, κ=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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h699 → h713

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

h711

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

Sociodemographic questions. Part I Self-administered

OMB NO=0925-0216 12/31/2007

h699 |__| **What is your current marital status?**

1=single/never married,
2=married/living as married/living with partner
3=separated
4=divorced
5=widowed
9=prefer not to answer

Which of the following best describes you?

Ethnicity (check which applies)

h700 |__| Hispanic or Latino
h701 |__| Not Hispanic or Latino

Race: (check ALL that apply)

h702 |__| Caucasian or white
h703 |__| African-American or black
h704 |__| Asian
h705 |__| Native Hawaiian or other Pacific Islander
h706 |__| American Indian or Alaska native
h707 |__| prefer not to answer

h708 |__| **What is the highest degree or level of school you have completed?**
(if currently enrolled, mark the highest grade completed, degree received)

0= no schooling
1=grades 1-8
2=grades 9-11
3=completed high school (12th grade) or GED
4=some college but no degree
5=technical school certificate
6=associate degree (Junior college AA, AS)
7=Bachelor's degree (BA, AB, BS)
8=graduate or professional degree (master's, doctorate, MD, etc.)
9=prefer not to answer

h709 |__| **Please choose which of the following best describes your current employment status?**

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 or full-time student
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

Sociodemographic questions. Part II. Self-administered

OMB NO=0925-0216 12/31/2007

h710 **What is your current occupation?** Write in _____

h711 |__|__| **Using the occupation coding sheet choose the code that best describes your occupation.**

h712 **YES** **NO** Do you have some form of health insurance?

h713 **YES** **NO** Do you have prescription drug coverage?

TECH18

h 714 → h 725

SF-12®

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.

SF-12® Health Survey (Standard)
Self-administered

OMB NO=0925-0216 12/31/2007

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:

h714

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
h715 2. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐	☐	☐
h716 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
h717 4. **Accomplished less** than you would like	☐	☐
h718 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
h719 6. **Accomplished less** than you would like	☐	☐
h720 7. Didn't do work or other activities as **carefully** as usual	☐	☐

TECH19

SF-12® Health Survey (Standard)
Self-administered

OMB NO=0925-0216 12/31/2007

h721 **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
h722 **9.** Have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
h723 **10.** Did you have a lot of energy?	☐	☐	☐	☐	☐	☐
h724 **11.** Have you felt downhearted and blue?	☐	☐	☐	☐	☐	☐

h725 **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
☐	☐	☐	☐	☐

TECH20

h726 → h746

Sleep Questionnaire

1. This questionnaire is self-administered at clinic exams and tech-administered for offsite exams.
2. For clinic exams the staff must check the form for completeness.
3. 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.
4. Two handouts are needed for this questionnaire for offsite exams.

For the statement:
Please indicate how often in the past month you experienced each of the following.
The handout should read:

Never

Rarely (1/month or less)

Sometimes (2-4/month)

Often (5-15/month)

Almost always (16-30/month)

For the question:
What is the chance that you would doze off or fall asleep (not just "feel tired") in each of the following situations?

No

Slight

Moderate

High

The handouts should be given to the participant at the appropriate time and explained to the participant.

h730 - h733

Never

Rarely (1/month or less)

Sometimes (2-4/month)

Often (5-15/month)

Almost always (16-30/month)

h734-h743

No

Slight

Moderate

High

Sleep Questionnaire. Part 1
Self-administered

OMB NO=0925-0216 12/31/2007

h726 |__|__| hours **How much sleep do you usually get at night (or your main sleep period) on weekdays or work days?** (Number of hours)

h727 |__|__| hours **How long does it usually take you to fall asleep at bedtime?** (Number of hours, 1=1hour or less)

Sleep Related Symptoms (days/nights)

h728 |__| **In the past 12 months, how often do you snore while you are sleeping?**

h729 |__| **In the past 12 months, how often do you snort, gasp, or stop breathing while you are asleep?**

0=Never
1=Rarely(1-2 nights/week)
2=Occasionally(3-4 nights/week)
3=Frequently(5/more nights/week)
9=Don't know

Please indicate how often <u>in the past month</u> you experienced each of the following.
(Circle one response for each item)

	Never	Rarely (1/month or less)	Sometimes (2-4/month)	Often (5-15/month)	Almost always (16-30/month)
h730 Have trouble falling asleep	0	1	2	3	4
h731 Wake up during the night and have trouble getting back to sleep.	0	1	2	3	4
h732 Wake up too early in the morning and be unable to get back to sleep.	0	1	2	3	4
h733 Feel excessively (or overly) sleepy during the day.	0	1	2	3	4

Sleep Questionnaire. Part 2
Self-administered

OMB NO=0925-0216 12/31/2007

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)

	No	Slight	Moderate	High
h734 Sitting and reading	0	1	2	3
h735 Watching TV.	0	1	2	3
h736 Sitting inactive in a public place (such as theater or a meeting)	0	1	2	3
h737 Riding as a passenger in a car for an hour without a break.	0	1	2	3
h738 Lying down to rest in the afternoon when circumstances permit.	0	1	2	3
h739 Sitting and talking to someone	0	1	2	3
h740 Sitting quietly after a lunch without alcohol.	0	1	2	3
h741 In a car, while stopped in traffic for a few minutes.	0	1	2	3
h742 At the dinner table.	0	1	2	3
h743 While driving	0	1	2	3

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
h744 Sleep apnea or obstructive sleep apnea.	0	1	9
h745 Insomnia.	0	1	9
h746 Restless legs.	0	1	9

TECH22

FFQ dataset

Guidelines for Review of Willet 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.

FFQ dataset

Instructions for Completing the Food Frequency Questionnaire

Thank you for participating in this research study. An important part of this study is the Food Frequency Questionnaire, designed to measure your dietary pattern over the past year. Remember, the information we get from the study is only as good as the information you give us. Accuracy is essential!

Please complete this form and bring it with you at the time of your appointment, or complete prior to the time of your home visit.

1) Please use a No. 2 pencil, and make sure the circles are completely darkened.

2) Please do not leave any questions blank. If the section does not apply to you, please fill in the "never" section.

3) Please do not separate, staple or rip the booklet

4) Please do not leave any stray marks. Make sure all erasures are complete.

FFQ dataset

DIET ASSESSMENT

ID:

1. Do you currently take multiple vitamins? (Please report individual vitamins under question 2.)

○ No ○ Yes → If yes, a) How many do you take per week? → ○ 2 or less ○ 3-5 ○ 6-9 ○ 10 or more

b) What specific brand do you usually use? → Specify exact brand and type

2. Not counting multiple vitamins, do you take any of the following preparations:

a) Vitamin A?
○ No ○ Yes, seasonal only ○ Yes, most months
If Yes, How many years? → ○ 0-1 yr. ○ 2-4 yrs. ○ 5-9 yrs. ○ 10+ yrs. ○ Don't know
What dose per day? → ○ Less than 8,000 IU ○ 8,000 to 12,000 IU ○ 13,000 to 22,000 IU ○ 23,000 IU or more ○ Don't know

b) Vitamin C?
○ No ○ Yes, seasonal only ○ Yes, most months
If Yes, How many years? → ○ 0-1 yr. ○ 2-4 yrs. ○ 5-9 yrs. ○ 10+ yrs. ○ Don't know
What dose per day? → ○ Less than 400 mg. ○ 400 to 700 mg. ○ 750 to 1250 mg. ○ 1300 mg. or more ○ Don't know

c) Vitamin B_6?
○ No ○ Yes → If yes, How many years? → ○ 0-1 yr. ○ 2-4 yrs. ○ 5-9 yrs. ○ 10+ yrs. ○ Don't know
What dose per day? → ○ Less than 10 mg. ○ 10 to 39 mg. ○ 40 to 79 mg. ○ 80 mg. or more ○ Don't know

d) Vitamin E?
○ No ○ Yes → If yes, How many years? → ○ 0-1 yr. ○ 2-4 yrs. ○ 5-9 yrs. ○ 10+ yrs. ○ Don't know
What dose per day? → ○ Less than 100 IU ○ 100 to 250 IU ○ 300 to 500 IU ○ 600 IU or more ○ Don't know

e) Selenium?
○ No ○ Yes → If yes, How many years? → ○ 0-1 yr. ○ 2-4 yrs. ○ 5-9 yrs. ○ 10+ yrs. ○ Don't know
What dose per day? → ○ Less than 80 mcg. ○ 80 to 130 mcg. ○ 140 to 250 mcg. ○ 260 mcg. or more ○ Don't know

f) Iron?
○ No ○ Yes → If yes, How many years? → ○ 0-1 yr. ○ 2-4 yrs. ○ 5-9 yrs. ○ 10+ yrs. ○ Don't know
What dose per day? → ○ Less than 5.1 mg. ○ 5.1 to 200 mg. ○ 201 to 400 mg. ○ 401 mg. or more ○ Don't know

g) Zinc?
○ No ○ Yes → If yes, How many years? → ○ 0-1 yr. ○ 2-4 yrs. ○ 5-9 yrs. ○ 10+ yrs. ○ Don't know
What dose per day? → ○ Less than 25 mg. ○ 25 to 74 mg. ○ 75 to 100 mg. ○ 101 mg. or more ○ Don't know

h) Calcium? (Include Calcium in Dolomite.)
○ No ○ Yes → If yes, How many years? → ○ 0-1 yr. ○ 2-4 yrs. ○ 5-9 yrs. ○ 10+ yrs. ○ Don't know
What dose per day? → ○ Less than 400 mg. ○ 400 to 900 mg. ○ 901 to 1300 mg. ○ 1301 mg. or more ○ Don't know

i) Are there other supplements that you take on a regular basis? Please mark if yes:
○ Folic acid ○ Vitamin D ○ B-Complex Vitamins ○ Cod liver Oil ○ Omega-3 Fatty-acids ○ Iodine ○ Copper ○ Brewer's Yeast ○ Beta-Carotene ○ Magnesium ○ Other (please specify):

3. For each food listed, fill in the circle indicating how often on average you have used the amount specified during the past year.

DAIRY FOODS	AVERAGE USE LAST YEAR: Never, or less than once per month	1-3 per mo.	1 per week (W)	2-4 per week	5-6 per week	1 per day (D)	2-3 per day	4-5 per day	6+ per day
Skim or low fat milk (8 oz. glass)	○	○	○	○	○	○	○	○	○
Whole milk (8 oz. glass)	○	○	○	○	○	○	○	○	○
Cream, e.g. coffee, whipped (Tbs)	○	○	○	○	○	○	○	○	○
Sour cream (Tbs)	○	○	○	○	○	○	○	○	○
Non-dairy coffee whitener (tsp.)	○	○	○	○	○	○	○	○	○
Sherbet or ice milk (½ cup)	○	○	○	○	○	○	○	○	○
Ice cream (½ cup)	○	○	○	○	○	○	○	○	○
Yogurt (1 cup)	○	○	○	○	○	○	○	○	○
Cottage or ricotta cheese (½ cup)	○	○	○	○	○	○	○	○	○
Cream cheese (1 oz.)	○	○	○	○	○	○	○	○	○
Other cheese, e.g. American, cheddar, etc., plain or as part of a dish (1 slice or 1 oz. serving)	○	○	○	○	○	○	○	○	○
Margarine (pat), added to food or bread; exclude use in cooking	○	○	○	○	○	○	○	○	○
Butter (pat), added to food or bread; exclude use in cooking	○	○	○	○	○	○	○	○	○

Please turn to page 2

FFQ dataset

3. (Continued) Please fill in your average use, during the past year, of each specified food.

Please try to average your seasonal use of foods over the entire year. For example, if a food such as cantaloupe is eaten 4 times a week during the approximate 3 months that it is in season, then the average use would be once per week.

FRUITS	Never, or less than once per month	1-3 per mo.	1 per week	2-4 per week	5-6 per week	1 per day	2-3 per day	4-5 per day	6+ per day
Raisins (1 oz. or small pack) or grapes	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Prunes (½ cup)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Bananas (1)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Cantaloupe (¼ melon)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Watermelon (1 slice)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Fresh apples or pears (1)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Apple juice or cider (small glass)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Oranges (1)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Orange juice (small glass)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Grapefruit (½)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Grapefruit juice (small glass)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Other fruit juices (small glass)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Strawberries, fresh, frozen or canned (½ cup)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Blueberries, fresh, frozen or canned (½ cup)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Peaches, apricots or plums (1 fresh, or ½ cup canned)	○	○	Ⓦ	○	○	Ⓓ	○	○	○

VEGETABLES	Never, or less than once per month	1-3 per mo.	1 per week	2-4 per week	5-6 per week	1 per day	2-3 per day	4-5 per day	6+ per day
Tomatoes (1)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Tomato juice (small glass)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Tomato sauce (½ cup) e.g. spaghetti sauce	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Red chili sauce (1 Tbs)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Tofu or soybeans (3-4 oz.)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
String beans (½ cup)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Broccoli (½ cup)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Cabbage or cole slaw (½ cup)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Cauliflower (½ cup)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Brussels sprouts (½ cup)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Carrots, raw (½ carrot or 2-4 sticks)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Carrots, cooked (½ cup)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Corn (1 ear or ½ cup frozen or canned)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Peas, or lima beans (½ cup fresh, frozen, canned)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Mixed vegetables (½ cup)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Beans or lentils, baked or dried (½ cup)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Yellow (winter) squash (½ cup)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Eggplant, zucchini, or other summer squash (½ cup)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Yams or sweet potatoes (½ cup)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Spinach, cooked (½ cup)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Spinach, raw as in salad	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Kale, mustard or chard greens (½ cup)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Iceberg or head lettuce (serving)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Romaine or leaf lettuce (serving)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Celery (4" stick)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Beets (½ cup)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Alfalfa sprouts (½ cup)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Garlic, fresh or powdered (1 clove or shake)	○	○	Ⓦ	○	○	Ⓓ	○	○	○

EGGS, MEAT, ETC.	Never, or less than once per month	1-3 per mo.	1 per week	2-4 per week	5-6 per week	1 per day	2-3 per day	4-5 per day	6+ per day
Eggs (1)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Chicken or turkey, with skin (4-6 oz.)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Chicken or turkey, without skin (4-6 oz.)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Bacon (2 slices)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Hot dogs (1)	○	○	Ⓦ	○	○	Ⓓ	○	○	○

Please go to page 3

FFQ dataset

3. (Continued) Please fill in your average use, during the past year, of each specified food.

MEATS (CONTINUED)	Never, or less than once per month	1-3 per mo.	1 per week	2-4 per week	5-6 per week	1 per day	2-3 per day	4-5 per day	6+ per day
Processed meats, e.g. sausage, salami, bologna, etc. (piece or slice)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Liver (3-4 oz.)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Hamburger (1 patty)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Beef, pork, or lamb as a sandwich or mixed dish, e.g. stew, casserole, lasagne, etc.	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Beef, pork, or lamb as a main dish, e.g. steak, roast, ham, etc. (4-6 oz.)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Canned tuna fish (3-4 oz.)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Dark meat fish, e.g. mackerel, salmon, sardines, bluefish, swordfish (3-5 oz.)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Other fish (3-5 oz.)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Shrimp, lobster, scallops as a main dish	○	○	Ⓦ	○	○	Ⓓ	○	○	○

BREADS, CEREALS, STARCHES	Never, or less than once per month	1-3 per mo.	1 per week	2-4 per week	5-6 per week	1 per day	2-3 per day	4-5 per day	6+ per day
Cold breakfast cereal (1 cup)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Cooked oatmeal (1 cup)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Other cooked breakfast cereal (1 cup)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
White bread (slice), including pita bread	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Dark bread (slice)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
English muffins, bagels, or rolls (1)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Muffins or biscuits (1)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Brown rice (1 cup)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
White rice (1 cup)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Pasta, e.g. spaghetti, noodles, etc. (1 cup)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Other grains, e.g. bulgar, kasha, couscous, etc. (1 cup)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Pancakes or waffles (serving)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
French fried potatoes (4 oz.)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Potatoes, baked, boiled (1) or mashed (1 cup)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Potato chips or corn chips (small bag or 1 oz.)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Crackers, Triskets, Wheat Thins (1)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Pizza (2 slices)	○	○	Ⓦ	○	○	Ⓓ	○	○	○

BEVERAGES		Never, or less than once per month	1-3 per mo.	1 per week	2-4 per week	5-6 per week	1 per day	2-3 per day	4-5 per day	6+ per day
CARBONATED BEVERAGES Consider the serving size as 1 glass, bottle or can for these carbonated beverages.	Low Calorie (sugar-free) types									
Low calorie cola, e.g. Tab with caffeine		○	○	Ⓦ	○	○	Ⓓ	○	○	○
Low calorie caffeine-free cola, e.g. Pepsi Free		○	○	Ⓦ	○	○	Ⓓ	○	○	○
Other low calorie carbonated beverage, e.g. Fresca, Diet 7-Up, diet ginger ale		○	○	Ⓦ	○	○	Ⓓ	○	○	○
	Regular types (not sugar-free)									
Coke, Pepsi, or other cola with sugar		○	○	Ⓦ	○	○	Ⓓ	○	○	○
Caffeine Free Coke, Pepsi, or other cola with sugar		○	○	Ⓦ	○	○	Ⓓ	○	○	○
Other carbonated beverage with sugar, e.g. 7-Up, ginger ale		○	○	Ⓦ	○	○	Ⓓ	○	○	○
OTHER BEVERAGES Hawaiian Punch, lemonade, or other non-carbonated fruit drinks (1 glass, bottle, can)		○	○	Ⓦ	○	○	Ⓓ	○	○	○
Decaffeinated coffee (1 cup)		○	○	Ⓦ	○	○	Ⓓ	○	○	○
Coffee (1 cup)		○	○	Ⓦ	○	○	Ⓓ	○	○	○
Tea (1 cup), not herbal teas		○	○	Ⓦ	○	○	Ⓓ	○	○	○
Beer (1 glass, bottle, can)		○	○	Ⓦ	○	○	Ⓓ	○	○	○
Red wine (4 oz. glass)		○	○	Ⓦ	○	○	Ⓓ	○	○	○
White wine (4 oz. glass)		○	○	Ⓦ	○	○	Ⓓ	○	○	○
Liquor, e.g. whiskey, gin, etc. (1 drink or shot)		○	○	Ⓦ	○	○	Ⓓ	○	○	○

Please turn to page 4

FFQ dataset

ID:

3. (Continued) Please fill in your average use during the past year, of each specified food.

SWEETS, BAKED GOODS, MISCELLANEOUS	Never, or less than once per month	1-3 per mo.	1 per week	2-4 per week	5-6 per week	1 per day	2-3 per day	4-5 per day	6+ per day
Chocolate (bars or pieces) e.g. Hershey's, M&M's	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Candy bars, e.g. Snickers, Milky Way, Reeses	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Candy without chocolate (1 oz.)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Cookies, home baked (1)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Cookies, ready made (1)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Brownies (1)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Doughnuts (1)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Cake, home baked (slice)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Cake, ready made (slice)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Sweet roll, coffee cake or other pastry, home baked (serving)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Sweet roll, coffee cake or other pastry, ready made (serving)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Pie, homemade (slice)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Pie, ready made (slice)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Jams, jellies, preserves, syrup, or honey (1 Tbs)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Peanut butter (Tbs)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Popcorn (1 cup)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Nuts (small packet or 1 oz.)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Bran, added to food (1 Tbs)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Wheat germ (1 Tbs)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Chowder or cream soup (1 cup)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Oil and vinegar dressing, e.g. Italian (1 Tbs)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Mayonnaise or other creamy salad dressing (1 Tbs)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Mustard, dry or prepared (1 tsp)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Pepper (1 shake)	○	○	Ⓦ	○	○	Ⓓ	○	○	○
Salt (1 shake)	○	○	Ⓦ	○	○	Ⓓ	○	○	○

4. How much of the visible fat on your meats do you remove before eating?
- ○ Remove all visible fat
- ○ Remove small part of fat
- ○ Remove majority
- ○ Remove none
- ○ (Don't eat meat)

5. What kind of fat do you usually use for frying and sautéing? (Exclude "Pam"-type spray)
- ○ Real butter
- ○ Vegetable oil
- ○ Lard
- ○ Margarine
- ○ Vegetable shortening

6. What kind of fat do you usually use for baking?
- ○ Real butter
- ○ Vegetable oil
- ○ Lard
- ○ Margarine
- ○ Vegetable shortening

7. What form of margarine do you usually use?
- ○ None
- ○ Stick
- ○ Tub
- ○ Spread
- ○ Low-calorie stick
- ○ Low-calorie tub

8. How often do you eat food that is fried at home? (Exclude the use of "Pam"-type spray)
- ○ Daily
- ○ 4-6 times per week
- ○ 1-3 times per week
- ○ Less than once a week

9. How often do you eat fried food away from home? (e.g. french fries, fried chicken, fried fish)
- ○ Daily
- ○ 4-6 times per week
- ○ 1-3 times per week
- ○ Less than once a week

10. How many teaspoons of sugar do you add to your beverages or food each day? → tsp.

11. What type of cooking oil do you usually use? → Specify type and brand

12. What kind of cold breakfast cereal do you usually use? → Specify type and brand

13. Are there any other important foods that you usually eat at least once per week?

Include for example: paté, tortillas, yeast, cream sauce, custard, horseradish, parsnips, rhubarb, radishes, fava beans, carrot juice, coconut, avocado, mango, papaya, dried apricots, dates, figs.

(Do not include dry spices and do not list something that has been listed in the previous sections.)

Other foods that you usually use at least once per week	Usual serving size	Servings per week
(a)		
(b)		
(c)		
(d)		

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PFT EXCLUSION CRITERIA

IN THE PAST 3 MONTHS HAVE YOU HAD:

- MAJOR SURGERY (Chest, abdominal, ~~or~~ Mouth OR brain, requiring hospitalization)?
- HEART ATTACK
- STROKE
- ANEURYSM OF THE BRAIN
- BP>210/110

DO YOU CURRETNLY HAVE ANY LIMITATION ON PHYSICAL ACTIVITY PRESCRIBED BY YOUR DOCTOR?

PFT dataset

Lung Function Testing at the Framingham Heart Study

1. Overview of pulmonary function testing at the Framingham Heart Study
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, began with the first Examination Cycle of Gen3.

Beginning with Examination 8 of the Offspring Cohort and its concurrent Omni Examination 3, a limited number of participants in each of the cohorts of the Framingham Heart Study will be undergoing post- bronchodilator spirometry, in addition to the pulmonary function testing that all participants undergo. 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 Cycle 8 exam components (stations)
6) administration of albuterol with the allowance of no less than 15 minutes and no more than 30 minutes
7) post-bronchodilator spirometry

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The timeline below summarizes the differences-

Table 1. Timeline for pulmonary function testing at FHS

	Start	10 minutes	15 minutes	20 minutes	25 minutes	28 minutes	40-55 minutes
Those doing only pre-bronchodilator spirometry and diffusion	Pre-bronchodilator spirometry	First Diffusion capacity	Questionnaire	Second Diffusion Capacity	Respiratory Questionnaire		
Those doing pre, post bronchodilator spirometry and diffusion	Pre-bronchodilator spirometry	First Diffusion capacity	Questionnaire	Second Diffusion Capacity	Bronchodilator Administration	Respiratory Questionnaire	Post-bronchodilator spirometry

2. Subject selection for pre- and post- bronchodilator administration

As noted above, some participants will have spirometry measured before and 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). FHS will use the simple measure of ratio of FEV1-to-FVC; participants with a FEV1-to-FVC ratio of less than 70% (absolute ratio) will be asked to undergo pre- and post- bronchodilator testing.

A. Pre-identified subjects

The majority of subjects undergoing post- bronchodilator spirometry will be pre-identified, in order to more evenly spread the time burden in clinic. Subjects who, at their most recently attended examination with satisfactory spirometry data, meet the criteria below will be scheduled and appropriately identified as candidates for post-bronchodilator spirometry.

Table2. Criteria for undergoing post- bronchodilator testing

	FEV1/FVC ratio*
Criteria	<70%

*ratio is absolute value, as opposed to percent predicted

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B. Subjects identified at current examination

Subjects will also be identified during ongoing examination for eligibility for post- bronchodilator spirometry testing; the criteria for selecting subjects not previously identified will be the same as for pre-identified subjects (Table 3.). Participants meeting these standards will be asked to perform post- bronchodilator testing.

3. Protocol

The methods for each of the pulmonary function maneuvers are detailed in the appendices. The information below is intended as a summary.

A. Subjects not undergoing post- bronchodilator spirometry

1) Pre- bronchodilator spirometry

According to the American Thoracic Society, "spirometry is a medical test that measures the volume of air an individual… exhales as a function of time. Flow, or the rate at which the volume is changing as a function of time, may also be measured with spirometry. Spirometry, like the measurement of blood pressure, is a useful screen of general health." (ATS, Standardization of Spirometry, 1994 Update) 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 volumes at particular time points. As the results of testing assume 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. For specific instructions on performing the spirometry session, see Appendix 1.

2) 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 (9-11 seconds), and then exhale. The spirometer 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 (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. The average of 2 acceptable maneuvers is reported. For complete instructions on using the spirometer to obtain diffusion maneuvers, see Appendix 2.

3) Questionnaire

Technicians will also administer a respiratory questionnaire. The questionnaire will help investigators to understand whether the

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participant has allergies, asthma v. COPD, and other pulmonary diseases. Further, the questionnaire will capture information on recent inhaler use, as it may ffect the post-bronchodilator spirometry, and prompt technicians to administer post-bronchodilator spirometry.

B. Subjects undergoing post- bronchodilator spirometry

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 Cycle 8 exam components they will receive two puffs of albuterol, 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) Questionnaire

The respiratory questionnaire will be modified to ask about most recent use of inhaled medications, particularly the beta agonists such as albuterol. Recent use of the medications may affect the results of the post-bronchodilator spirometry; consequently accurately recording the kind of medication and the time of most recent use is important. The table below lists the length of the effect of each of the medications.

Table 3. Bronchodilators and Generic names

	Short acting	Intermediate
	4-6 hours	**12 hours**
Drug trade names	***Proventil, Combivent, Ventolin, Maxair Xopenox, Volmax***	***Serevent, Advair, Foradil***
Generic drug names	***Albuterol,*** *levalbuterol,* ***pirbuterol***	***Salmeterol,*** *fluticasone/****salmeterol,*** ***formoterol***

4) Post- bronchodilator spirometry

Instructions for spirometry

The post-bronchodilator spirometry should be performed *no less than 15 minutes and no more than 30 minutes after* administering the albuterol. The procedures for using the spirometry are those for pre-bronchodilator spirometry; for specific instructions on performing the spirometry session, see Appendix 1.

Bronchodilator administration

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For specific instructions, please see the appendix on albuterol administration. Below is a summary of the procedure.

-Use Albuterol for bronchodilator response testing.
-Use a tube spacer with the metered dose inhaler.
- Activate the inhaler in the air to check that it is operating adequately.
- Instruct the participant to blow out to residual volume (RV), and then insert the tube in the participant's mouth.
- Instruct the participant to inhale slowly, and activate the inhaler during inspiration.
- The participant should hold their breath for about 10 seconds.
- Wait one minute and repeat for another inhalation.
- Repeat the spirometry (i.e., post- bronchodilator spirometry) no earlier than 15 minutes and no later than 30 minutes after administering the albuterol.

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Participant Testing
Spirometry/Forced Vital Capacity

You, the technician, are the critical part of the pulmonary function testing system, since you must guide the participant through breathing maneuvers that are highly dependent on participant effort. You must coach the participant to inhale maximally and then to exhale maximally. You also must judge the quality of his 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.

* ANY MAJOR Dental Surg?

Ask PFT Exclusions Criteria – Ask the participant if he has, within the past three months, had any major surgery (chest, abdominal or brain), a heart attack, a stroke, or an aneurysm. If the participant has an aneurysm, ask where it is. The participant's blood pressure should be less than 210/110. If either the systolic or diastolic exceeds this limit, do not perform the PFT. Ask the participant if he has any other medical concerns about participating in the PFT.

Position the Participant – Testing should usually be conducted in the sitting position; however, ~~obese participants (BMI >27) should stand~~. A chair (without wheels) should be positioned behind participants who stand for the test. Use the chair if the participant becomes light-headed or feels faint during testing. 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.

Dentures, if they are loose, should be removed and placed in a clean denture 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. 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.

Your 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.

PFT data set

FVC Test Steps

1) To begin doing the maneuvers, click on "Go to," then on "Forced Vital Capacity." This will bring you to 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 you- THEN have the participant connect to the mouthpiece and breathe normally.

4) Ensure that the participant has a noseclip in place. If the noseclip 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, noseclip 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 noseclip and breathe normally.

To summarize the testing process:

- *Once the participant is connected to the spirometer with a noseclip 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.*

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- *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.*

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!

FVC Maneuver Acceptability

According to the ATS standards, you should coach every participant to obtain at least three maneuvers that are "acceptable" and two that are "reproducible". The criteria for acceptability and reproducibility are described below. The accuracy of results depends much more on the quality of the maneuvers than on the instrument calibration.

Review the Results

According to the ATS standards, you should coach every participant to obtain **at least** three maneuvers that are "acceptable." The computer will show you the grades for "Effort Quality." When the grades are in green, they are acceptable and will have a "+" sign in front of each criteria. When one of the criterion was not reached, all three appear in red and the criteria not met have a "-" sign in front of them, so you can see what to have the participant correct on the next maneuver. Among those acceptable maneuvers, there must be two that are "reproducible," or within 5% of each other. In the chart at the bottom of the screen, the computer will put a (+) sign next to the value of FEV1 and FVC that are within 5% of each other- two **of the acceptable** maneuvers should have a (+) sign to demonstrate "reproducibility."

The "best" maneuver is the one with the highest sum of FVC + FEV1. Ignore the predicted and % predicted values displayed.

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 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.

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Saving the Results

Once you have three acceptable maneuvers, two of which are reproducible, testing is complete. Ensure that the "best" maneuver (highest sum of FEV1 and FVC) is highlighted by clicking on the box labeled "Effort __" at the top of the appropriate column. Click on the "Choose" tab at the top of the page. Highlight the number of the best maneuver that you chose. Now click on "Save."

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Participant Testing
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 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- "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 noseclip 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 "Blow it out, blow it out" 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. He must hold his breath for 12 seconds for the maneuver.

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.

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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.

To summarize-

- *Once in the Diffusion Capacity menu, Click on "Start Test" and prepare the participant*
- *Once the machine is set up, ensure that the participant is comfortable on the mouthpiece, with a good seal, and with a noseclip 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 breathhold 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. Three criteria are applied- Start of Test (SOT), Breathholding Time (BHT), and End of Test (EOT). If all three 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.

Per ATS standards allow 4 minutes between tests. Note that the machine takes several minutes to set up- you can start the setup process after two 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.

PFT data set

Saving the Test — DO NOT DO ⇒ MD³ WILL CHOOSE

Select the first acceptable and reproducible test by clicking on the top of the column label, which should read "Effort #_", then click on "Reported." Click on "Add to reported." Select the second acceptable and reproducible test by clicking on the top of the column label, then click on "Reported" and then on "Add to reported." This will report the average of the two maneuvers.

Click on "Save."

"Notes" Option

There is a tab on the upper left portion of the "Patient Information" page. 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." Be concise with comments entered here, as the length of the comments can cause the PFT report to print onto a second page.

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 2 copies are 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. An *A* is placed next to the name and sticker of all albuterol challenge participants (both pre-identified and clinic identified).

Participants Completing the PFT

Once the PFT is done, a green sheet labeled "PFT" is completed by attaching a participant label and the date onto the sheet and filing this in the participant's chart.

Participants Not Having a PFT

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.

A sheet labeled "PARTICIPANT DID NOT HAVE PULMONARY FUNCTION TEST" is completed by selecting the appropriate reason that the participant did not have the PFT.

PFT data set

The date and participant label are entered onto the sheet and the sheet is filed in the participant's chart.

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. ~~For tracking purposes, the technician will also add the participant's sticker, the date and the refusal reason to the sheet titled "ALBUTEROL REFUSALS---CYCLE 8 OFFSPRING".~~ per [redacted]
Go to Tech Notes & put in refusal w/ reason given

PARTICIPANTS DISQUALIFIED FROM ALBUTEROL CHALLENGE

Occasionally a participant who is pre-identified for the albuterol challenge cannot participate because he is disqualified from performing the PFT maneuver based on the clinical PFT protocol. The tech will add this participant's sticker to the sheet titled "~~PFT Disqualifications for Predetermined Albuterol Challenge: Offspring Cycle 8~~"
Go to tech notes & put in Disqualifications & reason for it.

PFT dataset

Participant Label:

PFT

Completed _____

Printed report to follow.

FHS-Clinic

for Admin Purposes only

DAILY PFT LOG – GENERATION 3 CYCLE 1

DATE	PARTICIPANT	COMMENTS	TECH

Respiratory Disease Questionnaire. Technician Administered.

OMB NO=0925-0216 12/31/2007

Respiratory Diagnoses

h646 |__|__|__| **Examiner ID**

h647 |__| **1. Since your last exam have you had asthma?** 0=No

If yes, fill ☞

h648 |__| Do you still have it?

h649 |__| Was it diagnosed by a doctor or other health professional? 1=Yes

h650 |__|__| At what age did it start? **(Age in years)**

h651 |__|__| If you no longer have it, at what age did it stop? **(Age in years)** 88=N/A

h652 |__| Have you received medical treatment for this in the past 12 months?

h653 |__| **2. Since your last exam have you had hay fever** (allergy involving the nose and/or eyes)**?** 0=No 1=Yes

h654 |__| **3. Since your last exam have you had pneumonia** (including bronchopneumonia)**?**

4. Since your last exam have you had ....

	Condition?	Health professional DX?	Age condition began
	(0=No, 1=Yes)		99=Unk
Chronic Bronchitis	h6655 |__|	h6656 |__|	h6657 |__|__|
Emphysema	h6658 |__|	h6659 |__|	h6660 |__|__|
COPD Chronic obstructive pulmonary disease	h6661 |__|	h6662 |__|	h6663 |__|__|
Sleep Apnea	h6664 |__|	h6665 |__|	h6666 |__|__|
Pulmonary Fibrosis	h6667 |__|	h6668 |__|	h6669 |__|__|

Inhaler Use

h670 |__| **5. Do you take inhalers or bronchodilators?** 0=No 1=Yes

If yes, fill ☞

h671 |__| Do you use any of these medications- Albuterol, Proventil, Ventolin, Combivent, Maxair, Volmax, Xopenex, Bronkoometer, pirbuterol, levalbuterol, or metaproterenol 0=No 1=Yes

h672 **If yes, fill ☞** |__|__| How many hours ago did you last use the medication, either by inhaler or nebulizer? **(Time in hours)**

h673 |__| Do you take any of the following inhalers? Serevent, Advair, Foradil, salmeterol, or formoterol 0=No 1=Yes

h674 **If yes, fill ☞** |__|__| How many hours ago did you last use the medication? **(Time in hours)**

TECH14

Respiratory Disease Questionnaire. Technician Administered.

OMB NO=0925-0216 12/31/2007

Triggered airway symptoms

1. When you are near animals, such as cats, dogs, or horses, near feathers, including pillows, quilts, or in a dusty or moldy part of the house, do you ever

h675 |__| Start to cough?

h676 |__| Start to wheeze?

h677 |__| Get a feeling of tightness in your chest? 0=No 1=Yes

h678 |__| Start to feel short of breath?

h679 |__| Get a runny or stuffy nose or start to sneeze?

h680 |__| Get itching or watering eyes?

2. When you are near trees, grass, or flowers, or when there is a lot of pollen in the air, do you ever

h681 |__| Start to cough?

h682 |__| Start to wheeze? 0=No 1=Yes

h683 |__| Get a feeling of tightness in your chest?

h684 |__| Start to feel short of breath?

h685 |__| Get a runny or stuffy nose or start to sneeze?

h686 |__| Get itching or watering eyes?

h687 |__| **3. Do you currently have a cat, dog, or other furry pets living in your home?** 0=No 1=Yes

TECH15

PFT data set

Participant Testing
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 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- "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 noseclip 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 "Blow it out, blow it out" 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. He must hold his breath for 12 seconds for the maneuver.

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.

PFT data set

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.

To summarize-

- *Once in the Diffusion Capacity menu, Click on "Start Test" and prepare the participant*
- *Once the machine is set up, ensure that the participant is comfortable on the mouthpiece, with a good seal, and with a noseclip 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 breathhold 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. Three criteria are applied- Start of Test (SOT), Breathholding Time (BHT), and End of Test (EOT). If all three 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.

Per ATS standards allow 4 minutes between tests. Note that the machine takes several minutes to set up- you can start the setup process after two 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.

PFT dataset

Saving the Test

Select the first acceptable and reproducible test by clicking on the top of the column label, which should read "Effort #_", then click on "Reported." Click on "Add to reported." Select the second acceptable and reproducible test by clicking on the top of the column label, then click on "Reported" and then on "Add to reported." This will report the average of the two maneuvers.

Click on "Save."

"Notes" Option

There is a tab on the upper left portion of the "Patient Information" page. 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." Be concise with comments entered here, as the length of the comments can cause the PFT report to print onto a second page.

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PFT dataset

Albuterol Administration in Pre- and Post- Bronchodilator Spirometry

This section is designed to describe the selection of subjects to undergo testing, and to describe medication administration. For details on performing the FVC maneuver, please see the section on FVC.

I. Subject selection: Subjects with evidence of airflow obstruction either at their most recent FHS exam or at the current exam will be asked to have spirometry measured before and after administration of albuterol, a medication that relaxes the muscles in the airways of the lungs. This will help investigators distinguish between participants with asthma and those with chronic obstructive pulmonary disease (COPD).

A. Pre-identified subjects- Subjects who met the criteria listed below (Table 1) at their most recent FHS examination will be asked to undergo spirometry measured before and after administration of albuterol. These subjects will be identified by the recruiting department who will check the prepared list of pre-identified albuterol challenge subjects at the time of scheduling. The recruiting staff will identify these participants for the clinic staff by placing an *A* next to the participant's name on the daily schedule sheet.

Any pre-identified albuterol participant who performs the pre-bronchodilator portion of the FVC and scores >70% in the FEV1/FVC ratio* will be excluded from the albuterol challenge.

B. Subjects identified at the current exam- Some subjects will have new evidence of airflow obstruction on their spirometry done at the current examination. Technicians will evaluate the first spirometry session to assess whether the subject meets the criteria listed below (Table 1).

Table 1. Criteria for spirometry measured before and after administration of albuterol

	FEV1/FVC ratio*
Criteria	<70%

II. Medication administration

A. Albuterol information- 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 an allergy to albuterol should not take the medication. 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 nervousness or palpitations or dry mouth.

B. The administration of the albuterol will not take place until the participant has completed all other components of the Cycle 8 Exam.

PFT data set

This will ensure that no other data will be affected by the possible side effects of albuterol.

C. Using the albuterol- The participant will be taking 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 15 minutes and no more than 30 minutes* between the administration of albuterol and the post-albuterol spirometry.

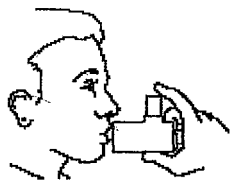
Getting ready

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

Figure 1. Using the inhaler



From the NHLBI's "Practical Guide for the Diagnosis and Management of Asthma" at http://www.nhlbi.nih.gov/health/prof/lung/asthma/practgde/practgde.pdf

For Admin Purposes Only

Daily PFT Log- Offspring Cycle 8

Date	Participant	Comments	Tech

PFT dataset

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PFT data set

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Figure 1. Using the inhaler

From the NHLBI's "Practical Guide for the Diagnosis and Management of Asthma" at http://www.nhlbi.nih.gov/health/prof/lung/asthma/practgde/practgde.pdf

If a participant is pre-identified as an albuterol challenge participant but scores >70% on the FEV1/FVC ratio, or meets exclusion criteria for the PFT test altogether, or refuses to participate in the albuterol challenge when offered, this participant is excluded from the albuterol challenge. **Please note this in the appropriate albuterol log at the central clinic desk for tracking purposes as well as in the PFT log in the PFT room.

For Admin Purposes Only

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

For Admin Purposes Only

Daily PFT Log- Offspring Cycle 8

Date	Participant	Comments	Tech

For Admin Purposes Only

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) Waist Girth Measurements
2) Height
3) Weight
4) Blood Pressure
5) Ankle-Brachial Blood Pressure Measurements

1) Waist Girth Measurements

Each technician, paired with another technician and out of each other's view, performs each waist measurement.

Waist Girth: Measurements with a difference of > .5 in. are repeated.
Waist at Iliac Crest: Measurements with a difference of > .5 in. are repeated.
Sagitial Abdominal Diameter: Measurements with a difference of > ~~4~~ .8 mm are repeated. 12/05 per JM/VR

2) 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.
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.

4) Blood Pressure

Each technician, paired with a second technician and out of each other's view, performs the blood pressure measurement on the same participant. If the difference in SBP and/or DSP is greater that 4mmHg or the average of the readings for each tech differs by more than 3mmHg, the measurement is repeated.

For Admin Purposes Only

QC Measurements For Month/Year_____

Framingham Heart Study
Intertech Quality Control Measurements **Blood Pressure Measurements**

ID number _____

1st/2nd Measurement? 1=1st 2=2nd (circle one) 1 2

Date of measurement:_____

Tech ID # _____ _____

Blood Pressure Measurements

Each technician, paired with a second technician and out of each other's view, performs the blood pressure measurement on the same participant. If the difference in SBP and/or DBP is greater than **4mmHg** or if the average of the readings for each tech differs by more than **3mmHg**, the measurement is repeated.

Cuff Size: _____

Palpated Systolic Pressure: _____

Systolic Blood Pressure (SBP) _____

Diastolic Blood Pressure (DBP) _____

Repeat SBP _____

Repeat DBP _____

Cuff size:
0=Pedi
1=Regular
2=Large
3=Thigh

Keyer1:_____
Keyer2:_____

qcintertech042604bp.doc

For Admin Purposes Only

_____ / _____ (tech1/tech2 - see below)

Framingham Heart Study
Intertech Quality Control Measurements

Waist @ Umbilicus,
Waist @ Iliac Crest, Waist by Caliper

QC Measurement for Month/Year : _____

Participant ID # _____ **Measurement Date** _____

Tech ID # _____ **circle one** **1=1st measurer (tech1)** **2=2nd measurer (tech2)**

Waist Measurements:
Each technician, paired with another technician and out of each other's view, performs each waist measurement.
Measurements with a difference of > **.5 in**. on the umbilicus measurement are repeated.
Measurements with a difference of > **.5 in**. on the iliac crest measurement are repeated.
Measurements with a difference of > ~~4~~ **mm** on the caliper measurement are repeated.

8 12/05 per SM/UR

Umbilicus Waist Measurement

_____in. Repeat Umbilicus Measurement _____in.

Iliac Crest Waist Measurement

_____in. Repeat Iliac Crest Measurement _____in.

Caliper Waist Measurement

_____mm Repeat Caliper Measurement _____mm.

Keyer1 :_____

Keyer2:_____ intertechwaist040105.doc

For Admin Purposes Only

_____ / _____ (tech1/tech2 - see below)

Framingham Heart Study
Intertech Quality Control Measurements
Height and Weight

QC Measurement for Month/Year: _____

Participant ID # _____ **Measurement Date _____**

Tech ID# _____ circle one 1=1st measurer(tech1) 2=2nd measurer(tech2)

Height and Weight Measurements:
Each technician, paired with another technician 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 (between techs) the measurement is repeated.

Height _____
(Record in inches rounded down to the nearest ¼ inch)

Weight _____
(Record in whole pounds rounded to nearest pound. Over .5 = higher, under .5 = lower)

If there is a 1 pound weight or 0.25 inch height difference between tech measurements then repeat:

Repeat Height _____

Repeat Weight_____

Keyer1:_____
Keyer2:_____ intertechhtwta040105

For Admin Purposes Only

___/___ **QC Measurements for Month/Year_____**

Framingham Heart Study

Intertech Quality Control Measurements

Ankle – Arm Doppler Measurements

Participant ID #_____ Date _____

1st/2nd Measurement → Circle one: 1 2

Tech ID#_____

AAD Measurement

Each technician, paired with a second 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 one round of measurements and compares those readings to the *average* of the first tech's readings. If the difference between technician readings is greater than 10 mmHg for any one measurement, then that measurement is repeated. Each tech records his/her own MIL.

Cuff Sizes: 0 = Pedi 1 =Regular 2 = Large 3 = Thigh

Cuff Size RA _____ Cuff Size LA _____

Cuff Size RL _____ Cuff Size LL _____

Maximum Inflation Level RA_____ Maximum Inflation Level RL_____

Initial Measurement:

RA _____ **LA** _____

RL _____ **LL** _____

Repeat Measurement- ***for tech 2 only*****- (if tech 1 and tech 2 differ by > 10 mmHg)**

RA _____ **LA** _____

RL _____ **LL** _____

Location: _____ **Ankle = 0 Foot (Dorsal) =1**

Keyer 1:_____

Keyer 2:_____ **qcintertechaad082905**

Appendix Exam 8

A. Exam Form

a. Appointment Letter
b. Tracking Information Form
c. Complete Exam Form
d. Summary Sheet to PCP
e. Referral Tracking/Adverse Events
f. Participant Letter

B. Exam Referral Forms/Other

a. Neurology Clinic Referral
b. Stroke Tracking Referral
c. Record of Telephone Encounter
d. Record of In-Clinic Medical Encounter
e. Routing Sheet

C. Supervisor Observation Forms

a. Ankle-Brachial Blood Pressure Measurement
b. Blood Pressure and Maximum Inflation
c. ECG
d. Height
e. KATZ – ADL's
f. MMSE
g. NAGI
h. Observed Physical Performance
i. Physical Activity
j. PFT
k. Self Report Performance
l. Weight

D. Problems/Corrective Action Log

E. New England Counties for MMSE Scoring

F. WORLD Scoring for MMSE

For Admin Purposes Only

The Framingham Heart Study

A Project of the National Heart, Lung, and Blood Institute and Boston University

Dear _____,

We thank you for participating in the Framingham Heart Study. Your clinic appointment is scheduled for _____ at _____ A.M.

The Framingham Heart Study's **new** address is [redacted], in the [redacted] The Framingham Heart Study offices are **located in the wing at the** [redacted] of the Building. **There is reserved parking for participants behind the** [redacted] **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 **DO 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 since your last visit with us. **PLEASE BRING THIS LETTER WITH YOU TO THE CLINIC.** 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]

Thank you once again for helping in our battle against heart disease!

Sincerely yours,

[redacted]

[redacted]
Director
Framingham Heart Study

OVER →

OMB No=0925-0216 Exp. 12/31/2007

[redacted]

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For Admin Purposes Only

Social Security Number: |__|__|__| - |__|__| - |__|__|__|__|

DISCLOSURE STATEMENT FOR SOCIAL SECURITY NUMBER: provision of the social security number is voluntary and unwillingness to do so will not have any effect upon the receipt of any benefits or programs of the United States Government. The information we receive will be used only for statistical purpose. Data from this study will be linked with data supplied by the National Center for Health Services. This information is collected under the authority of Section 421 (42USC 285b-3) of the Public Health Service Act.

Doctor(s)/Health Care Provider you want your report sent to:

Name	Address	Telephone

Hospitalizations, Emergency Room Visits, or Day Surgeries since your last clinic visit:

Date	Reason	Hospital Name & Address	Doctor's Name

Doctor's Office Visits

Date	Reason	Doctor's Name

For Admin Purposes Only

Neurology Clinic Referral Form

ID#:_____ Name:_____
Date:____/____/____ Person Making Referral:_____

Source of Referral:_____
1 = Hospital Admission
2 = Biennial Exam
3 = Offspring Exam
4 = Family
5 = Medical Records
6 = Other (Please specify)
7 = Review

Reason for Referral:_____
_____
Reason for Hospitalization (if applicable):_____
_____

Living Situation (if applicable): _____
1 = Own Home
2 = Elderly House
3 = Hospital
4 =Relative's Home
5 = Nursing Home
6 = Other

DISPOSITION (OFFICE USE)

Date Opened: ____/____/____
Date Closed: ____/____/____

1. To be scheduled for Neuro Clinic
2. Seen in Neuro Clinic: ____/____/____
3. Medical Records to be Obtained
4. Medical Records Complete: ____/____/____
5. Review Status:_____
   1 = Reviewed
   2 = Awaiting review
   3 = No review to be done
6. Enrolled Case in Stroke Study:_____
   1 = No
   2 = Yes
   Date:____/____/____
7. Reasons Not Seen:_____
   1 = N/A
   2 = Refused
   3 = Deceased
   4 = Out of state
8. Previously Seen:_____
   1 = Stroke
   2 = Dementia

For Admin Purposes Only

Stroke Tracking Referral Form
The Framingham Study

* Please complete the upper portion of this form if you identify a new neurological event.

ID#:_____ Name:_____

Date Opened: ____/____/____

Date of Event: ____/____/____ Date Type:____ (0=Exact, 1=Approximate)

Source of Referral:_____

1 = Hospital Admission
2 = Biennial Exam
3 = Offspring Exam
4 = Family
5 = Medical Records
6 = Review
7 = Other (Please specify)

Initials:_____

Reason for Referral:_____

Reason for Hospitalization:_____ (1=Neurology, 2=Other, 8=NA)

Comments:_____

_____

_____

DISPOSITION (FOR TRACKING PERSONNEL TO COMPLETE)

1. Dictation:_____ (0=Awaiting, 1=In)
2. To be Scheduled in Stroke Clinic:_____ (0=No, 1=Yes, 2=Pending)
3. Date Seen in Stroke Clinic:____/____/____
4. Reason Not Seen in Clinic:_____ (1=NA, 2=Refused, 3=Deceased, 4=Out of State)
5. Part of PSIP Follow-Up Protocol:_____ (0=No, 1=Yes, 9=Unknown)
6. Previously Seen:_____ (0=No, 1=Stroke, 2=Dementia, 3=Other)
7. Medical Records needed:_____ (0=No, 1=Yes)
8. Date:____/____/____
9. CT/MRI/MRA to be obtained:_____ (0=No, 1=Yes)
10. Date:____/____/____
11. Review Status:_____ (1=Awaiting Review, 2=Reviewed, 3=Need Info)
12. Date Reviewed:____/____/____
13. Status of Case:_____ (1=Open, 2=Closed)
14. Date:____/____/____
15. Diagnosis:_____
    (1=Stroke, 2=TIA, 3=? TIA, 4=Parkinson's, 5=No CVA, 6=Other Neuro, 7=Migraine, 10=?Stroke, 20=Recurrent TIA, 9=Unknown)

For Admin Purposes Only

Record Of Telephone Encounter
(to be filed in chart)

Participant's ID#: _____ Participant's Name: _____

Date of Incident: ____/____/____

Person Contacted: _____

_____

Regarding: _____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Contact Made By: _____

_____

_____

For Admin Purposes Only

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: _____

For Admin Purposes Only

Cohort Exam 8
Home Visit/Nursing Home Visit Routing Sheet

Participant Label: _____

Date of Visit: ___/___/___

Offsite Technician: _____

Chart Flow	Initial & Date Completed
MD Chart/ECG Review in Clinic ↓	
Offsite Technician ↓	
Linda Clark ↓	
Neurology Group ↓	
[redacted]	

* Routing Sheet to be returned to Elizabeth Oberacker *

For Admin Purposes Only

Date: _____ **Tech ID#**_____

Supervisor:_____ **Participant**_____

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	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): a. Right arm b. Right ankle c. Left ankle d. Left arm
		Apply ankle cuffs with midpoint of bladder over posterior tibial artery, with lower end of bladder approximately 3 cm above medial malleolus.

For Admin Purposes Only

ANKLE-BRACHIAL DOPPLER BLOOD PRESSURE MEASUREMENT
OFFSPRING EXAM 8 SUPERVISOR CHECKLIST

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	Right-Arm Systolic Blood Pressure Measurement
		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.

For Admin Purposes Only

ANKLE-BRACHIAL DOPPLER BLOOD PRESSURE MEASUREMENT
OFFSPRING EXAM 8 SUPERVISOR CHECKLIST

Yes	No	Right-Ankle Systolic Blood Pressure Measurement
		Connect right ankle cuff to the manometer.
		Apply ultrasound jelly over posterior tibial artery.
		Locate posterior tibial 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 and ankle BP recorded.

Yes	No	Left-Ankle Systolic Blood Pressure Measurement
		Connect left ankle cuff to the manometer
		Apply ultrasound jelly over posterior tibial artery.
		Locate posterior tibial 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 ankle systolic blood pressure.

Yes	No	Left-Arm Systolic Blood Pressure Measurement
		Attach left 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.

For Admin Purposes Only

ANKLE-BRACHIAL DOPPLER BLOOD PRESSURE MEASUREMENT
OFFSPRING EXAM 8 SUPERVISOR CHECKLIST

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.

Comments/Corrections:
Supervisor:
Date:

For Admin Purposes Only

Date: _____ **Tech ID#**_____

Supervisor:_____ **Participant**_____

Blood Pressure and Maximum Inflation
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	Blood Pressure Cuff Placement
		Bare participant's left arm to above the point of the shoulder.
		Determine correct cuff size using guidelines inside the cuff.
		Palpate the brachial artery.
		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.
		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.
		Wrap the cuff snugly about the arm, with the palm of the participant's hand turned upward.
		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.

Yes	No	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.
		Attach the cuff tubing to the sphygmomanometer.
		Palpate the radial pulse.
		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.
		Deflate the cuff quickly and completely.
		The maximal inflation level is 30 mmHg **above** the systolic pressure.

For Admin Purposes Only

BLOOD PRESSURE AND MAXIMUM INFLATION OFFSPRING EXAM
SUPERVISOR CHECKLIST

Date: _____ **Tech ID#**_____

Supervisor:_____ **Participant**_____

Yes	No	Guidelines for Accurate Blood Pressure Readings
		The participant should be in a seated position for at least 5 minutes before the blood pressure is measured.
		All readings are made to the nearest even digit.
		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).
		All readings are made to the top of the meniscus, the rounded surface of the mercury column
		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.

Yes	No	Blood Pressure Readings
		Following any previous inflation, wait at least 30 seconds after the cuff has completely deflated.
		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).
		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.
		Open the thumb valve slightly. Allow the cuff to deflate, maintaining a constant rate of deflation at approximately 2 mmHg per second.
		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).
		Deflate the cuff fully by opening the thumb valve.
		Remove the stethoscope. Neatly enter systolic and diastolic readings in the spaces provided on the form.

For Admin Purposes Only

Date: _____ **Tech ID#**_____

Supervisor:_____ **Participant**_____

ECG 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	ECG Procedures
		Participant is informed that ECG is going to be done. Procedure is explained. Participant is asked to lie on bed, get comfortable.
		Tech establishes a rapport with participant so participant is at ease with procedure. Answers any questions participant may have.
		Electrode location V2 is located in the 4th intercostals space at the left sternal border, a mark is made with pencil.
		V1 is found at the same level as V2 but at the right sternal border, a mark is made.
		The E point is located at the intersection of the 5th intercostal space and the mid-clavicular line, a mark is made.
		A line is drawn at mid axillary in exact vertical center plane of the thorax.
		V6 is located in the mid axilla at the same level as the E point. (The heart square should be firmly placed on the body and kept on a horizontal plane from the E point to the mid-axillary point).
		The difference between the E0 measurement and V6 measurement is calculated.
		The difference from the above calculation is located in the heart square and V4 is located on the chest, a mark is made.
		V3 is located midway between V2 and V4, a mark is made.
		V5 is located midway between V4 and V6, a mark is made
		Alcohol wipe is used to clean each area, V1, V2, V3, V4, V5, V6 and RA, LA, RL, LL
		Chest Electrodes are placed at V1, V2, V3, V4, V5, V6 with the body of the electrode placed centrally on each pencil measurement, tab extending down.
		RA electrode is located on the upper (dorsal) surface of right forearm, placed with tab extending away from body.
		LA electrode is located on the upper (dorsal) surface of left forearm, placed with tab extending away from body.
		RL electrode is located on the inside surface of the right lower leg, placed with tab extending away from body.
		LL electrode is located on the inside surface left lower leg, placed with tab extending away from body.

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Yes	No	ECG Procedures (cont'd)
		Leads are connected to electrodes in the following order: RL, LL, RA, LA, V1, V2, V3, V4, V5, V6.
		All leads are rechecked for proper placement
		The participant's identifying information is typed into the MAC.
		Participant is requested to relax and lie quietly while ECG recording is in process.
		When tracing appears acceptable, the ECG is printed and reviewed for errors
		Leads are disconnected and electrodes gently removed
		2 copies of the ECG is printed and stamped with the correct exam number.

Comments/Corrections:
Supervisor:
Date:

For Admin Purposes Only

Date: _____ **Tech ID#**_____

Supervisor:_____ **Participant**_____

Standing Height 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	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.
		Record measurement to the **nearest 1/4 inch, rounding down.**

Note: Measurement is not taken during offsite visits.

For Admin Purposes Only

Date: _____ **Tech ID#**_____

Supervisor:_____ **Participant**_____

Self-Reported Performance – KATZ-ADL's
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	Activities of Daily Living
		Ask the participant: *During the course of a normal day, can you do the following activities independently or do you need human assistance or the use of a device?* The answers will be coded by the examiner as: **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
		Dressing • Undressing and redressing • Picking out clothes, dress oneself including buttoning, fastening, etc. • Devices such as: velcro, elastic laces.
		Bathing • Including getting in and out of tub or shower • Getting water, soap, towel, and other necessary items and washing oneself. • Devices such as: bath chair, long handled sponge, hand held shower, safety bars.
		Eating • Able to eat from a dish and drink from a cup • Devices such as: rocking knife, spork, long straw, plate guard

Updated 11/14/05

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KATZ-ADL'S OFFSPRING EXAM 8
SUPERVISOR CHECKLIST

Yes	No	Activities of Daily Living (Continued)
		Transferring • Getting in and out of a chair • Arising from a sitting position to a standing position and back • Devices such as: sliding board, grab bars, special seat.
		Toileting activities • Using the bathroom facilities and handling clothing • Devices such as: special toilet seat, commode

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 score the participant's responses correctly?
		Did the technician review the form for completeness?

Comments/Corrections:
Supervisor:
Date:

Updated 11/14/05

For Admin Purposes Only

Date: _____ **Tech ID#**_____

Supervisor:_____ **Participant**_____

MMSE Offspring Exam
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.

Methods
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
Scoring for Administered Individual Items
Score **0** for the following reasons: 1. Incorrect response 2. *I don't know* 3. Unintelligible response in context of other intelligible responses (see scoring of **9** as well). 4. Participants attempted to respond but responds incorrectly (i.e. they are demonstrating that they heard the question and are making an attempt to respond to it).

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MMSE OFFSPRING EXAM
SUPERVISOR CHECKLIST

Yes	No	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.
		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.
		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. Month — Correct Response January — Winter February — Winter March — Winter or Spring April — Spring May — Spring June — Spring or Summer July — Summer August — Summer September — Summer or Fall October — Fall November — Fall December — Fall or Winter
		What day of the week is it? Ask the participant what town, county, and state we are 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?

For Admin Purposes Only

MMSE OFFSPRING EXAM
SUPERVISOR CHECKLIST

Yes	No	Questions (Continued)
		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. 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).
		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. For tabulating a total MMSE score for screening purposes, please determine a total score between 0-5 for this item). 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.
		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 Correct responses include: watch, wristwatch, timepiece Code 1 = correct answer

Updated 11/14/05

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For Admin Purposes Only

MMSE OFFSPRING EXAM
SUPERVISOR CHECKLIST

Yes	No	Questions (Continued)
		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 Code **1** = correct for correct answer.
		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. Code **1** = correct when the participant correctly repeated the phrase. Code **0** = incorrect when the participant did not repeat the phrase exactly. 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.
		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. Code **1** = correct when the participant closes his/her eyes. Code **0** = incorrect when the participant did not close his/her eyes.
		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. Written commands, such as *sit down*, where the subject is implied, are considered correct responses. d. Spelling and/or punctuation errors are not counted as errors. Code **1** = correct if the participant wrote a complete sentence as directed. 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 **0** = incorrect when the participant did not write a complete sentence as directed. Code **6** = Low vision

Updated 11/14/05

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MMSE OFFSPRING EXAM
SUPERVISOR CHECKLIST

Yes	No	Questions (Continued)
		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. Code "**0**" = incorrect when the participant's figure did not match.
		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). Code: **1** for <u>each</u> correctly performed act (code **6** if low vision).

For Admin Purposes Only

MMSE OFFSPRING EXAM
SUPERVISOR CHECKLIST

Yes	No	Factors Affecting Mental Status Testing	NO	YES	MAYBE	UNKNOWN
		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
		Paralysis	0	1	2	9
		Depression/Possible Depression	0	1	2	9
		Aphasia	0	1	2	9
		Coma	0	1	2	9
		Parkinsonism or neurological impairment	0	1	2	9
		Other	0	1	2	9

Yes	No	Technician Review
		Did the technician ask the questions exactly as written on the form?
		Did the technician correctly use the handouts?
		Did the technician score the participant's responses correctly?
		Did the technician review the form for completeness?
		Did the technician review the form for neurology referrals?

Comments/Corrections:
Supervisor:
Date:

Updated 11/14/05

For Admin Purposes Only

Date: _____ **Tech ID#**_____

Supervisor:_____ **Participant**_____

NAGI Questions
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	Questions
		Show and explain the answer key *before* administering the questionnaire. The participant is to choose one of the following answers for each activity: No Difficulty A Little Difficulty Some Difficulty A Lot of Difficulty Unable to Do Don't Do on MD Orders Unable to Assess Difficulty Because Not Done as Part of Daily Activities
		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 MD Orders, or if you are Unable to Assess Difficulty Because the activity is not done as part of your daily activities.*
		Read each activity separately, and go through the level of difficulty for each one until the participant understands the response choices.

Updated: 11/14/05

For Admin Purposes Only

NAGI SUPERVISOR CHECKLIST

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?

Comments/Corrections:
Supervisor:
Date:

Updated: 11/14/05

For Admin Purposes Only

Date: _____ **Tech ID#**_____

Supervisor:_____ **Participant**_____

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. 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.

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OBSERVED PHYSICAL PERFORMANCE MEASURES OFFSPRING EXAM 8
SUPERVISOR CHECKLIST

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.

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.*

For Admin Purposes Only

OBSERVED PHYSICAL PERFORMANCE MEASURES OFFSPRING EXAM 8
SUPERVISOR CHECKLIST

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.*
		If a walking aid is used, this will be recorded. **Coding** **0**=No aid **1**=Cane **2**=Walker **3**=Wheelchair **4**=Other **9**=Unknown
		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.

Comments/Corrections:
Supervisor:
Date:

For Admin Purposes Only

Date: _____ **Tech ID#**_____

Supervisor:_____ **Participant**_____

Physical Activity 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.

Yes	No	Method
		Hand participant a copy of the Physical Activity Questionnaire.
		Explain that the first section is Rest and Activity for a Typical Day (24 hours).
		The day is broken up into different types of activities.
		Read through each activity. ▪ Sleep ▪ Sedentary ▪ Slight Activity ▪ Moderate Activity ▪ Heavy Activity Explain that a total number of hours for a typical day must equal 24 hours.
		Give examples as needed.
		Make adjustments according to participant until the total number of hours equals 24.
		Ask the next two questions regarding walking and climbing stairs, allowing participant to answer, based on the choices given.
		On the reverse side is a list of Recreational Activities.
		Explain that if a participant has done the activity listed in the past year, they should say yes, if not they should answer no.
		If a participant answers yes, then the next three questions are asked: how many times in a two week period of time, how much time per session and how many months during the past year.
		Other recreational activities may be added (i.e., hockey, basketball, downhill skiing) and listed under OTHER

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PHYSICAL ACTIVITY QUESTIONNAIRE OFFSPRING EXAM 8
SUPERVISOR CHECKLIST

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?

Comments/Corrections:
Supervisor:
Date:

For Admin Purposes Only

Date: _____ **Tech ID#**_____

Supervisor:_____ **Participant**_____

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, BP>210/110.
		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.

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PFT OFFSPRING EXAM
SUPERVISOR CHECKLIST

Yes	No	Spirometry/Forced Vital Capacity
		Position the Participant – Testing should usually be conducted in the sitting position; however, obese participants (BMI >27) should stand. A chair (without wheels) should be positioned behind participants who stand for the test. Use the chair if the participant becomes light-headed or feels faint during testing. 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 noseclip 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 you have three acceptable maneuvers, two of which are reproducible, testing is complete. Ensure that the "best" maneuver (highest sum of FEV1 and FVC) is highlighted by clicking on the box labeled "Effort __" at the top of the appropriate column. Click on the "Choose" tab at the top of the page. Highlight the number of the best maneuver that you chose. Now click on "Save."
		Look at the FEV!/FVC ratios and if they are >70%, ask the participant if he would do and Albuterol Challenge and give a brief explanation of this.

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PFT OFFSPRING EXAM
SUPERVISOR CHECKLIST

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.
		Starting the Test: The computer 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 noseclip is in place. Once the participant is attached and breathing normally, press the spacebar
		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
		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.
		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 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

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PFT OFFSPRING EXAM
SUPERVISOR CHECKLIST

Yes	No	Diffusion Capacity (cont'd)
		Once the red line is horizontal, press the spacebar, ending the test.
		Wait 4 minutes between each maneuver
		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
		Saving the Test: Select the first acceptable and reproducible test by clicking on the top of the column label, which should read "Effort #_", then click on "Reported." Click on "Add to reported." Select the second acceptable and reproducible test by clicking on the top of the column label, then click on "Reported" and then on "Add to reported." This will report the average of the two maneuvers. Click on "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." .

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PFT OFFSPRING EXAM
SUPERVISOR CHECKLIST

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. 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. 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.

For Admin Purposes Only

PFT OFFSPRING EXAM
SUPERVISOR CHECKLIST

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. An *A* is placed next to the name and sticker of all albuterol challenge participants (both pre-identified and clinic identified).
		Once the PFT is done, a green sheet labeled "PFT" is completed by attaching a participant label and the date onto the sheet and filing this in the participant's chart.
		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. A sheet labeled "PARTICIPANT DID NOT HAVE PULMONARY FUNCTION TEST" is completed by selecting the appropriate reason that the participant did not have the PFT. The date and participant label are entered onto the sheet and the sheet is filed in the participant's chart.
		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. For tracking purposes, the technician will also add the participant's sticker, the date and the refusal reason to the sheet titled "ALBUTEROL REFUSALS---CYCLE 8 OFFSPRING".
		PARTICIPANTS DISQUALIFIED FROM ALBUTEROL CHALLENGE: Occasionally a participant who is pre-identified for the albuterol challenge cannot participate because he is disqualified from performing the PFT maneuver based on the clinical PFT protocol. The tech will add this participant's sticker to the sheet titled "PFT Disqualifications for Predetermined Albuterol Challenge: Offspring Cycle 8"

Comments/Corrections:
Supervisor:
Date:

For Admin Purposes Only

Date: _____ **Tech ID#**_____

Supervisor:_____ **Participant**_____

Self-Reported Performance Part 1
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	Socio-demographics
		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. It is important to ask whether others lives in the same household for < 3 months per year or > 3 months per year. The list is: Spouse Significant other Children Friends Relatives Coding **0** = No **1** = Yes, less than 3 months per year **2** = Yes, more than 3 months per year **9** = Unknown

Updated 11/14/05

For Admin Purposes Only

SELF REPORT PERFORMANCE-LIVING ARRANGEMENT/USE OF SERVICES/ROSOW-BRESLAU/CES-D
OFFSPRING EXAM 8 SUPERVISOR OBSERVATIONS

Yes	No	Use of Nursing and Community Services
		Coding for the following questions is: **0** = No **1** = Yes **9** = Unknown
		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 outpatient programs?

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? (Scrub floors, wash windows, rake leaves, mow lawn). *(Note:* Code **2** if person **does not** do this activity).
		Are you able to walk half a mile without help? (Walk one half mile or 4-6 blocks without stopping for more than 5 minutes). *(Note:* Code **2** if person does not do this activity).
		Are you able to walk up and down one flight of stairs without help?

Yes	No	CES-D
		During the past week, I felt that everything I did was an effort.
		During the past week, I could not "get going".

For Admin Purposes Only

SELF REPORT PERFORMANCE-LIVING ARRANGEMENT/USE OF SERVICES/ROSOW-BRESLAU/CES-D
OFFSPRING EXAM 8 SUPERVISOR OBSERVATIONS

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 score the participant's responses correctly?
		Did the technician review the form for completeness?

Comments/Corrections:
Supervisor:
Date:

For Admin Purposes Only

WEIGHT MEASUREMENT OFFSPRING EXAM
SUPERVISOR CHECKLIST

Date: _____ **Tech ID#**_____

Supervisor:_____ **Participant**_____

Weight Measurement
Supervisor Checklist
Offsite

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
		The participant should remove slippers or shoes.
		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.
		Ask the participant to step onto the scale.
		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.
		Read the digital display while participant is on the scale.
		Have the participant step off the scale.
		Record the weight to the nearest pound; round up if ≥ 0.5, round down if < 0.5
		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

For Admin Purposes Only

Date: _____ **Tech ID#**_____

Supervisor:_____ **Participant**_____

Weight Measurement
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	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**.

For Admin Purposes Only

Problems/Corrective Action Log

Anthropometrics

Date	Problem	Date	Corrective Action

For Admin Purposes Only

Problems/Corrective Action Log

Questionnaires

Date	Problem	Date	Corrective Action

For Admin Purposes Only

Problems/Corrective Action Log

Ankle-Arm Doppler

Date	Problem	Date	Corrective Action

For Admin Purposes Only

Problems/Corrective Action Log

ECGs

Date	Problem	Date	Corrective Action

h589

Cognitive Function: MMSE WORLD Scoring Protocol

The official total score for the MMSE (i.e. the scores used for statistical analyses) are computer generated. Examiners record individual test item scores on the MMSE test form. The one exception is "WORLD" where examiners record the response of subjects in the exact order that it is given by the subject.

If a participant has an evident cognitive impairment and the MMSE must be scored to determine if the participants consent should be waived, then "WORLD" will need a score.

In order to score world, a staff member must use the master sheet listing all of the possible word combinations with the points for each spelling.

h589

```
/*PROGRAM CREATED BY KAREN MUTATLIK AND SUSAN BLEASE MODIFIED 05/21/04
  modified version of the program from janet cobb it is for examCYCLE#*/

/*program masterworld.sas*/
/*purpose: for scoring "WORLD" at a particular exam cycle "CYCLE#"*/
/*to use this program - copy this program, replace CYCLE# = exam cycle number*/
/*you must create a data set from the minimental exam (either clean from
/fram/data or unclean from exam tables, prior to runing this program*/
/*call the incoming exam data set examCYCLE#*/

/*DO NOT MAKE CHANGES TO THIS MASTER PROGRAM
  COPY THIS PROGRAM TO A PROGRAM CALLED WORLDCYCLE#.sas,
  where the cycle# is the number of the exam cycle you are working with*/

libname in '.';
libname out '.';
libname fram '/fram/data';

options nocenter ls = 80 ps=59;

/*take in world variable from examCYCLE# data*/
/*pad spaces with # to make data fit program*/
/*replace g485 with appropriate variable for cycle*/

data change; set fram.examCYCLE#;                                    *update;
if g485 = "-1" then g485 = " ";
if g485 = "0" then g485 = " ";
if g485 = "6" then g485 = " ";
if g485 = "66666" then g485 = " ";
if g485 = "9" then g485 = " ";
if g485 = "99999" then g485 = " ";
if g485 = "blank" then g485 = " ";

data pad; length g485 $5; set change;
keep id g485;
g485=translate(g485,"#"," ","#####", "####.");

data name; set pad;
rw_worCYCLE# = lowcase(g485);                                        *update;

/*FROM MASTER PROGRAM FOR SCORING WORLD*/
data scoreCYCLE#; set name;                                          *update;

              /**********5 points**********/

if rw_worCYCLE# in ('dlrow', 'd;rpw') then worldCYCLE#=5;            *update;

              /**********4 points**********/                        *update;
else if rw_worCYCLE# in
      ('d#row','dl#ow','dlow#','dlowr','dlr#w','dlro#','dlrod',
       'dlroe','dlrof','dlrol','dlrw#','dlrwo','dluow','dorow','drow#',
       'lrow#','dldow','dloow','dlror','dlros','drrow','dwrow','dllow',
       'dlrou','dltow','drowl','lrowd','dlrdw','dlowf','dloww','dlrlw',
       'dllro','dlraw','dliow','slrow','dlaow','dlowa','dlowd',
       'rlrow','dlvow','dlroo','dlowo','dlowl','dl-ow','tlrow')
    then worldCYCLE#=4;                                              *update;
```

h589

```
                /***********3 points************/                    *update;
 else if rw_worCYCLE# in
      ('#dlow','#dlrw','#lrow','#rowl','dl##w','dl#ol','dlaw#','dld#w',
       'dlerw','dlo##','dlo#w','dloa#','dloaw','dlolo','dlorw','dlot#',
       'dlouw','dlr##','dlw##','dlwo#','dlwod','dlwor','dlwro','dolow',
       'dorod','dow##','dowl#','dowr#','dr#ow','dr#w#','drlow','dro##',
       'drold','drolo','drolw','drorl','drorw','dros#','drwro',
       'dulrw','ldrow','llow#','lrw##','dlarw','dldrw','dldw#','dleiw',
       'dlohw','dlold','dlolw','dloro','dlral','dlrdl','dlwao',
       'dlwol','dlwow','drdw#','dro#d','dro#w','drol#','low##',
       'lro##','dlodw','dlol#','dlrld','dluo#','dluod','dlw#o','dlwoo',
       'drlw#','drouw','drw##','lrorw','dl0#w','dla#w','delro','dlod#',
       'dlood','dlore','dlurw','dlwrd','drohw','ldraw','clowr','elor#',
       'lrod#','dl-lw','dlbob','doroy','drawr','elow#','lrdwr','lrouo',
       'alrod','dldou','dlrd#','dlrf#','dluw#','dlwr#','dowlo','drod#',
       'dowo#','drew#','dowld','douw#','droiw','dlrlo','dloy#','dro-w',
       'olrw#','lowrd','lowld','lorow','dulow','dlour','ddrw#','darw#',
       'dlolr','dlo-w','druow','lrolw')
        then worldCYCLE#=3;                                             *update;

             /****************2 points ****************/                *update;
else if rw_worCYCLE# in
     ('#lord','d#old','der##','dlord','dluro','do###','dol#w',
      'dolfw','dolw#','dor##','dor#w','dorld','dorlw','dorw#','dr###',
      'drl#w','dwl##','dwo##','dwold','dworl','jrood','ldow#','ldowr',
      'ldwor','llaw#','lod##','lr###','lword','lwr##','soaow','d-o-#',
      'd-o-l','d-r-l','d-r-o','d-w-o','dl###','dlaro','dlorg','do##w',
      'do#w#','dol##','dold#','dolro','dolwd','dor#l','dord#','dorl#',
      'drl##','duorw','dwrld','lerod','lo#w#','now_i','oww##','rod##',
      'd###w','dly##','drld#','dw###','dwrol','elw##','ldrol','ldrw#',
      'lw###','d-l-r','d-lr-','d_l_r','lro#w','d#r##','d#w##',
      'dla##','dldr#','dolor','dolr#','dwlro','dwor#','dworw','dwow#',
      'rolow','darlw','dlorh','draof','drlod','dwolw','dwr##','dwro#',
      'elhw#','dlld#','doold','doldo','dwlor','ealow','iow##','lorw#'
      'dlor#','dlorl','dolrw','dolod','dool#','doul#','drlrw','dwol#',
      'elorw','ldro#','lold#','lorwd','dlndr','dalw#','daw##','dplw#',
      'dldlo','driow','docb#','dwrdl','edrol','wlrld','rolw#','roldw',
      'owold','lduow','duolw','dolrl','dolhw','doldw','dluor','dllor',
      'dle##','dlc##','dlbla','loaw#','dlorb','drd##')
           then worldCYCLE#=2;                                          *update;

             /***********1 point***********/                           *update;
else if rw_worCYCLE# in
      ('d####','daeni','dole#','dolm#','dolrd','ldo#w','ldorw','lordw',
      'odo#w','orldw','wod##','world','wrold','odnom','wlo#w','d#-r-',
      'd-l-o','l####','ldouw','lno#w','lord#','rdo##','sro#w','wlrod',
      'htor#','norlw','wol##','word#','wlrow','d_l_o','dna##','ld###',
      'ler##','old##','rdl##','wloud','worl#','wsic#','dile#','ldolo',
      'rld##','warld','dolwr','w####','wlord','dorli','dylor','ldw##',
      'odw##','wl###','worar','odn##','drlor','drlro','ldok#','to###',
      'dlon#','dwal#','wlor#','rdld#','wyde#','wld##','wrroc','wr###'
      'wlrol','rldwo','dwld#','dalyo')
           then worldCYCLE#=1;                                          *update;

             /**************0 points**********/                         *update;
else if rw_worCYCLE# in ('ldorl','ldor#','wold#','smmp#','ord##','#####',
      'gorl#','24ing','worlc','wolmd','worlt','wolc#','ole##')
```

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```
            then worldCYCLE#=0;                                          *update;

else worldCYCLE#=.;                                                      *update;

/*    removed so no unscored fall through
if rw_worCYCLE# in ('""###','#-#-#','no_tr') then worldCYCLE# = .;       *update;
*/

data score0 score1 score2 score3 score4 score5 unscored problem;
  set scoreCYCLE#;
if worldCYCLE#=0 then output score0;                                     *update;
else if worldCYCLE#=1 then output score1;                                *update;
else if worldCYCLE#=2 then output score2;                                *update;
else if worldCYCLE#=3 then output score3;                                *update;
else if worldCYCLE#=4 then output score4;                                *update;
else if worldCYCLE#=5 then output score5;                                *update;
else if worldCYCLE#=. then output unscored;                              *update;
else output problem;

title2 'worldCYCLE# score from karens modified program, score=5';        *update;
proc freq data=score5; table rw_worCYCLE#; run;                          *update;

title2 'worldCYCLE# score from karens modified program, score=4';        *update;
proc freq data=score4;table rw_worCYCLE#;run;                            *update;

title2 'worldCYCLE# score from karens modified program, score=3';        *update;
proc freq data=score3;table rw_worCYCLE#;run;                            *update;

title2 'worldCYCLE# score from karens modified program, score=2';        *update;
proc freq data=score2;table rw_worCYCLE#;run;                            *update;

title2 'worldCYCLE# score from karens modified program, score=1';        *update;
proc freq data=score1;table rw_worCYCLE#;run;                            *update;

title2 'worldCYCLE# score from karens modified program, score=0';        *update;
proc freq data=score0; table rw_worCYCLE#; run;                          *update;

                                                                         *update;
title2 'worldCYCLE# score form karens modified program, not scored or missing';
proc freq data=unscored;table rw_worCYCLE#;run;
*update;
title 'CK FREQS AND RERUN 04/13/04 ALL ARE NOW SCORED - NO PRINTOUT EXPECTED';

data chcase; set scoreCYCLE#;                                            *update;
rw_worCYCLE#=upcase(rw_worCYCLE#);                                       *update;

data out.worldCYCLE#; set chcase;                                        *update;
keep id worldCYCLE# rw_worCYCLE#;                                        *update;
proc sort; by id;
```