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1. Exam Components

Generation 3 - Exam 1 Components

1. Obtain informed consent. Complete intake form (family and tracking information)
2. Phlebotomy
3. Anthropometric Measurements
 - a. Height and Weight
 - b. Neck Circumference
 - c. Waist Girth
4. Technician Obtained Resting Blood Pressure
5. Electrocardiogram
6. Technician Administered Questionnaires
 - a. Physical Activity Questionnaire
 - b. Pedigree verification and health history of nonparticipating parent
7. Physician Administered Medical History and Physical Exam
 - a. Resting Blood Pressure (2)
8. Brachial Artery Reactivity
9. Arterial Tonometry
10. Echocardiogram
11. Pulmonary Function
 - a. Respiratory Diagnoses Questionnaire
 - b. Spirometry
 - c. Diffusing Capacity
12. Self Administrated Questionnaires
 - a. Sociodemographic Questionnaire
 - b. SF-12
 - c. CES-D

13. Exit Interview – Technician administered

- a. Willett Diet Questionnaire
- b. Review of Referral Form
- c. Information on CT Scan
- d. Feedback

14. Subclinical Examination

Coronary Calcium by Multidetector CT (subset): Men age ≥ 35 ; women age ≥ 40

2. Equipment for Exam Procedures

Equipment For Exam Procedures

1. Scale to measure body weight in lbs.: Detecto Scale
Worcester Scale Co., Inc.
228 Brooks Street
Worcester, MA
508-853-2886 *g3a 444*

2. Weight to calibrate scale: 50 lbs.
Worcester Scale Co., Inc. (See address above) *g3a 444*

3. Accu Hite Stadiometer
Quick Medical *g3a 446*
425-831-5963
888-345-4858

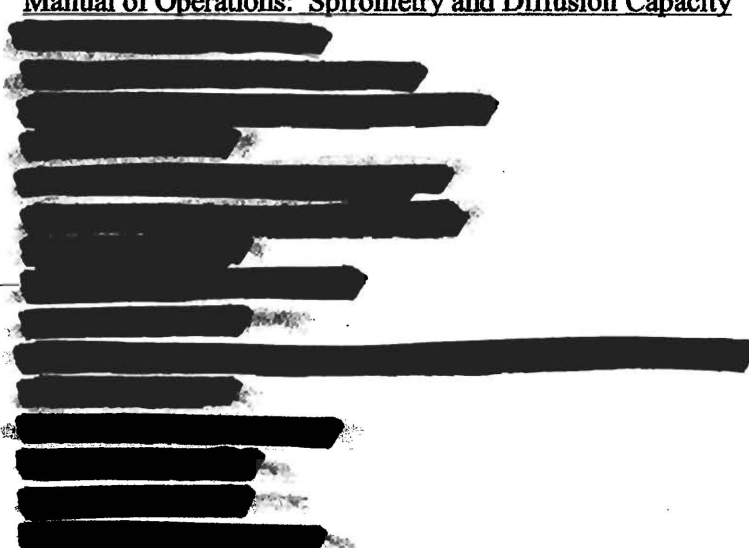
4. Heart Square by Heartware Inc.
Purchased from: Nova Heart

5. Marquette Mac5000 (electrocardiogram cart)
Marquette Electronics
100 Marquette Drive
Jupiter, FL 33468-9100
Tech support: [REDACTED]
[REDACTED]
Sales Rep: [REDACTED]
[REDACTED]
Applications: [REDACTED]
EKG g3a352-g3a386

6. Acquisition Module for Mac5000
Cam-14 (see address above)

7. Mac PC (see information for Mac5000 above)
backup portable ECG machine

8. Portable Standard mercury column sphygmomanometer: Baumanometer 300 Model
W.A. Baum Co., Inc *g3a 290, g3a 291*
620 Oak Street *g3a 347, g3a 348*
Copiague, NY 11726 *g3a 456, g3a 457*
516-226-3940

- 9. Bauman blood pressure cuffs in four sizes: regular adult, large adult, pediatric and thigh.
- 10. Litman stethoscope tubing and earpieces with bell: Classic II
- 11. Gulick retractable tape measure
 Novell Products
 3266 Yale Bridge Road
 Rockton, IL 61072
 815-624-4888
 815-555-1212
 800-323-5143
- 12. Tailor's plastic tape measure
- 13. Pulmonary Function Test (PFT), please see:
Manual of Operations: Spirometry and Diffusion Capacity

- 14. Spirometer: Collins CPL pf
 Collins Medical, Inc.
 220 Wood Road
 Braintree, MA 02184-2403
 800-225-5157
 781-843-0610 – Main Number
 800-635-3200 – Tech Support
 Sales Rep/Customer Service: Kevin Gwozdz
 800-321-9384/ext. 209
- 15. 3 Liter calibration syringe Model #021156 (Collins)

g3a290, g3a291
 g3a347, g3a348
 g3a456, g3a457

g3a449
 g3a451

see PFT
 data set

16. Parts for Spirometer: (Collins) *see PFT dataset*

- a. DCII Disposable Filter and Mouthpiece #022464
- b. Disposable Noseclips #021261
- c. Nafion Tubing #360031

17. Gases *see PFT dataset*

- a. Oxygen Gas:
- b. Lung Diffusion Mix: .3%CO, .3%CH4, 21% O2, Bal N2

Air Gas
199 Southwest Cutoff - Rte. 20
Worcester, MA 01604



Equipment Calibration Time Table

For Administrative Purposes Only

| <u>Activity</u> | <u>Daily</u> | <u>Weekly</u> | <u>Monthly</u> | <u>Yearly</u> |
|---------------------------|--------------|---------------|----------------|---------------|
| Detecto Scale | | | | |
| Zero Reading | X | | | |
| 50# Weight | | X | | |
| Professionally Calibrated | | | | X |
| Manometer | | | | |
| Zero Reading | X | | | |
| Check Inflation System | | | X | |
| Stadiometer | | | | |
| Check Level | | | X | |
| PFT Equipment | | | | |
| Calibrate | X | | | |
| Measuring Tapes | | | | |
| Calibrate | | | X | |
| ECG Machine | | AS | NEEDED | |

NOTE: Most Weekly calibrations are performed on Monday.
 Most Monthly calibrations are performed on the first Monday of the month.

3. Informed Consent



RESEARCH CONSENT FORM
Generation III Exam 1.7

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

Background

The Framingham Heart Study is an observational study designed to identify the relationship between risk factors, genetics, cardiovascular disease, and other health conditions over three generations. As a person who has at least one parent in the Framingham Heart Study, you are invited to participate.

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, joint disease, bone loss, deafness, cancer, and other major 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 3500 subjects to be asked to participate in this study.

The research will take place at the following location(s): Boston University Medical Center.
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, electrocardiogram, and lung function. You will also be asked to have procedures such as an echocardiogram and vascular testing. (See below for further descriptions)

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.

Echocardiogram: This is a picture of your heart using ultrasound waves instead of radiation.

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 and urine specimens

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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 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 living tissue sample (cell line). A cell line provides an unlimited supply of DNA and allows researchers to test your blood without the need to obtain more blood from you in the future. 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.

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 major 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 without your consent. 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 30-40 minutes:

- a. Brachial ultrasound measures the ability of a blood vessel in your arm (brachial artery) to get bigger (dilate) when exposed to increased blood flow; this measures the health of the blood vessel lining. A technician will perform brachial ultrasound before, during, and after 5 minutes of blood pressure cuff inflation on your lower arm.
- b. Fingertip pulse test measures your pulse at a fingertip on each hand while the technician is performing the ultrasound test.
- c. 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.

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

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 (████) █████ and ask for the lab manager.

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**RESEARCH CONSENT FORM
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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 (617) 638-7207. 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, Vol. 60, No. 13, Friday, January 20, 1995, pages 4264-4266.

Risks and Discomforts

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

The Brachial Ultrasound Test: The main risks are tingling or mild pain, and painless red spots (petechiae). About 0.5% of participants who have the brachial ultrasound test develop painless red spots after the test on the same arm; the red spots go away after a few days without any treatment.
The Fingertip Pulse Test: The fingertip device is made of latex and may cause a reaction if you have an allergy to latex. If you have a known latex allergy, inform the technician and he/she 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.

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.

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

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**RESEARCH CONSENT FORM
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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 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.

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.

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 initial beside each statement you agree with:

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**RESEARCH CONSENT FORM
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_____ I agree to participate in the physical examination and genetic studies of factors contributing to heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, joint disease, bone loss, deafness, cancer, and other major diseases and health conditions.

_____ 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.

_____ I agree to allow the creation of a cell line from my blood sample.

_____ 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.)

_____ I agree to allow the Framingham Heart Study to release the findings from tests and examinations to my physician, clinic, or hospital.

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 617-638-7207. 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 _____

Compensation for Research Related Injury

If you think you have been injured by being in this study, please let the investigator know right away. You can get treatment for the injury at Boston Medical Center. 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.

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**RESEARCH CONSENT FORM
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Right to Refuse or Withdraw

Taking part in this study is voluntary. You have the right to refuse to take part in this study. You will suffer no penalty if you do not take part in this study. If you do not take part in this study you will not lose any benefits to which you are entitled. Your present or future medical care at Boston Medical Center will be the same whether or not you take part in the study.

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.

9.1



**RESEARCH CONSENT FORM
Generation III Exam 1.7**

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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

Informed Consent

The Consent Form is administered in the Admitting Station at the time of the Clinic Exam. The participant is given the Consent Form and is instructed to read it carefully and to please check off the boxes on the last page, and date and sign it. The boxes the participants are asked to check off are as follow:

Yes No

I agree to participate in the Physical Examination and Genetic Studies of factors contributing to heart, lung, and blood diseases, stroke, dementia, osteoarthritis, osteoporosis, deafness, cancer, and other major diseases and health conditions.

Yes No

I agree to provide a blood sample from which DNA can be extracted. The DNA will be made available to researchers studying the diseases listed above.

Yes No

I agree to allow the creation of a cell line from my blood sample.

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: your or your heirs will not benefit financially from this, not will your DNA be sold to anyone)

If the participant has any questions regarding information in the boxes or the consent form, they are encouraged to ask at this time. A duplicate copy of the consent form is given to the participant for his/her own records. Once the consent has been read and signed it is reviewed by the Admitting Station staff, specifically checking for signature and that the boxes are checked. In the event that any of the boxes are checked "no," this should be reported to the Laboratory Director or the Patient Coordinator. The consent should be placed back in the chart with the signature page displayed.

Common questions that are generated are:

1. What is DNA used for?

Answer: DNA is used for research to see which specific genes are linked to heart disease. Once those are identified, then the question remains, how do you turn those genes off to prevent heart disease.

2. What is a Cell Line?

Answer: A Cell Line is a blood sample that is handled in a specific way to enable us to grow DNA forever.

3. Are you going to clone me?

Answer: No.

Consent by Substituted Judgment

When Consent by Substituted Judgment should be administered:

1. In cases where Cognitive Impairment is noted on the roster screen "Cog Imp"
2. In cases where the consent status is a "3, 4, or 5"
 - 3 = Likely to require consent by substituted judgment as well as own informed consent.
 - 4 = Incompetent to give informed consent; has legally appointed guardian and needs consent by substituted judgment.
 - 5 = Referred for assessment of competence to provide consent; status could not be determined.
3. At any time in the recruitment process, in the admitting process, or during the exam if there should be even the slightest question of cognitive impairment, steps should be taken to determine whether consent by substituted judgment is needed.

How Consent by Substituted Judgment is obtained:

In order to obtain Consent by Substituted Judgment, a member of the immediate family, i.e., a parent or sibling should be identified. Ideally, the proxy for the participant should be identified in the F14 screen. This person should be legal guardian. This may be a family member or a designated Power of Attorney.

The Consent by Substituted Judgment should be obtained prior to the exam, unless the proxy will be present during the exam.

In cases where there is no person identified, a contact person can be identified through the F18 screen which is the family screen. Each family member should be checked through his or her roster screens to establish the best possible contact person, i.e., age, geographical location, relation to the participant, etc.

If the contact person denies the presence of any problems and says the participant can sign any necessary form, it should be explained that we prefer to have both the participant and the contact person sign the consent.

In a case where the participant is on site and it has been determined that Consent by Substituted Judgment should be administered, an attempt should be made to identify and reach a contact person. Verbal consent should be obtained immediately and followed up by written Consent by Substituted Judgment.

4. Intake

Intake For Administrative
Purposes Only

1. For all 'd items, recite the preprinted information to the participant and have them confirm.

Example: "We have your date of birth as 12/9/59, is that correct?"

Do not say: "What is your date of birth?" And then check to see if we have it right.

2. If 'd INFORMATION IS:
 - a. CORRECT, then circle.
 - b. INCORRECT, then make correction with blue or red ink (so that it will show up easily) and leave the corrected information uncircled.
3. SPELLING CHECK for participant and street name:
 - Recite spelling of first name, middle initial, and last name of participant, ask them to confirm.
 - Recite spelling of street name, ask them to confirm.
4. Update all shaded regions on the Roster.
5. If an item does not apply to that person, for example, they do not have a second address, then write NA in first space of that item.
6. Ask if the participant has any question. Thanks very much.

For Administrative
Purposes Only

GEN 3 EXAM 1 ADMITTING FORM

1 Keyer: _____

SECTION A - TRACKING INFORMATION (SELF)

Date this information was collected: 2/1/02

Interviewer #: 999

- Please circle all printed information (marked with O) if correct, otherwise enter 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: **3- 2**

2. Name: **Ms. Julie A EXAMPLE**
(Prefix) (First) (MI) (Last)

3. Date of Birth: **09/13/1972**

4. Sex: **Female**

5. Address: **1 ~~Gilbert~~ St** *Giburt*

Framingham **MA** **01702**
(City) (State) (Zip Code)

Home Phone Number: **617-555-1212**

Work Phone Number: **617-555-1221**

Cell Phone Number: **1818 1-1222-1111**

6. Email: **seya@aol.com**

7. Preferred Method of Contact: Home: **1 - Yes**
Work: **8 - N/A**
Email: **8 - N/A**
Cellular: **1 - Yes**

| | |
|---|-------|
| 0 | No |
| 1 | Yes |
| 2 | Never |
| 8 | N/A |

5. Phlebotomy

Phlebotomy Protocol (Gen3 Exam 1)

(New / Revised) g3a712-
g3a718

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)
- 1 x 4.5 ml blue top (citrate)
- 2 x 8.5 ml yellow top (ACD)
- 2 x 8 ml blue tiger top (CPT)

Total volume of blood drawn is 112.5 ml (3.8 ounces).

EDTA

1. EDTA plasma used for cholesterol, HDL cholesterol, triglycerides and glucose measured fresh at the Heart Study.
2. EDTA plasma and red cells saved in several aliquots for future measurements. Stored at -80 C.
3. Buffy coat samples saved from all 5 EDTA Vacutainers. Sent to [REDACTED] for extraction of DNA.

Serum

1. Serum used for creatinine and uric acid, measured fresh at the Heart Study.
2. Serum saved in several aliquots for future measurements. Stored at -80 C.

Citrate

1. Citrate plasma saved for fibrinogen, stored at -80 C.
2. Citrate plasma saved in several aliquots for future measurements. Stored at -80 C.

ACD

ACD whole blood shipped twice weekly to [REDACTED]
[REDACTED] Used for extraction of DNA.

CPT

CPT whole blood shipped daily to [REDACTED]
[REDACTED] Lymphocytes are cryopreserved in preparation for future immortalization.

Urine

As part of the Gen3 Exam 1 clinic visit participants are asked to provide a random urine sample. Samples are tested qualitatively for pH, protein, glucose, ketone and blood with reagent test strips. Urine creatinine is measured fresh at the Heart Study. Urine saved in several aliquots for future measurements. Store at -80 C.

(Old version)
g3a712-g3a718

Phlebotomy Protocol

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)
- 1 x 4.5 ml blue top (citrate)
- 2 x 8.5 ml yellow top (ACD)
- 2 x 8 ml blue tiger top (CPT)

Total volume of blood drawn is 112.5 ml (3.8 ounces).

EDTA

1. EDTA plasma used for cholesterol, HDL cholesterol, triglycerides and glucose measured fresh at the Heart Study.
2. EDTA plasma sent to Tufts HNRC [REDACTED] for other lipids.
3. EDTA plasma and red blood cells sent to Tufts HNRC [REDACTED] for homocysteine, vitamins B6, B12 and folate.
4. EDTA plasma saved in several aliquots for future measurements. Stored at -80 C.
5. Buffy coat samples saved from all 5 EDTA Vacutainers. To be sent to Framingham Genetics Laboratory at Boston Medical Center for extraction of DNA.

Serum

1. Serum used for creatinine and uric acid, measured fresh at the Heart Study.
2. Serum saved in several aliquots for future measurements. Stored at -80 C.

Citrate

1. Citrate plasma saved for fibrinogen, stored at -80 C.
2. Citrate plasma saved in several aliquots for future measurements. Stored at -80 C.

ACD

ACD whole blood shipped twice weekly to Framingham Genetics Laboratory at Boston Medical Center. Used for extraction of DNA.

CPT

CPT whole blood shipped daily to Fairview University Medical Center in Minneapolis, Minnesota. Lymphocytes are cryopreserved in preparation for future immortalization.

Urine

As part of the Gen3 Exam 1 clinic visit participants are asked to provide a random urine sample. Samples are tested for pH, protein, glucose, ketone and blood with reagent test strips. Urine save in several aliquots for future measurements. Store at -80 C.

6. Height Measurement

Standing Height Measurement

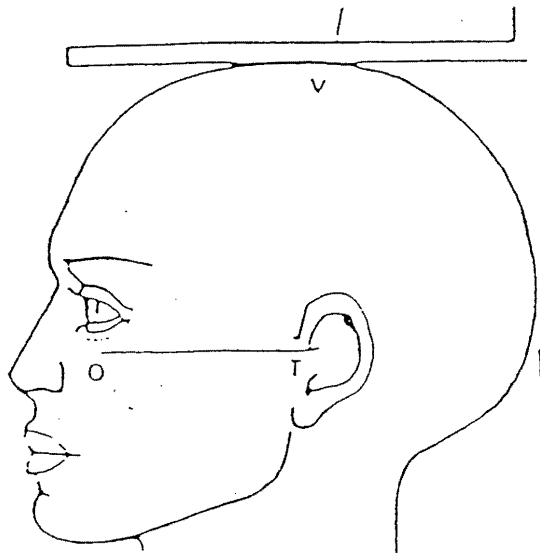
g3a44b

1. 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 (see next page). 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 carpenter square down snugly (but not tightly) 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.**

Standing Height Measurement

g3a446

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

7. Weight Measurement

Weight Measurement

g3a444

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 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 .**
9. Calibrate the scale daily.

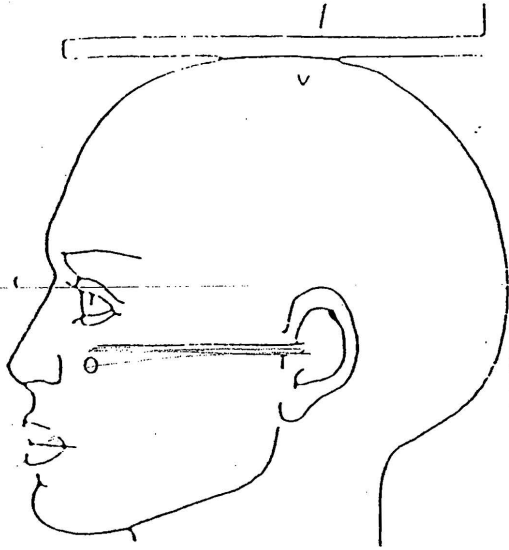
8. Neck Circumference

Neck Circumference

g3a449

1. Participant stands erect, arms hanging loosely at sides, weight equally distributed on both feet, head positioned in the Frankfort horizontal plane. (See figure 1, next page).
2. Standing to face the left side of the participant, identify the thyroid cartilage by gentle palpation of the neck. Gently place your left index and second fingers on the front of the neck and ask the subject to swallow to help find the correct spot. You should feel a slight depression.
3. Place the superior border of the anthropometric tape just inferior to the laryngeal prominence.
4. Apply the tape snugly, but not tightly, perpendicular to the long axis of the neck, which is not necessarily in the horizontal plane. (See figure 2, next page) at approximately a 90 degree angle.
5. Record the neck circumference to the nearest 1/4 inch, rounding down.
6. The pressure on the tape should be the minimum required to maintain skin contact.

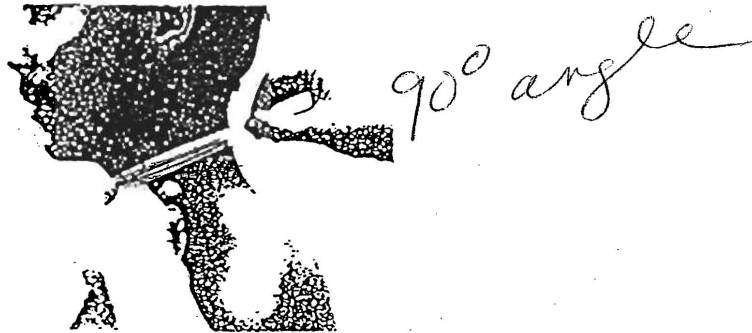
Neck Girth



ORBITALE: Lower margin of eye socket

TRAGION: Notch above tragus of ear or at upper margin of zygomatic bone at that point

FRANKFORT PLANE: Orbitale-tragion horizontal line



Measurement of minimal neck circumference.

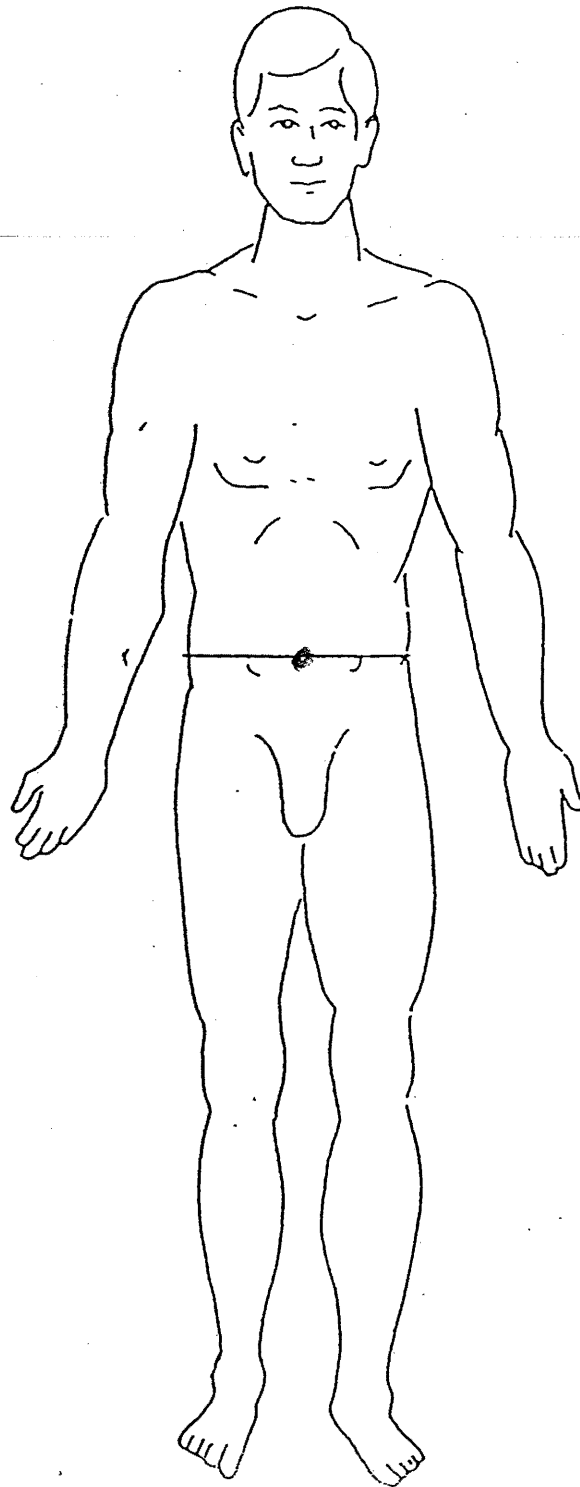
9. Waist Circumference

Waist Girth (Circumference)

g3a451

1. Participant stands erect, arms hanging loosely at sides, weight equally distributed on both feet, facing straight ahead.
2. Apply anthropometric tape at the level of the umbilicus, underneath the gown (see figure on following page).
3. Apply tape snugly but not tightly.
4. Make sure the tape is horizontal and not twisted, checking from both the front and back.
5. Record measurement **to the nearest 1/4 inch, rounding down.**

Waist Girth



Waist Girth at level
of umbilicus.

10. Technician's Seated Blood Pressure

Technician's Seated Blood Pressure

g3a 456, g3a 457

A. Equipment:

1. One standard Litman stethoscope tubing and earpieces with bell: Classic II 3M
2. One standard mercury column sphygmomanometer: Baumanometer
3. BP cuffs in four sizes
 - Large adult cuff
 - Regular adult cuff
 - Pediatric cuff
 - Thigh 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.

g3a456, g3a457

C. Determination of Maximal Inflation Level

For each participant, determine the maximal inflation level, or the pressure to which the cuff is to be inflated for blood pressure measurement. This assures that the cuff pressure at the start of the reading exceeds the systolic blood pressure and thus allows the first Kortokoff sound to be heard.

1. Attach the cuff tubing to the sphygmomanometer.
2. Palpate the radial pulse.
3. Inflate the cuff rapidly until the radial pulse is no longer felt (palpated systolic pressure) by inflating rapidly to 70 mmHg, then inflating by 10 mmHg increments.
4. Deflate the cuff quickly and completely.
5. The maximal inflation level is 30 mmHg **above** the palpated systolic pressure.

D. Guidelines for Accurate Blood Pressure Readings:

1. The participant should be in a seated position for at least 5 minutes before the blood pressure is measured.
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.

E. Blood Pressure Readings:

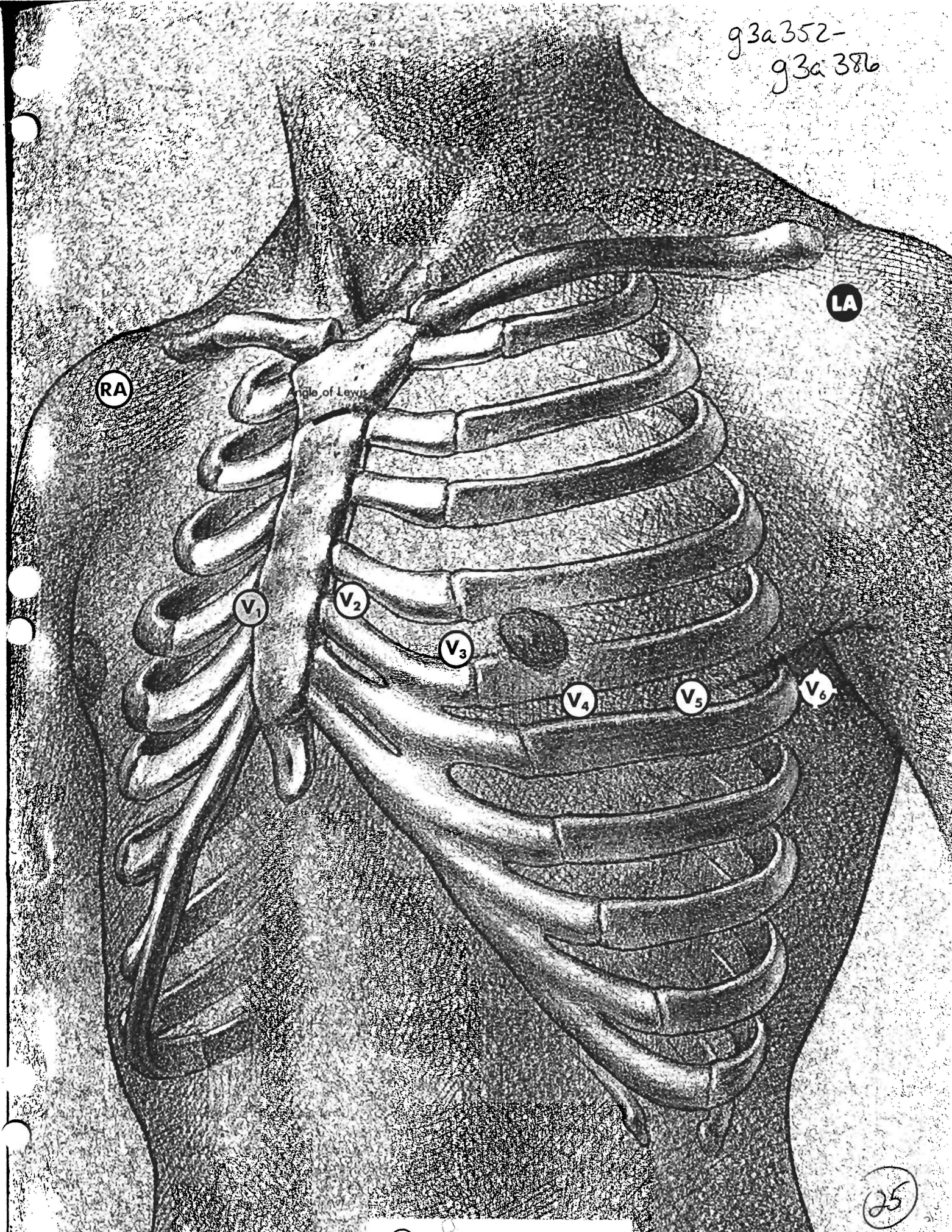
1. Following any previous inflation, wait at least 30 seconds after the cuff has completely deflated.

g3a456, g3a457

2. By closing the thumb valve and squeezing the bulb, inflate the cuff at a rapid but smooth continuous rate to the maximal inflation level (30 mmHg above palpated systolic pressure).
3. The examiner's eyes should be level with the mid-range of the manometer scale and focused at the level to which the pressure will be raised.
4. Open the thumb valve slightly. Allow the cuff to deflate, maintaining a constant rate of deflation at approximately 2 mmHg per second.
5. Using the bell of the stethoscope, listen throughout the entire range of deflation, from the maximum pressure past the systolic reading (the pressure where the FIRST regular sound is heard), until 10 mmHg BELOW the level of the diastolic reading (that is, 10 mmHg below the level at which the LAST regular sound is heard).
6. Deflate the cuff fully by opening the thumb valve.
7. Remove the stethoscope. Neatly enter systolic and diastolic readings in the spaces provided on the form.

11. ECG

g3a352-
g3a386



RA

LA

V1

V2

V3

V4

V5

V6

Angle of Lewis

25

ECG Lead Placement

g3a352- g3a386

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. Place electrodes on **TOP** of the breast.

The participant may now lower the left arm in a more comfortable position.

6. **V3:** Exactly halfway between **V2** and **V4**.
7. **V5:** Exactly halfway between **V4** and **V6**.

g3a352 - g3a386

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.

8. Before electrodes are placed on the participant, ask if he/she is known to be allergic to alcohol swabs. 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 swab and drying with a washcloth.
9. Precordial electrodes are attached in the following order: V1, V2, V3, V4, V5, V6. The body of the electrode is placed centrally at the pencil mark with the tab extending downward.
10. Attach limb leads in the following order: right leg (RL), left leg (LL), right arm (RA), left arm (LA). This will avoid lead reversal. Recheck all leads for proper placement.
11. 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. 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.

g3a352-g3a386

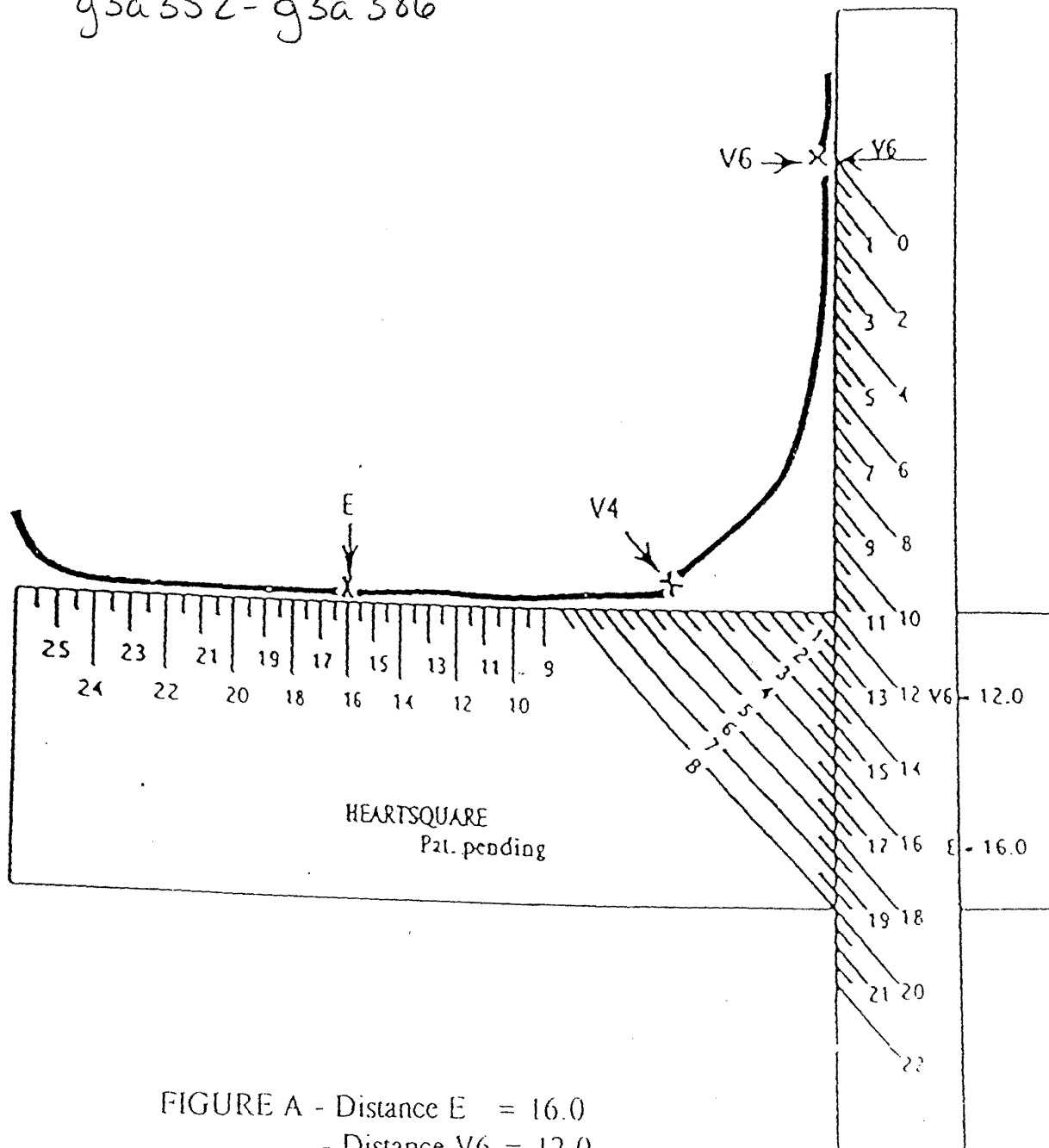


FIGURE A - Distance E = 16.0
- Distance V6 = 12.0

Follow 45° line from 16.0 at V6 arm
to locate V4.

MAC-PC Entries: E = 160 ("height")
V6 = 120 ("weight")

12. Physical Activities Questionnaire

Administration of Physical Activity Questionnaire

g3a596 - g3a612

1. Hand participant a copy of the Physical Activity Questionnaire.
2. Explain that the first section is Rest and Activity for a Typical Day (24 hours).
3. The day is broken up into different types of activities.
4. Read through each activity.
 - Sleep
 - Sedentary
 - Slight Activity
 - Moderate Activity
 - Heavy ActivityExplain that a total number of hours for a typical day must equal 24 hours.
5. Give examples as needed.
6. Make adjustments according to participant responses until the total number of hours equals 24.
7. Ask the next two questions regarding walking and climbing stairs, allowing participant to answer, based on the choices given.
8. On the reverse side is a list of Recreational Activities and time per week spent on average over the past year.
9. Explain that the time listed going from left to right at the top is the average time per week spent on an activity over the past year.
10. The activities listed in the left column going down are recreational activities.
11. The tech checks the box which participant states reflects the time he/she spends on the activity, covering each activity. Zero, should be used when the activity has not been done for any time over the past year.
12. Other recreational activities may be added (i.e., hockey, basketball, downhill skiing) and placed on the form where participant feels appropriate.

13. Pedigree Verification

Pedigree Verification

g3a614-g3a653

Both Mother and Father identifying information is gathered on this form.

General Notes:

1. All the pedigree information (except ID#) should come from the participant only and from no other source (including the roster or admitting form). ***We want to know what participant reports.*** If there are inconsistencies between what they report and other data we have, data management staff will resolve later.
2. Do not use the admitting form as a guide for ID# and date of birth of parents – this should be collected independently by two different people.
3. For the sections that say “biological mother/father”, make sure you are asking “**BIOLOGICAL**”.
4. You should only get the participant’s mother and father’s date of birth from the participant. You should not get this information from the roster. You can write roster DOB on the form next to DOB participant reported.
5. Record unknown month or day as “99”, unknown year as “9999”:
year unknown: 02/03/9999
day unknown: 02/99/1980
month unknown : 99/03/1980
date unknown: 99/99/9999
6. If the participant does not know who their biological mother/father is, then write “**UNKNOWN**” for unknown and “**ADOPTED**” for adopted in the space for the mother/father’s first name.
7. In rare cases, there may be a person who has **TWO** biological parents who are **NOT** in the study. The form does not allow for two nonparticipating biological parents health history. In this case, a blank health history form should be filled out and stapled to the existing form.

Procedure:

1. Begin by asking if the participant’s Mother is in the Study. If Yes, then a 1 is used for the Offspring and a 2 is used for Cohort. If No, then a \emptyset is filled in and skip to question 2.

Fill in:

- Mother’s First Name
- Middle Initial
- Last Name

g3a614-g3a653

- Maiden Name
- Ask for the Mother's Date of Birth

The ID# is looked up in the roster.

- Ask if Mother is a Biological Parent. If Yes, fill in a 1 and go to "Father" section of form, question 3.

2. Begin this section by again asking if Father is in the study. If No, then fill in with a \emptyset and skip to question 4.

Fill in:

- Father's First Name
- Middle Initial
- Last Name
- Ask for Father's Date of Birth.

The ID# is looked up in the roster.

- Ask if Father is a Biological Parent. If Yes, fill in a 1 and the form is finished. If No, go to question 4.

If a parent is not a Biological Parent, then the section on Biological Mother or Father is filled out.

Fill In:

- Biological Mother's First Name
- Biological Mother's Last Name
- Biological Mother's Date of Birth

Or

- Biological Father's First Name
- Biological Father's Last Name
- Biological Father's Date of Birth

If the Biological Mother or Father is in the study, an ID# is looked up and recorded.

Ask if the Biological Parent is in the Study. The ID# is filled in, if the parent is in the Study.

If the participant has a non-participating parent, then the Medical Health History is filled out on this parent.

14. SF-12

SF-12®

g3a 506 - g3a 517

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®.

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).

The SF-12® is self-administered during the clinic visit. The clinic technicians review form for completion.

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

g3a5d6-g3a517

**SF-12® Health Survey (Standard)
Self-administered**

|7|0|2|0|9| FORM NUMBER OMB NO=0925-0216

This questionnaire asks for your views about your health. This information will help you keep track of how you feel and how well you are able to do your usual activities.

Please answer every question by marking one box. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is:

- | | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Excellent | Very good | Good | Fair | Poor |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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 |
|---|-----------------------------------|--------------------------------------|---------------------------------------|
| Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Climbing several flights of stairs | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

- | | Yes | No |
|--|--------------------------|--------------------------|
| 4. Accomplished less than you would like | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Were limited in the kind of work or other activities | <input type="checkbox"/> | <input type="checkbox"/> |

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

- | | Yes | No |
|---|--------------------------|--------------------------|
| 6. Accomplished less than you would like | <input type="checkbox"/> | <input type="checkbox"/> |
| Didn't do work or other activities as carefully as usual | <input type="checkbox"/> | <input type="checkbox"/> |

g3a506-g3a517
SF-12® Health Survey (Standard)
Self-administered

[7|0|2|1|0] FORM NUMBER OMB NO=0925-0216

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 |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks...

| | All of the time | Most of the time | A good bit of the time | Some of the time | A little of the time | None of the time |
|---|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 9. Have you felt calm and peaceful? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. Did you have a lot of energy? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. Have you felt downhearted and blue? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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 |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

15. CES-D

THE CES-D SCALE

g3a518 - g3a537

The depression questions used in the HANES I survey were the 20-item set of the CES-D developed and validated by then Center for Epidemiologic Studies, National Institute of Mental Health (NIMH).

Instructions for Scale Scoring of the CES-D:

Each item had a range of four response options which indicated how often the survey examinee had felt that way during the past week:

| <i>Code</i> | <i>Response option</i> |
|-------------|--|
| 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) |

Questionnaire items 4, 8, 12, and 16 were worded in a positive (i.e., nondepressed) direction. The other 16 scale items were worded in a negative direction to elicit depressive symptomatology directly. To score the CES-D, the sense of the four positive questionnaire items was reversed by subtracting their coded value (indicating the response option selected) from 3. Then the coded values for all 20 items were summed into a total score. The range of possible scores was 0 – 60.

The CED-D is self-administered during the clinic visit and technician reviewed the form for completeness.

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
Public Health Service, Office of Health Research, Statistics, and Technology
National Center for Health Statistics, Hyattsville, MD April 1980

«LName», «FName»
 93a518-93a537
CES-D Scale (Self-administered)

7|0|2|1|1| FORM NUMBER

OMB NO=0925-0216

Circle the number for each statement which best describes how often you felt or behaved this way DURING THE PAST WEEK.

| Circle best answer for each question DURING THE PAST WEEK | Rarely or none of the time (less than 1 day) | Some or a little of the time (1-2 days) | Occasionally or moderate amount of time (3-4 days) | Most or all of the time (5-7 days) |
|--|---|--|---|---|
| 1. I was bothered by things that usually don't bother me. | 0 | 1 | 2 | 3 |
| 2. I did not feel like eating; my appetite was poor. | 0 | 1 | 2 | 3 |
| 3. I felt that I could not shake off the blues, even with help from my family and friends. | 0 | 1 | 2 | 3 |
| 4. I felt that I was just as good as other people. | 0 | 1 | 2 | 3 |
| 5. I had trouble keeping my mind on what I was doing. | 0 | 1 | 2 | 3 |
| 6. I felt depressed. | 0 | 1 | 2 | 3 |
| 7. I felt that everything I did was an effort. | 0 | 1 | 2 | 3 |
| 8. I felt hopeful about the future. | 0 | 1 | 2 | 3 |
| 9. I thought my life had been a failure. | 0 | 1 | 2 | 3 |
| 10. I felt fearful. | 0 | 1 | 2 | 3 |
| 11. My sleep was restless. | 0 | 1 | 2 | 3 |
| 12. I was happy. | 0 | 1 | 2 | 3 |
| 13. I talked less than usual. | 0 | 1 | 2 | 3 |
| 14. I felt lonely. | 0 | 1 | 2 | 3 |
| 15. People were unfriendly. | 0 | 1 | 2 | 3 |
| 16. I enjoyed life. | 0 | 1 | 2 | 3 |
| 17. I had crying spells. | 0 | 1 | 2 | 3 |
| 18. I felt sad. | 0 | 1 | 2 | 3 |
| 19. I felt that people disliked me | 0 | 1 | 2 | 3 |
| 20. I could not "get going" | 0 | 1 | 2 | 3 |

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16. PFT Manual of Operations

See PFT dataset

FRAMINGHAM HEART STUDY



SPIROMETRY AND DIFFUSION CAPACITY

MANUAL OF OPERATIONS

Date: 1/8/2002

see PFT data set

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see PFT data set

Overview of the PFT Station

Participants will undergo several pulmonary function tests, and respond to a technician administered questionnaire during the visit. The goals of the pulmonary function station include-

- 1) Spirometry
 - a. Three acceptable maneuvers
 - b. Two of the acceptable maneuvers must be within 5% of each other
- 2) Diffusion of Carbon Monoxide
 - a. Two acceptable maneuvers
 - b. The acceptable maneuvers must be within 10% of each other
- 3) Respiratory questionnaire

The visit should adhere to the following schedule-

- 1) Input of participant information
- 2) A blood pressure and subsequent review of exclusionary criteria are needed before testing begins
- 3) Explanation of Forced Vital Capacity maneuver briefly, with technician demonstrating the maneuver to the participant
- 4) Successful completion of Forced Vital Capacity testing
- 5) Explanation of Diffusion of Carbon Monoxide testing, with technician demonstration
- 6) Initial Diffusion of Carbon Monoxide testing maneuver
- 7) Administration of Respiratory questionnaire
- 8) Second, and, if necessary, third Carbon Monoxide testing maneuver (limit of 3 diffusion maneuvers)

The Collins Medical contact for the PFT equipment is:

Kevin Gwozdz
Collins Medical
220 Wood Road
Braintree, MA 02184-2403
Main (800) 225-5157
Direct (800) 321-9384 ext 209
Tech Support (800) 635-3200
kgwozdz@collinsmedical.com

see PFT data set

Background

Spirometry records the relationship between airflow (FEV1) and the exhaled volume of air during a breathing maneuver called the FVC maneuver (forced vital capacity maneuver). The most common lung diseases reduce forced expiratory flow. Such "obstructive" lung diseases include asthma, bronchitis, and emphysema. The ratio of FEV1/FVC is very sensitive for detecting mild airways obstruction, such as that due to mild airway inflammation secondary to exposure to cigarette smoke, asthma triggers, and mild pulmonary congestion due to CVD.

FEV1: is the most important spirometry variable, short for Forced Expiratory Volume in one second. It is convenient to think of it as the average flow rate during the first second of the FVC maneuver. It is reduced with airflow obstruction.

FEV1/FVC RATIO: is the most sensitive and specific index of airways obstruction measured by a spirometer. It is normally above 70%.

FVC: is the Forced Vital Capacity, the volume of air exhaled during the maneuver named after it. The subject takes as deep a breath as possible and then quickly exhales as much air as possible. The FVC is reduced with restrictive disorders.

PEF: stands for Peak Expiratory Flow, the highest flow measured during the FVC maneuver. It is a good index of effort used at the onset of the maneuver.

PRED: is short for the predicted value of a PF parameter. It is determined from the regression equation from a large population study of supposedly normal people.

BACK EXTRAPOLATION: is the standard method used to determine "time zero" when measuring the FEV1. The amount of slowly exhaled volume at the start of the maneuver excluded from the FEV1 by this technique is called the back extrapolated volume (BEV or EV). The BEV should be less than 5% of the vital capacity, otherwise the maneuver is considered to have started too slowly.

DIFFUSION CAPACITY OF CARBON MONOXIDE: is a measure of the lung's ability to transfer gas into the bloodstream (volume of gas (carbon monoxide) transferred per minute per mmHg of mean pressure gradient). This volume is derived using the total lung capacity derived from a single breath dilution of an inert tracer gas (He, or CH₄).

Background information for this manual was taken from "Spirometry – Manual of Operations, Cardiovascular Health Study." [REDACTED]

See PFT data set

Daily Equipment Calibration Protocol

- 1) Turn on computer, monitor, printer, spirometer, and open the gas tanks.
- 2) Once Windows has fully initialized, double click on the "CPL Diagnostics" icon

Plus/SQL2000 CPL Diagnostic window

1) Leak Check

- Click on the "Leak Test" tab
- Place two brass weights on bell
- Click on "Start" 'STATIC LEAK TEST IS IN PROGRESS'
- As instructed by the computer, place the stopper in the spirometer.
- You will then be brought to 'DYNAMIC LEAK TEST IS IN PROGRESS.'
- Click on "OK."
- Remove stopper and weights
- 'NO LEAKS DETECTED' click on "OK"

2) Balloon Check

- Click on the "Balloon Check" tab
- Click on the boxes next to each balloon, thus placing a check mark in each box
- Click on "Inflate"
- Visually inspect each of the balloons to ensure that they are inflated
- Click on "Deflate"

3) Close the CPL Diagnostics window.

Double click on the "Collins-Plus 2000 Version 4.02B" icon

Click on "Tools"

Click on "Calibrate" or hit the spacebar

Click on: Barometric Pressure/Temperature Check

- 1) Enter "Room Temperature" in centigrade, hit "ENTER"
- 2) Using the barometer, get the barometric pressure (shown in "in.Hg"). Using the conversion formula, find the barometric pressure in "mmHg." ENTER this number.

The conversion formula is:

CONVERSION:

1 in=25.4mm

multiply in.Hg by 25.4

Product = mmHg

- 3) hit "ENTER"

see PFT data set

Click on: **Volume Cal Check**

The 3.00 liter Hans Rudolph calibration syringe is used. Make sure that the syringe has been stored very close to the spirometer so that they remain at the same temperature. Flush the syringe and the spirometer at least 3 times with room air.

- 1) Click on "**Spirometry Calibration**"
- 2) Ensure that the plunger is fully depressed (in). Connect the syringe hose to the spirometer filter.
- 3) Click on "**Calibrate**"
- 4) Following the directions, **pull** the plunger all the way out, then hit the space bar
- 5) Following the directions, **push** the plunger all the way in, then hit the space bar
- 6) Click on "**Continue**"
- 7) Leave the syringe connected for the pneumotach calibration

Click on: **Pneumotach Calibration**

- 1) From the main menu, click on "**Tools**"
- 2) Click on "**Calibration**"
- 3) Click on "**Pneumotach Calibration**"
- 4) Click on "**Calibrate**"
- 5) Following the instructions, make sure that no air is moving through the spirometer
- 6) Click on "**Continue**"
- 7) Ensure that the syringe is connected, then click on "**Continue**"
- 8) Following the instructions, press the spacebar, then smoothly and quickly draw in 3L, then press the spacebar
- 9) Following the instructions, press the spacebar, then smoothly and quickly push out 3L, then press the spacebar
- 10) Click on "**Continue**"

Gas Analyzer Calibration:

- 1) From the main menu, click on "**Tools**"
- 2) Click on "**Calibration**"
- 3) Click on "**Gas Analyzer Calibration**"
- 4) Click on "**Next**"
- 5) Let the machine run
- 6) Click on "**Next**"
- 7) Click on "**Finish**"

see PFT dataset

Printing Report:

- 1) From the main menu, click on "Tools"
- 2) Click on "Calibration"
- 3) Click on "Print Calibration Report"
Click on the boxes next to: "Barometric Pressure/Temperature Calibration"
"Spirometer Calibration"
"Pneumotach Calibration"
"Gas Analyzer Calibration"
- 4) When checks appear next to each of these, click on "Print"
- 5) Select the HP Deskjet 845c
- 6) Click on "Print"
- 7) After the report prints, click on "Close"
- 8) Insert the Calibration Report into the binder labeled "PFT Daily List, Comment, and Calibration Log."

Calibration Syringe Care:

The 3.00 liter calibration syringe should be stored next to the spirometer so that it remains at the same temperature as the spirometer. Store the syringe with the plunger pushed all the way in. Take care not to drop the syringe.

see PFT data set

Entering Participant Information

From the Windows desktop, double click on the "Plus 2000 Version 4.02B" icon. Enter all the participant information above the "Optional" card. You may either tab between fields, or use the mouse to click into a field. Once the information card is appropriately completed, click on "Save" which will put the participant's information in the "Cache" as seen in the navigation bar (top of the screen, next to "Notes").

Date:

Once you begin entering information, the computer will ask you (in a pop-up screen) for a date for these pulmonary function testings- ensure that the date is correct.

ID#:

Enter the participant's 5 digit FHS ID number and verify that it is correct. If you enter it in error, use the backspace key to correct it.

Name:

Enter the participant's first name, tab to the next field then his last name. Use all capital letters.

Date of birth:

Enter the participant's date of birth; the computer automatically calculates the age.

Height:

Enter the participant's measured standing height in inches (for Protocol see Generation 3 Clinic Manual).

Weight:

Enter participant's weight in pounds (for Protocol see Generation 3 Clinic Manual).

Gender:

Press M for male and F for female.

Race Correction:

Put a check mark in the box next to "Race Correction" only if a participant is African-American.

Editing:

If a mistake was made when entering information, use mouse to move the cursor to the error. Then begin typing the correct information.

Saving the information:

Once the data is satisfactorily entered, click on "Save."

see PFT dataset

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.

Ask PFT Exclusions Criteria – Ask the participant if s/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.

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 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. 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.

see PFT dataset

FVC Test Steps

- 1) To begin doing the maneuvers, click on "Go to," then on "Spirometry," 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.
- 5) Once the participant is connected to the spirometer, noseclip in place, and is breathing normally, press the space bar. (This will have the computer track the regular breathing of the participant.
- 6) Once you are both ready, have 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. Shout "**BLAST OUT!!!**" Lower your voice a bit and say "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 and breathe normally.

To summarize the testing process:

- *Once the participant is connected to the spirometer with a nose clip on, push the space bar.*
- *After a couple of breaths, have the participant take as deep a breath as possible.*
- ***While the participant is inspiring, press the space bar.***
- *As soon as the participant has reached maximal inspiration, have him blast out all the air in their lungs.*
- *Once he has blown out for at least 6 seconds **and** the graph of his breathing has become flat and you see the "Good Effort" message, push the spacebar to end the test.*

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

see PFT dataset

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 criteria 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

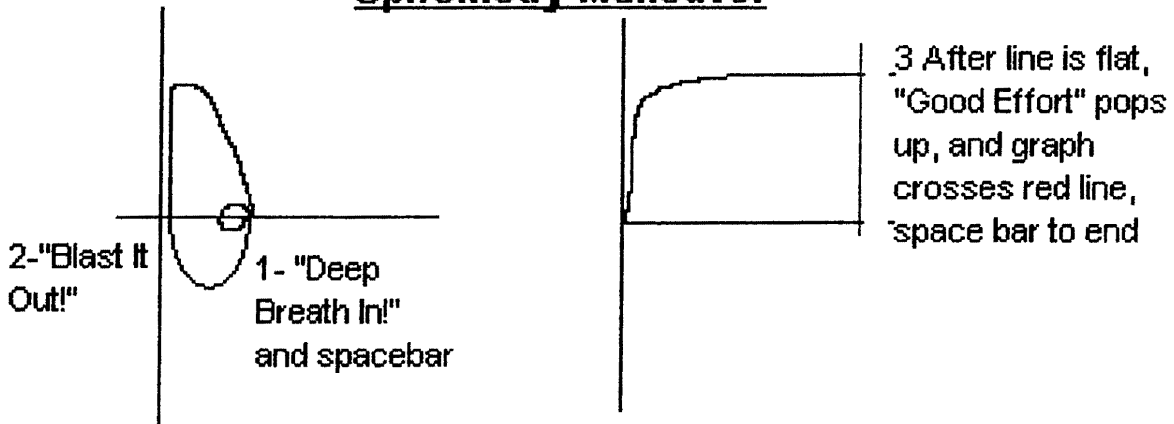
Don't exhaust the participant by asking him to perform more than **eight** FVC maneuvers. If you haven't obtained 3 acceptable maneuvers by the time you have done 8 maneuvers, it is unlikely that you will. Click on “Notes” which will bring you to a screen where you may add comments as to why the participant was not able to successfully complete testing.

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. This should highlight the number of the best maneuver that you chose with an “X” next to it. Now click on “Save.”

see PFT dataset

Spirometry Maneuver



see PFT data set

Participant Testing Diffusion Capacity

Setting up

After completing the FVC maneuvers-

- Click on "Go to"
- Click on "Spirometry"
- 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 breath 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. When the machine has completed this, you will be asked "Is a filter being used in the test effort?" Answer "yes." The machine will then include 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 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** have him 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 to close the valve and keep air from escaping.

See PFT data set

- 7) Once the participant's graph crosses the vertical line on the screen, **IMMEDIATELY** have him 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*
- *Answer "yes" as to whether you are using a filter.*
- *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 criteria is not met, then all three appear in red. The failed criteria 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.

see PFT data set

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.

Printing Reports

After saving the PFT, click on “**File**” tab and click on “**Print Report.**” Select HP Deskjet 845c. Print 2 copies.

Log Book

All participants are entered into the “PFT Daily Log, Comment, and Calibration” binder. Enter, by date, each participant name. An FHS generated sticker with the name and ID number can be used.

Participants 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.

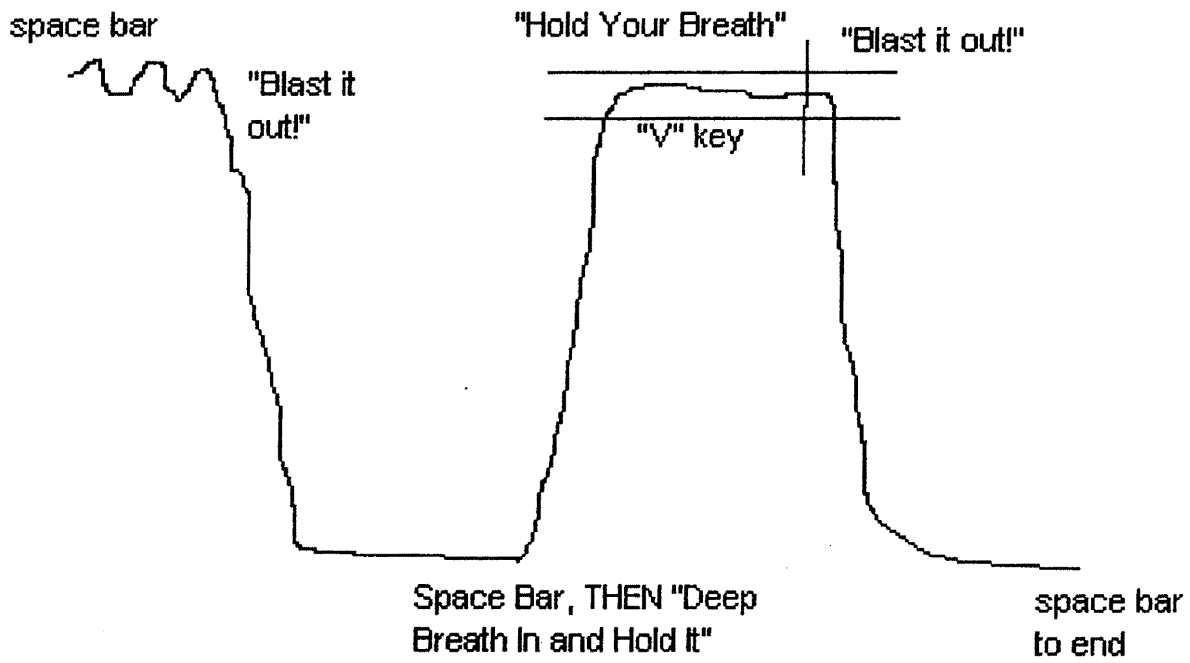
Participants not having a PFT during their clinic visit are entered into the computer with an additional entry under “Technician Notes.” Include additional reason why a PFT was not done and print one copy for the participant’s FHS chart.

Uninterruptible Power Supply:

In the event of a power failure, the PFT machine has a back-up power supply. The unit is an APC Smart-UPS 1500 dry cell battery back-up that provides approximately 15 minutes of additional power. If a power failure occurs during testing, the technician can finish the PFT maneuver and save the data.

see PFT dataset

The DICO Maneuver



Respiratory Disease Questionnaire. Technician Administered.

7|0|2|0|3| FORM NUMBER OMB NO=0925-0216

Respiratory Diagnoses

Examiner ID

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

if yes fill

1. Have you ever had asthma?

Do you still have it?

Was it diagnosed by a doctor or other health professional?

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

At what age did it start? (Age in years)

If you no longer have it, at what age did it stop? (Age in years)

Have you received medical treatment for this in the past 12 months?

2. Have you ever had hay fever (allergy involving the nose and/or eyes)?

3. Have you ever had bronchitis?

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

4. Have you ever had pneumonia (including bronchopneumonia)?

5. Have you ever had ...

| | Have Condition? | Health professional DX? | Age condition began |
|--------------------|----------------------------|--------------------------|---|
| | (0=No, 1=Yes, 9=Unk) | | 99=Unk |
| Chronic Bronchitis | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> |
| Emphysema | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> |
| COPD | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> |
| Sleep Apnea | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> |
| Pulmonary Fibrosis | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> |

6. Have you ever had ...

Any other chest illnesses? If yes, please specify: _____

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

Any chest operations? If yes, please specify: _____

Any chest injuries? If yes, please specify: _____

Respiratory Disease Questionnaire. Technician Administered.

|7|0|2|0|4| FORM NUMBER OMB NO=0925-0216

| Triggered airway symptoms | | |
|--|---|--|
| 1. When you are near animals, such as cats, dogs, or horses, near feather, including pillows, quilts, or in a dusty or moldy part of the house, do you ever | | |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | Start to cough? Start to wheeze? Get a feeling of tightness in your chest? Start to feel short of breath? Get a runny or stuffy nose or start to sneeze? Get itching or watering eyes? | 0=No 1=Yes 9=Unknown |
| 2. When you are near trees, grass, or flowers, or when there is a lot of pollen in the air, do you ever | | |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | Start to cough? Start to wheeze? Get a feeling of tightness in your chest? Start to feel short of breath? Get a runny or stuffy nose or start to sneeze? Get itching or watering eyes? | 0=No 1=Yes 9=Unknown |
| 3. When you are at your current job, do you ever | | |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | Start to cough? Start to wheeze? Get a feeling of tightness in your chest? Start to feel short of breath? Get a runny or stuffy nose or start to sneeze? Get itching or watering eyes? | 0=No 1=Yes 9=Unknown <i>8=No</i> |
| 4. When you are near strong odors such as perfume or bleach, do you ever | | |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | Start to cough? Start to wheeze? Get a feeling of tightness in your chest? Start to feel short of breath? | 0=No 1=Yes 9=Unknown |
| 5. When you exercise or exert yourself or when the air is cold, do you ever | | |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | Start to cough? Start to wheeze? Get a feeling of tightness in your chest? Start to feel short of breath? | 0=No 1=Yes 9=Unknown |
| <input type="checkbox"/> | 6. Do you currently have a cat, dog, or other furry pets living in your home? | |
| <input type="checkbox"/> | 7. Have you ever been exposed at work to vapors, gas dust or fumes? | |
| <input type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> Total years exposed | 0=No, 1=Yes 9=Don't know 99=Don't know |

54.1

g3a 539- g3a 565

The Respiratory Disease Questionnaire
(Technician Administered)

The technician administers this questionnaire to the participant between the first and second diffusion maneuvers. Machine preparation for the second maneuver should be started before the questionnaire is administered.

The questionnaire is administered exactly as written. The answers are recorded in numbers, as indicated in the answer keys to the right of the questions. The technician follows the prompts on the questionnaire for the progression to follow, based on 'Yes', ("if yes fill in ...") and 'No' responses.

There are questions that require explanation if the participant's response is 'Yes'. (Questions 5 & 6). If the participant has the specific information requested, the technician records that information.

If, on question 7, the participant answers 'Yes', that h/she has been exposed at work to vapors, gases, dust or fumes, **but also states that h/she uses a protective mask**, then the technician asks if the participant feels that lung exposure occurred despite the use of the mask. The use of the mask and the answer are written in the free space for question 7.

see PFT dataset

Changing the Tanks

1. Make sure that the tank is turned off by closing the valve clockwise.
2. Loosen the regulator by turning the screw on the back of the regulator.
3. Remove the regulator.
4. Check that valve on new tank is sealed in cellophane. If not, do not use and call Airgas for a replacement.
5. Place the regulator on the new bottle.
 - a. Ensure that the yellow gasket covers the outlet on the valve stem
 - b. Ensure the two pins on the regulator go into the receptacles on the valve stem.
 - c. CO valve is an outside thread. O2 valve is an inside thread.
6. Tighten the regulator by turning the screw on the back of the regulator.
7. Be sure that the valves are closed.

see PFT dataset

Supply List

For use with the Collins Comprehensive Pulmonary Laboratory (CPL)

Collins 2000 Plus/SQL Software version 4.03

And the Hewlett-Packard Deskjet 845c Printer

| <u>Item</u> | <u>Item Number</u> | <u>Vendor</u> |
|---|--------------------|--|
| Lung Diffusion Mix (.3% CO, .3% CH ₄ , 21% O ₂ , BAL N ₂) Size 200 | Z04NI78552003060 | Airgas East 199 Southeast Cutoff, Rt. 20 Worcester, MA 01604 (800) 562-3815 ext.4 jim.mariani@airgas.com |
| APC Smart-UPS Interruptible Power Supply | | Mill City Connections |
| Disposable Noseclip 100/box | | Moore Medical |
| HP 840c Black Ink Cartridge | | W.B. Mason |
| HP 840c Color Ink Cartridge | | W.B. Mason |

CPLpf System Catalogue – No. 004010

| | | |
|--|---------|---------|
| DC II Filter with Mouthpiece (White) 400/box | 0022464 | Collins |
| Balloon Kit – Set of 4 (B1, B2, B3, B4) | 700885 | Collins |
| Balloon Maintenance Kit | 710076 | Collins |
| Disposable Hydrus Dessicator Columns | 21501 | Collins |

CPL System Catalogue – No. 004000

| | | |
|---------------|--------|---------|
| Nafion Tubing | 360031 | Collins |
|---------------|--------|---------|

See PFT dataset

Maintenance Schedule

Maintenance information taken from:
The Instruction Manual for the Collins Comprehensive Pulmonary Laboratory (CPL)
No. 760096, Version August 2000

| <u>Item</u> | <u>Frequency</u> | <u>Page</u> |
|--|------------------------------|-------------|
| Cleaning of CPL Covers and External Components | As Needed | 23 |
| Replacing CO ₂ Absorbent Cartridge | Every 3 Months | 26 |
| Replacing Desiccator Columns | When Blue Granules turn Pink | 27 |
| Replacing Balloon Cuffs in Valve* | As Needed | 31 |
| Cleaning of Balloon Valve | As Needed | 35 |
| Change Nafion Tubing | Every 4 months | 29 |
| 3.00 Liter Hans Rudolph Calibration Syringe | Annually | |

Send to:
PDS Ferraris
CardioRespiratory
908 Main Street
Louisville, CO 80027
(800) 574-7374

* The balloons must be inflated and deflated 50 times before use. We have an extra balloon valve so that a full set of balloons are prepped and readied for use. The valves are switched with the prepped balloons already attached when needed.

For Administrative Purposes Only

Spirometry
Supervisor Checklist for DLCO

Date: _____

Technician #: _____

Supervisor: _____

Participant name & ID #: _____

Instruction: Check that each procedure is carried out correctly. Circle **y** (*yes*) if correct. If incorrect, circle **n** (*no*) and provide an explanation in the comment section following the item. Items are presented in the sequence of the examination procedure, but may require confirmation before or after the examination.

DLCO Preparation:

Comments:

- y n The participant is still seated in the chair.
- y n The technician clicks on the 'Spirometry' tab and selects 'Diffusion' and clicks on 'Start Test' to start the machine prep.

DLCO Testing Procedure:

- y n While the machine preps for the diffusion maneuver, the tech explains the testing procedure. The participant is instructed that s/he will still use the noseclip and the mouthpiece and that s/he will still start the test by breathing normally into the machine. The tech explains that at a point during the normal breathing, the participant will be asked to "Blow everything out" or to "Empty out your lungs". The participant is told that s/he will then be instructed to take in a **fast, deep** breath and then to hold the breath for 12 seconds. S/he is told that a valve will be closed to help hold the breath. The participant is told that after 12 seconds s/he will be asked to "Blow out all the air" and coached to keep blowing out until asked to stop.
- y n The breathing technique for diffusion is then demonstrated by the tech. At some point during instructions, the tech will explain that 2 reproducible maneuvers are needed and that it may be necessary to do 3 trials to achieve this.
- y n When the tech sees the prompt on the screen, the participant is instructed to place the mouthpiece in his/her mouth and to start breathing normally. The tech checks the mouthpiece placement and also checks for a tight lip seal.
- y n The tech watches the participant and the screen for normal breathing patterns. After 2-3 normal breathes in and out, the tech explains that after the next breath in, the participant can blow all of the air out of his/her lungs. The tech watches for normal inhalation wave and then prompts with "Now push all the air out, keep going, keep going, keep going."

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- y n The tech watches the participant and then checks the screen for the plateau indicating maximum exhalation. The tech prompts the participant to "Take a fast, deep breath in and hold it!" Coaching with "Hold it, hold it, good job, keep holding your breath" (etc), the tech watches for the timing line to intersect the line marking 12 seconds. The tech then prompts the participant to "Blow the air out, blow all of the air out, keep going..." until the tech can again see a bottom plateau indicating the participant has fully exhaled. The participant is then instructed to take the mouthpiece out and that the maneuver is complete.
- y n The tech looks at the grades for this maneuver (as with the FVC) and, if all positive, continues with the participant for another DLCO maneuver. If the grades are not all positive, then the tech reviews whatever improvement is needed.
- y n The tech waits at least 4 minutes between DLCO maneuvers.
- y n There must be 2 reproducible (within 10%) DLCO maneuvers. The maximum number of DLCO maneuvers does not exceed 3.
- y n The tech picks the best DLCO maneuver and clicks on that box to highlight and choose it. The tech saves this portion of the spirometry exam.
- y n The tech clicks on 'Notes' tab if there is any pertinent information that should be included with this participant's testing.
- y n The tech prints out 2 copies of this test and initials both copies in the lower left corner.

Overall Comments of Supervisor:

Instructions to technician/corrective action:

Signature, Supervisor 8/02

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Spirometry

Supervisor Checklist for FVC

Date: _____

Technician #: _____

Supervisor: _____

Participant name & ID #: _____

Instruction: Check that each procedure is carried out correctly. Circle y (yes) if correct. If incorrect, circle n (no) and provide an explanation in the comment section following the item. Items are presented in the sequence of the examination procedure, but may require confirmation before or after the examination.

FVC Preparation:

Comments:

- y n The participant is seated in the chair.
- y n Participant is asked if s/he has, within the past three months, had any major surgery, a heart attack, stroke or aneurysm, or if s/he has had any recent procedures that would be adversely affected by inhaling and exhaling strenuously.
- y n Participant's blood pressure is <210/120
- y n Participant's name, ID#, birthdate, height, weight, and gender are correctly entered. Technician's initials are entered in the 'Administrator's' box. This screen is saved and the participant's name appears in the 'Cache' at the top of the screen.
- y n The technician clicks on the 'Spirometry' tab and then onto the FVC screen and starts the PFT machine prep. (Spirometry bell fills up.)

FVC Testing Procedure:

- y n The participant is given a kit with a mouthpiece and filter and shown how to put it together. Tech helps if necessary.
- y n The tech explains the procedure for testing, explaining to breathe normally and, when prompted, take in as deep a breath as possible and then blow out, into the mouthpiece, as hard and fast as possible, maintaining the exhale for 6 seconds or until told to stop. The tech demonstrates the correct technique, including how to use the mouthpiece.
- y n The participant is advised to stop blowing if s/he feels light-headed or dizzy or if s/he feels any discomfort.
- y n Participant is made aware that 3 matches are needed, and that it may take more than three trials to achieve this goal.

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- y n When prompted by the screen message, the tech tells participant to place the mouthpiece into her/his mouth. The tech checks correct placement of the mouthpiece and makes sure a noseclip is in place.
- y n Examiner instructs participant to breathe in and out normally and watches the graph screen. At the appropriate time, tech instructs the participant to "Take a deep breath in!" followed by "Blast it out!".
- y n The tech *watches the participant* to make sure s/he follows instructions.
- y n The tech *continuously coaches* the participant to "Keep pushing!", "Keep going!", "Empty out all the air!" or uses similar commands.
- y n When the 'Good Effort' message appears on the screen, (which will be after at least 6 seconds of continuous exhalation) tech instructs the participant to stop and take the mouthpiece out of his/her mouth.
- y n The tech saves each maneuver by clicking on the 'Save' tab on the toolbar.
- y n The tech makes sure the participant is feeling well and repeats the procedure until 3 acceptable maneuvers (2 of which must be reproducible within 5%) are obtained. The tech stops if the participant wants to quit testing. The tech stops testing after 8 unsuccessful (unacceptable by protocol) maneuvers for FVC have been completed.
- y n The tech selects the trial with the highest sum of FVC and FEV1 for printing by clicking on the top row of that selected trial and then clicking on the 'Choose' tab on the toolbar. The selected trial number appears with a check mark under the 'Choose' tab.

Overall Comments of Supervisor:

Instructions to technician/corrective action:

Signature, Supervisor 8/02

For Administrative Purposes Only

PFT DATABASE BACKUP

Extracting the Database to a File:

1. Within the Plus2000 program, click on Database Utilities. The program allows a search, so a single ID number can be backed up, or all of the data within a specific date range can be backed up.
2. Set the date 'From' and 'To' be backed up and click 'OK'
3. A list of all participants within that range will appear on the left side of the screen.
4. Use the 'Select All' option or select only specific tests to back up. Whatever is selected will move to the right of the screen.
5. Click on the 'Extract' option and enter a filename into the prompt.
6. The status bar at the bottom of the screen will follow the status of the extraction process until it is complete. The more data there is, the longer this will take.

Backing up the Database:

1. The software is equipped with a Database Backup/Restore Wizard.
2. Go to: Start/All Programs/Plus2000.
3. Once the program starts, click on 'Backup' and the prompt asks for a filename. Put in the filename and the process will complete.

Appendix

For Administrative Purposes Only

PFT DAILY PROCEDURES

1. TURN ON: SPIROMETER SWITCH, COMPUTER, AND MONITOR.
2. OPEN VALVES ON GASES. TURN:
COUNTERCLOCKWISE ALL THE WAY TO OPEN
CLOCKWISE ALL THE WAY TO CLOSE
3. CALIBRATE EQUIPMENT
4. PRINT CALIBRATION REPORT FOR LOG RECORD
5. DATE LOG BOOK AND PUT ID STICKERS FOR EACH EXPECTED PARTICIPANT
6. RECORD ANY/ALL COMMENTS IF ISSUES ARISE OR IF PARTICIPANT REFUSES TEST OR HAS TO STOP TEST
7. SHUT DOWN SPIROMETER, MONITOR, AND COMPUTER AT END OF TESTING
8. CLOSE THE GAS VALVES, CLOCKWISE ALL THE WAY EVERY DAY AFTER TESTING IS DONE

see PFT dataset

PFT EXCLUSIONS CRITERIA

IN THE PAST THREE MONTHS HAVE YOU HAD:

- MAJOR SURGURY (Chest, Abdominal, or Brain requiring hospitalization)?
- HEART ATTACK?
- STROKE?
- ANEURYSM?

WHERE IS THE ANEURYSM?

- BP > 210/110?

| Measured Value | -2% | +2% | -5% | +5% |
|----------------|-------|-------|--------|--------|
| 0.5 | 0.49 | 0.51 | 0.475 | 0.525 |
| 0.55 | 0.539 | 0.561 | 0.5225 | 0.5775 |
| 0.6 | 0.588 | 0.612 | 0.57 | 0.63 |
| 0.65 | 0.637 | 0.663 | 0.6175 | 0.6825 |
| 0.7 | 0.686 | 0.714 | 0.665 | 0.735 |
| 0.75 | 0.735 | 0.765 | 0.7125 | 0.7875 |
| 0.8 | 0.784 | 0.816 | 0.76 | 0.84 |
| 0.85 | 0.833 | 0.867 | 0.8075 | 0.8925 |
| 0.9 | 0.882 | 0.918 | 0.855 | 0.945 |
| 0.95 | 0.931 | 0.969 | 0.9025 | 0.9975 |
| 1 | 0.98 | 1.02 | 0.95 | 1.05 |
| 1.05 | 1.029 | 1.071 | 0.9975 | 1.1025 |
| 1.1 | 1.078 | 1.122 | 1.045 | 1.155 |
| 1.15 | 1.127 | 1.173 | 1.0925 | 1.2075 |
| 1.2 | 1.176 | 1.224 | 1.14 | 1.26 |
| 1.25 | 1.225 | 1.275 | 1.1875 | 1.3125 |
| 1.3 | 1.274 | 1.326 | 1.235 | 1.365 |
| 1.35 | 1.323 | 1.377 | 1.2825 | 1.4175 |
| 1.4 | 1.372 | 1.428 | 1.33 | 1.47 |
| 1.45 | 1.421 | 1.479 | 1.3775 | 1.5225 |
| 1.5 | 1.47 | 1.53 | 1.425 | 1.575 |
| 1.55 | 1.519 | 1.581 | 1.4725 | 1.6275 |
| 1.6 | 1.568 | 1.632 | 1.52 | 1.68 |
| 1.65 | 1.617 | 1.683 | 1.5675 | 1.7325 |
| 1.7 | 1.666 | 1.734 | 1.615 | 1.785 |
| 1.75 | 1.715 | 1.785 | 1.6625 | 1.8375 |
| 1.8 | 1.764 | 1.836 | 1.71 | 1.89 |
| 1.85 | 1.813 | 1.887 | 1.7575 | 1.9425 |
| 1.9 | 1.862 | 1.938 | 1.805 | 1.995 |
| 1.95 | 1.911 | 1.989 | 1.8525 | 2.0475 |
| 2 | 1.96 | 2.04 | 1.9 | 2.1 |
| 2.05 | 2.009 | 2.091 | 1.9475 | 2.1525 |
| 2.1 | 2.058 | 2.142 | 1.995 | 2.205 |
| 2.15 | 2.107 | 2.193 | 2.0425 | 2.2575 |
| 2.2 | 2.156 | 2.244 | 2.09 | 2.31 |
| 2.25 | 2.205 | 2.295 | 2.1375 | 2.3625 |
| 2.3 | 2.254 | 2.346 | 2.185 | 2.415 |
| 2.35 | 2.303 | 2.397 | 2.2325 | 2.4675 |
| 2.4 | 2.352 | 2.448 | 2.28 | 2.52 |
| 2.45 | 2.401 | 2.499 | 2.3275 | 2.5725 |
| 2.5 | 2.45 | 2.55 | 2.375 | 2.625 |
| 2.55 | 2.499 | 2.601 | 2.4225 | 2.6775 |
| 2.6 | 2.548 | 2.652 | 2.47 | 2.73 |
| 2.65 | 2.597 | 2.703 | 2.5175 | 2.7825 |
| 2.7 | 2.646 | 2.754 | 2.565 | 2.835 |
| 2.75 | 2.695 | 2.805 | 2.6125 | 2.8875 |
| 2.8 | 2.744 | 2.856 | 2.66 | 2.94 |
| 2.85 | 2.793 | 2.907 | 2.7075 | 2.9925 |
| 2.9 | 2.842 | 2.958 | 2.755 | 3.045 |
| 2.95 | 2.891 | 3.009 | 2.8025 | 3.0975 |
| 3 | 2.94 | 3.06 | 2.85 | 3.15 |

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| | | | | |
|------|-------|-------|--------|--------|
| 3.05 | 2.989 | 3.111 | 2.8975 | 3.2025 |
| 3.1 | 3.038 | 3.162 | 2.945 | 3.255 |
| 3.15 | 3.087 | 3.213 | 2.9925 | 3.3075 |
| 3.2 | 3.136 | 3.264 | 3.04 | 3.36 |
| 3.25 | 3.185 | 3.315 | 3.0875 | 3.4125 |
| 3.3 | 3.234 | 3.366 | 3.135 | 3.465 |
| 3.35 | 3.283 | 3.417 | 3.1825 | 3.5175 |
| 3.4 | 3.332 | 3.468 | 3.23 | 3.57 |
| 3.45 | 3.381 | 3.519 | 3.2775 | 3.6225 |
| 3.5 | 3.43 | 3.57 | 3.325 | 3.675 |
| 3.55 | 3.479 | 3.621 | 3.3725 | 3.7275 |
| 3.6 | 3.528 | 3.672 | 3.42 | 3.78 |
| 3.65 | 3.577 | 3.723 | 3.4675 | 3.8325 |
| 3.7 | 3.626 | 3.774 | 3.515 | 3.885 |
| 3.75 | 3.675 | 3.825 | 3.5625 | 3.9375 |
| 3.8 | 3.724 | 3.876 | 3.61 | 3.99 |
| 3.85 | 3.773 | 3.927 | 3.6575 | 4.0425 |
| 3.9 | 3.822 | 3.978 | 3.705 | 4.095 |
| 3.95 | 3.871 | 4.029 | 3.7525 | 4.1475 |
| 4 | 3.92 | 4.08 | 3.8 | 4.2 |
| 4.05 | 3.969 | 4.131 | 3.8475 | 4.2525 |
| 4.1 | 4.018 | 4.182 | 3.895 | 4.305 |
| 4.15 | 4.067 | 4.233 | 3.9425 | 4.3575 |
| 4.2 | 4.116 | 4.284 | 3.99 | 4.41 |
| 4.25 | 4.165 | 4.335 | 4.0375 | 4.4625 |
| 4.3 | 4.214 | 4.386 | 4.085 | 4.515 |
| 4.35 | 4.263 | 4.437 | 4.1325 | 4.5675 |
| 4.4 | 4.312 | 4.488 | 4.18 | 4.62 |
| 4.45 | 4.361 | 4.539 | 4.2275 | 4.6725 |
| 4.5 | 4.41 | 4.59 | 4.275 | 4.725 |
| 4.55 | 4.459 | 4.641 | 4.3225 | 4.7775 |
| 4.6 | 4.508 | 4.692 | 4.37 | 4.83 |
| 4.65 | 4.557 | 4.743 | 4.4175 | 4.8825 |
| 4.7 | 4.606 | 4.794 | 4.465 | 4.935 |
| 4.75 | 4.655 | 4.845 | 4.5125 | 4.9875 |
| 4.8 | 4.704 | 4.896 | 4.56 | 5.04 |
| 4.85 | 4.753 | 4.947 | 4.6075 | 5.0925 |
| 4.9 | 4.802 | 4.998 | 4.655 | 5.145 |
| 4.95 | 4.851 | 5.049 | 4.7025 | 5.1975 |
| 5 | 4.9 | 5.1 | 4.75 | 5.25 |
| 5.05 | 4.949 | 5.151 | 4.7975 | 5.3025 |
| 5.1 | 4.998 | 5.202 | 4.845 | 5.355 |
| 5.15 | 5.047 | 5.253 | 4.8925 | 5.4075 |
| 5.2 | 5.096 | 5.304 | 4.94 | 5.46 |
| 5.25 | 5.145 | 5.355 | 4.9875 | 5.5125 |
| 5.3 | 5.194 | 5.406 | 5.035 | 5.565 |
| 5.35 | 5.243 | 5.457 | 5.0825 | 5.6175 |
| 5.4 | 5.292 | 5.508 | 5.13 | 5.67 |
| 5.45 | 5.341 | 5.559 | 5.1775 | 5.7225 |

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17. Appendix

17. a. Postcard Mailing

For Administrative purposes only



NO POSTAGE
NECESSARY
IF MAILED
IN THE
UNITED STATES

BUSINESS REPLY MAIL
FIRST-CLASS MAIL PERMIT NO. 1271 FRAMINGHAM, MA

POSTAGE WILL BE PAID BY ADDRESSEE

FRAMINGHAM HEART STUDY
5 THURBER ST
FRAMINGHAM, MA 01702-9917



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For Administrative purposes only

Please send me more information

I would like to participate



Name/Address Correction, Please



For Administrative Purposes Only
The Framingham Heart Study

Dear

For the past half century the Framingham Heart Study has pioneered in the discovery of risk factors for heart disease and stroke. Findings from Framingham about the adverse health effects of high blood pressure, smoking, high cholesterol and other conditions have improved the health of countless people worldwide.

These achievements have been made possible by the remarkable dedication of the Study participants--your parents and grandparents. Now the study is about to enter a new phase: the enrollment of a third generation of participants. **We are delighted to invite you to be part of this landmark study.** We believe this step is of vital importance to increase our understanding of the causes of heart disease and stroke, and especially how these conditions affect families.

What would your participation involve? As part of the Third Generation you will be asked to visit the Framingham Heart Study clinic for an examination. You may benefit directly from information obtained and tests performed at your visit, the results of which will be sent to your designated physician. Of course, all testing is free of charge.

If you are interested in finding out more about joining Framingham's Third Generation Study, please fill out the enclosed prepaid postcard and return it to us. In the next few months, you will receive additional information about the Third Generation Study, including how to enroll.

The Framingham Heart Study owes its success to the participation of your parents and grandparents. The future success of the Study depends on your participation in this newest phase, the Third Generation of the Framingham Heart Study. We hope you will join us in this important project. Your participation will ensure that people all over the world will continue to benefit from future discoveries about medical conditions that will be made in Framingham.

Welcome to the Framingham Heart Study!

Yours sincerely,

Director, Framingham Heart Study
National Heart, Lung, and Blood Institute

Principal Investigator, Framingham Heart Study
Boston University

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The Framingham Heart Study
The National Heart, Lung & Blood Institute
and Boston University

The Framingham Heart Study

Thank you...

for your loyal commitment to the betterment of
the public health worldwide.

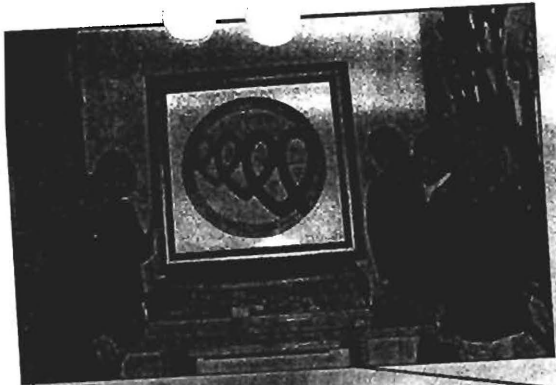


For Administrative Purposes Only

Framingham Heart Study
73 Mt. Wayte Avenue
Framingham, MA 01702
Tel (800) 854-7582
Fax (508) 626-1262

www.nhlbi.nih.gov/about/framingham/index.html

*Three Generations
1948 - 1971 - 2002*



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What is the Framingham Heart Study?

♥ The Framingham Heart Study is a long term community health study begun in 1948 to identify factors that contribute to the development of heart disease and stroke. Over these past 53 years, "risk factors" such as elevated cholesterol, high blood pressure, obesity, diabetes, and smoking have become familiar terms throughout the world. The original study group consisted of 5,209 men and women from the town of Framingham; in 1971 the Heart Study enrolled its second study sample consisting of 5,124 offspring (and some spouses of offspring) of original participants; and now in 2002 the Heart Study will enroll a third generation of participants. This third generation will provide a unique opportunity for Heart Study researchers to look at patterns of disease within families and to search for genetic factors linked to cardiovascular disease and its risk factors. The National Heart, Lung, and Blood Institute funds the Heart Study through a contract with Boston University School of Medicine.

How can I become a participant in the third generation of the Framingham Heart Study?

♥ We are looking for those who have at least one parent in the offspring study and will be 20 years of age by December 31, 2004. If you are eligible, you may participate regardless of where you live. At this time spouses will not be included.

If I am eligible, what will happen next?

♥ You will receive a questionnaire within the next three years from the third generation coordinator, [REDACTED], or a member of her staff. After you return the completed form to her, you will be contacted to schedule an appointment to visit our clinic.

What will happen during my clinic visit?

♥ During your visit you will have an opportunity to ask any questions you may have and be provided with details about the study. You will then be asked if you wish to participate in the study and to sign a consent form. A physician will obtain your medical history and perform a brief examination. You will undergo several tests administered by trained technicians using state-of-the-art equipment. These tests may include an echocardiogram (a test that provides images of the heart) and lung function (blowing into a container that measures your lung capacity). You may be asked to participate in other tests as well.

The time spent during this clinic visit will be approximately four hours or less.

Is the information I provide confidential?

♥ All the information you provide is held in the strictest confidence and will be used for research purposes only. Your anonymity will be protected at all times. Your medical and health history will NEVER be divulged to anyone without your permission. Blood samples that are collected will have a bar code and will not have your name on them.

What is the benefit of my participation?

♥ First and foremost your participation will enable the Framingham Heart Study to continue to make valuable research discoveries to improve the health of people worldwide. The direct benefit to you will be that the results of your medical tests will be sent to you and your designated physician. This will all be done free of charge. If necessary, arrangements can be made to help with transportation costs associated with your clinic visit.

What if I have questions?

♥ You may call the Framingham Heart Study at a number listed below any time between 8a.m. and 5p.m. At other times you may leave a voicemail message, and someone will call you back as soon as possible to answer any questions you may have.

What if I am already enrolled?

♥ If you are already enrolled in the original cohort or offspring study, you will be contacted by one of our staff to schedule a clinic visit in the usual manner. If you have a child who will be 20 years old before December 31, 2004, who would like to join the Framingham Heart Study but has not received any information from us, please provide one of our study coordinators with his or her contact information.

| Study Group | Coordinator |
|------------------|-------------|
| Third Generation | [REDACTED] |
| Original Cohort | [REDACTED] |
| Offspring Study | [REDACTED] |
| Omni Study | [REDACTED] |

For Admin Purposes Only

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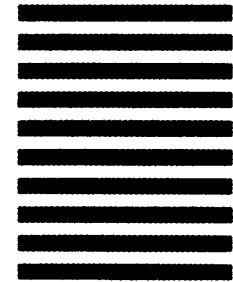
17. b. Enrollment Forms

BUSINESS REPLY MAIL
FIRST-CLASS MAIL PERMIT NO. 1271 FRAMINGHAM MA
POSTAGE WILL BE PAID BY ADDRESSEE

**FRAMINGHAM HEART STUDY
73 MT WAYTE AVE STE 2
FRAMINGHAM MA 01702-9774**



NO POSTAGE
NECESSARY
IF MAILED
IN THE
UNITED STATES



For Administrative Purposes Only

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Framingham Heart Study



Confidential Questionnaire

INSTRUCTIONS ON RETURNING THIS FORM

Please return in closed envelope to:
 [Redacted]
 Framingham Heart Study
 73 Mt. Wayte Street
 Framingham, MA 01702

Telephone Numbers:
 [Redacted]

THANK YOU!
 for completing this form and returning it to us.

For Administrative Purposes Only

You have been invited to enroll in the THIRD GENERATION OF THE FRAMINGHAM HEART STUDY. Please read the enclosed brochure and help us by completing this brief enrollment form.

1 Do you want to participate in the Framingham Heart Study?

Yes, I would like to participate. YES

No, I do not wish to participate. NO

(Please comment in section 5.)

2 Your name and address. (Please Print)

Dr. Mr. Mrs. Ms. (Circle One)

First _____ M.I. _____ Last _____

Street # _____ Street Name _____ Apt. # _____

City _____ State _____ Zip _____

() ()

Home Phone: _____ Work Phone: _____

E-mail _____

Check preferred method(s) of contact:

Home Work Email

3 Date of Birth _____ / _____ / _____ Male

Month Day Year

Female

(Please Check One)

4 Your parents' names and dates of birth, even if deceased. (Please Print)

Mother: _____ D.O.B. ____ / ____ / ____

First M.I. Last Month Day Year

Father: _____ D.O.B. ____ / ____ / ____

First M.I. Last Month Day Year

Please check if they EVER participated in the Framingham Heart Study.

Mother Yes No Unsure

Father Yes No Unsure

5. Comments: _____ 75

17. c. Appointment Letter
Mailing



For Administrative Purposes Only
The Framingham Heart Study

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 73 Mt. Wayte Avenue, in the **Perini Building**. The Framingham Heart Study offices are located in the wing at the **Franklin Street** side of the Building. **There is reserved parking for participants behind the Franklin Street wing.** Please see the enclosed map. The building is handicap accessible.

You should bring slippers and if you choose, bring your own robe. In order to perform certain tests, we ask that you **NOT** eat after 8:00 P.M. the previous evening. You may have **water, decaffeinated black coffee or tea (no creamer, milk or sugar)** that evening and again in the morning before your appointment. A urine sample will be collected when you arrive.

Please **take any prescription medications**, as you normally would.

Using the enclosed **MEDICATION BAG**, please bring all prescription and nonprescription medications you currently take or have taken in the past month **in their original containers. They will be returned to you before you leave.**

ON THE BACK OF THIS SHEET, please list information regarding hospitalizations and major illnesses you have experienced in the past. **PLEASE BRING THIS LETTER WITH YOU TO 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 _____, Project Coordinator at _____ locally and for long distance at _____

Welcome to the Framingham Heart Study!

Sincerely yours,

Director
Framingham Heart Study

OVER →

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For Administrative 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

| Date | Reason | Hospital Name & Address | Doctor's Name |
|-------|--------|-------------------------|---------------|
| _____ | _____ | _____ | _____ |
| _____ | _____ | _____ | _____ |
| _____ | _____ | _____ | _____ |

Doctor Office Visits

| Date | Reason | Doctor's Name |
|-------|--------|---------------|
| _____ | _____ | _____ |
| _____ | _____ | _____ |
| _____ | _____ | _____ |

For Administrative Purposes Only

DIRECTIONS

Mass Pike Eastbound, Exit 12 or Route 9 Eastbound

Route 9 East to the "Edgell Rd, Main St, Framingham" exit. Turn right at the end of ramp to Main Street/Union Ave. Take the 2nd right onto Franklin Street. Follow Franklin St for ½ mile (past the blinking light). Take a left into the Heart Study (Perini) parking lot. Go to the far left of the parking lot, behind the building to the Heart Study parking spaces.

Mass Pike Westbound, Exit 13

After tollbooth, bear right towards Framingham, Route 30 West. Proceed on Route 30 straight until the end. Turn right onto Route 9 West. Follow Route 9 West to the "30 West, Framingham, Southboro" exit. At the end of the ramp (at the traffic light, not before!) go left onto Main Street. Go through 1 quick traffic light and take the 2nd right onto Franklin Street. Follow Franklin St for ½ mile (past the blinking light). Take a left into the Heart Study (Perini) parking lot. Go to the far left of the parking lot, behind the building to the Heart Study parking spaces.

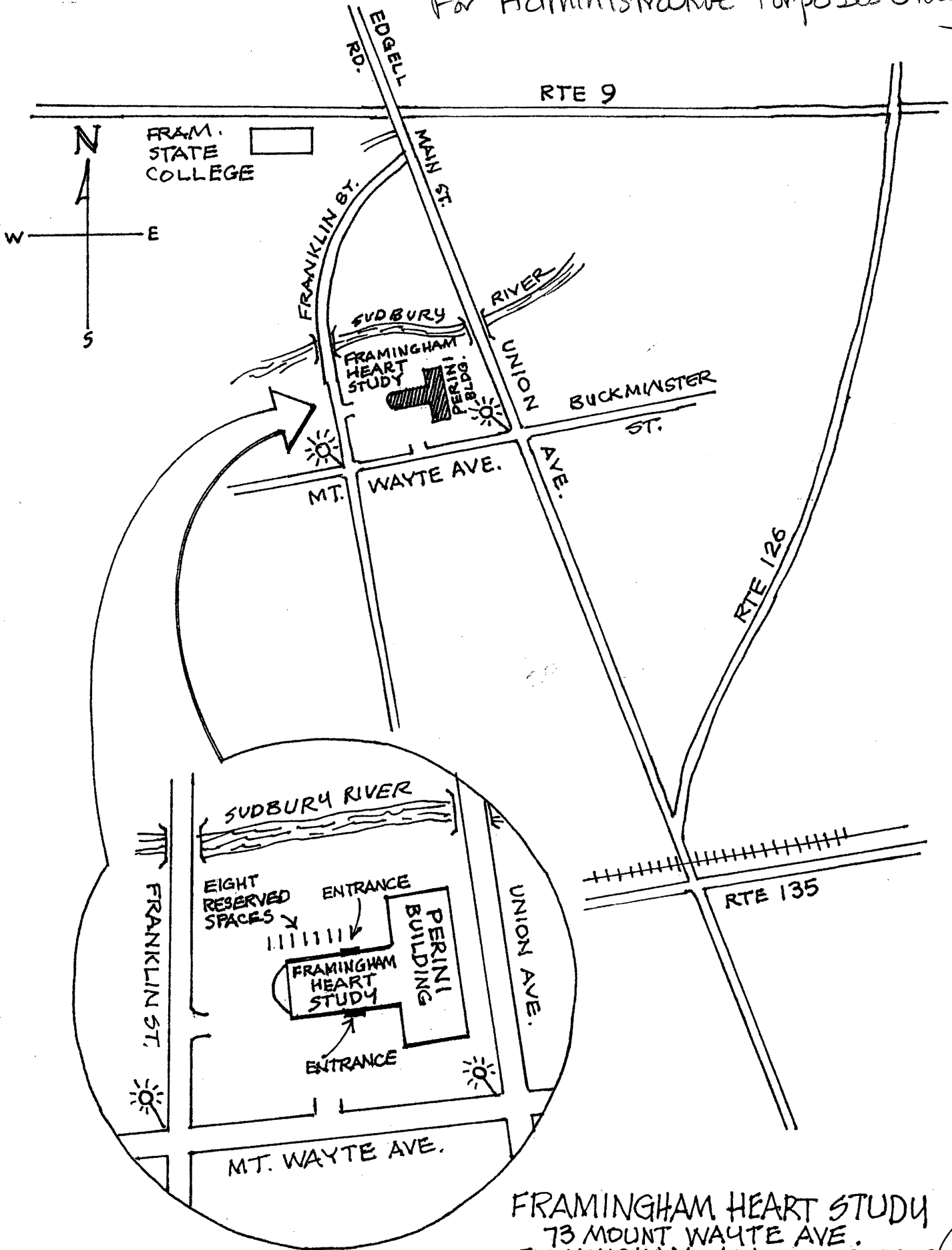
Route 9 Westbound

Follow Route 9 West to the "30 West, Framingham, Southboro" exit. At the end of the ramp (at the traffic light, not before!) go left onto Main Street. Go right onto Franklin Street. Follow Franklin St for ½ mile (past the blinking light). Take a left into the Heart Study (Perini) parking lot. Go to the far left of the parking lot, behind the building to the Heart Study parking spaces.

PLEASE SEE MAP ON BACK.

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For Administrative Purposes Only



FRAMINGHAM HEART STUDY
73 MOUNT WAYTE AVE.
FRAMINGHAM, MA 01702-5803

508.872.6562

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17. d. Intake Form

For Administrative Purposes Only

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1

Keyer: _____

GEN 3 EXAM 1 ADMITTING FORM

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: _____

2. Prefix: _____

3. Name: _____
 (First) (MI) (Last)

4. Date of Birth: _____

5. Sex: _____

6. Address: _____

 (City) (State) (Zip Code)

Home Phone Number: _____

Work Phone Number: _____

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

7. Email: _____

8. Preferred Method of Contact: Home: 1 - Yes
 Work: 1 - Yes
 Email: 1 - Yes
 Cellular: _____

| | |
|---|-------|
| 0 | No |
| 1 | Yes |
| 2 | Never |
| 8 | N/A |

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For Administrative Purposes Only

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SECTION A - TRACKING INFORMATION (SELF)

9. Also Known As: _____

10. Maiden Name: _____

11. 2nd Address: _____

(City)

(State)

(Zip Code)

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

12. 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.

13. Place of Employment: _____

Address: _____

(City)

(State)

(Zip Code)

Occupation: _____

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SECTION B – TRACKING INFORMATION (SPOUSE/PARTNER)

CURRENT SPOUSE/PARTNER

1. Current Spouse/Partner's Name: _____
(Prefix) (First) (MI) (Last)

(Please Circle one)

Status: Spouse / Partner / Divorce

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

(City) (State) (Zip Code)

3. Telephone Number if Different: |_|_|_|_| - |_|_|_|_| - |_|_|_|_|_|

4. Work Telephone Number: |_|_|_|_| - |_|_|_|_| - |_|_|_|_|_|

PREVIOUS SPOUSE/PARTNER

1. Previous Spouse/Partner's Name: _____
(Prefix) (First) (MI) (Last)

(Please Circle one)

Status: Spouse / Partner / Divorce

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

(City) (State) (Zip Code)

3. Home Telephone Number: |_|_|_|_| - |_|_|_|_| - |_|_|_|_|_|

4. Work Telephone Number: |_|_|_|_| - |_|_|_|_| - |_|_|_|_|_|

For Administrative Purposes Only 4

SECTION C – TRACKING INFORMATION (PARENTS)

FATHER

1. Father's Name: _____
(First) (MI) (Last)

2. Date of Birth: **10/14/1925**

Please spell out first, middle, last names and date of birth to verify. Circle if correct, otherwise edit.

3. Living: Yes / No

4. Father's Address: _____
(Number) (Street) (Apt. #)

(City) (State) (Zip Code)

5. Father's Telephone Number: |_|_|_|_| - |_|_|_|_| - |_|_|_|_|_|

PARENT VERIFICATION

Is the father's name correct (refer to question #1 above)?

YES



If " " is the CORRECT father's name, enter " " into Roster.



NO



If " " is NOT the correct father's name, find the CORRECTED father's name in Roster.



Record Roster ID Number and Date of Birth below.

If the correct name DOES NOT APPEAR, fill-in the spaces below with "9"s

Ex: ID#: 9-9999
DOB: 99-99-99

If the correct name APPEARS, record Roster ID Number and Date of Birth below.

If the correct name DOES NOT APPEAR, fill-in the spaces below with "9"s

Ex: ID#: 9-9999
DOB: 99-99-99

Record Roster ID Number here: |_|_| - |_|_|_|_|_|

Record Roster Date of Birth here: |_|_| - |_|_| - |_|_|_|

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For Administrative Purposes Only 5

SECTION C - TRACKING INFORMATION (PARENTS)

MOTHER

1. Mother's Name: _____
(First) (MI) (Last)

2. Date of Birth: _____

3. Living: Yes / No

4. Mother's Address: _____
(Number) (Street) (Apt. #)

(City) (State) (Zip Code)

5. Mother's Telephone Number: |_|_|_|_| - |_|_|_|_| - |_|_|_|_|_|

Please spell out first, middle, last names and date of birth to verify. Circle if correct, otherwise edit.

PARENT VERIFICATION

Is the mother's name correct (refer to question #1 above)?

YES



If "_____" is the CORRECT mother's name, enter "_____" into Roster.



Record Roster ID Number and Date of Birth below.

If the correct name DOES NOT APPEAR, fill-in the spaces below with "9"s

Ex: ID#: 9-9999
DOB: 99-99-99

NO



If "_____" is NOT the correct mother's name, find the CORRECTED mother's name in Roster.



If the correct name APPEARS, record Roster ID Number and Date of Birth below.

If the correct name DOES NOT APPEAR, fill-in the spaces below with "9"s

Ex: ID#: 9-9999
DOB: 99-99-99

Record Roster ID Number here: |_|_| - |_|_|_|_|_|

Record Roster Date of Birth here: |_|_| - |_|_| - |_|_|

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For Administrative Purposes Only

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SECTION D - CONTACTS

RELATIVE AT DIFFERENT ADDRESS

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

2. Relationship: _____

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

(City) (State) (Zip Code)

4. Telephone number: | | | | - | | | | - | | | | |

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

CLOSE FRIEND AT DIFFERENT ADDRESS

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

2. Relationship: _____

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

(City) (State) (Zip Code)

4. Telephone number: | | | | - | | | | - | | | | |

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

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For Administrative Purposes Only 7

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:

[] [] [] - [] [] [] - [] [] [] []

For Administrative Purposes Only 8

SECTION F – SIBLINGS (BROTHERS AND SISTERS)

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

Number of Sibling(s): _____

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

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

Tech ID#: _____

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

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

 (City) (State) (Zip Code)

Also Known As: _____
 (Prefix) (First) (MI) (Last)

Telephone number: |_|_|_| - |_|_|_| - |_|_|_|_|_|

(Please Circle one)
 Gender: Male / Female Relationship: Full / Half / Step / Adopted

Date of Birth: |_|_| - |_|_| - |_|_| Age: _____

Living: Yes / No

If NO, Year of Death: |_|_|_|_|

Cause of Death: _____

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

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SECTION F – SIBLINGS (BROTHERS AND SISTERS)

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

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

(City) (State) (Zip Code)

Also Known As: _____
(Prefix) (First) (MI) (Last)

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

(Please Circle one)

Gender: Male / Female

Relationship: Full / Half / Step / Adopted

Date of Birth: | | | | - | | | | - | | | | Age: _____

Living: Yes / No

If NO, Year of Death: | | | | |

Cause of Death: _____

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

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SECTION F – SIBLINGS (BROTHERS AND SISTERS)

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

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

(City) (State) (Zip Code)

Also Known As: _____
(Prefix) (First) (MI) (Last)

Telephone number: |_|_|_| - |_|_|_| - |_|_|_|_|_|

(Please Circle one)

Gender: Male / Female

Relationship: Full / Half / Step / Adopted

Date of Birth: |_|_| - |_|_| - |_|_| Age: _____

Living: Yes / No

If NO, Year of Death: |_|_|_|_|

Cause of Death: _____

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

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SECTION F - SIBLINGS (BROTHERS AND SISTERS)

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

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

(City) (State) (Zip Code)

Also Known As: _____
(Prefix) (First) (MI) (Last)

Telephone number: |__|__|__| - |__|__|__| - |__|__|__|__|

(Please Circle one)

Gender: Male / Female

Relationship: Full / Half / Step / Adopted

Date of Birth: |__|__| - |__|__| - |__|__| Age: _____

Living: Yes / No

If NO, Year of Death: |__|__|__|

Cause of Death: _____

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

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SECTION F – SIBLINGS (BROTHERS AND SISTERS)

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

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

(City) (State) (Zip Code)

Also Known As: _____
(Prefix) (First) (MI) (Last)

Telephone number: |_|_|_|_| - |_|_|_|_| - |_|_|_|_|_|

(Please Circle one)

Gender: Male / Female

Relationship: Full / Half / Step / Adopted

Date of Birth: |_|_|_|_| - |_|_|_|_| - |_|_|_|_| Age: _____

Living: Yes / No

If NO, Year of Death: |_|_|_|_|_|

Cause of Death: _____

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

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SECTION F – SIBLINGS (BROTHERS AND SISTERS)

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

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

(City) (State) (Zip Code)

Also Known As: _____
(Prefix) (First) (MI) (Last)

Telephone number: |__|__|__| - |__|__|__| - |__|__|__|__|

(Please Circle one)

Gender: Male / Female

Relationship: Full / Half / Step / Adopted

Date of Birth: |__|__| - |__|__| - |__|__| Age: _____

Living: Yes / No

If NO, Year of Death: |__|__|__|__|

Cause of Death: _____

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

More than 6 siblings? Yes _____ No _____

If YES, attach additional sheets!!!

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For Administrative Purposes Only

SECTION G – CHILDREN

List all children in birth order.

Number of Children: _____

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

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

(City) (State) (Zip Code)

Also Known As: _____
(Prefix) (First) (MI) (Last)

Telephone number: |_|_|_| - |_|_|_| - |_|_|_|

(Please Circle one)

Gender: Male / Female

Relationship: Full / Step / Adopted

Date of Birth: |_|_| - |_|_| - |_|_| Age: _____

Living: Yes / No

If NO, Year of Death: |_|_|_|

Cause of Death: _____

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

SECTION G - CHILDREN

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

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

(City) (State) (Zip Code)

Also Known As: _____
(Prefix) (First) (MI) (Last)

Telephone number: |_|_|_| - |_|_|_| - |_|_|_|_|_|

(Please Circle one)

Gender: Male / Female

Relationship: Full / Step / Adopted

Date of Birth: |_|_| - |_|_| - |_|_| Age: _____

Living: Yes / No

If NO, Year of Death: |_|_|_|_|

Cause of Death: _____

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

SECTION G – CHILDREN

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

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

(City) (State) (Zip Code)

Also Known As: _____
(Prefix) (First) (MI) (Last)

Telephone number: |_|_|_| - |_|_|_| - |_|_|_|

(Please Circle one)

Gender: Male / Female

Relationship: Full / Step / Adopted

Date of Birth: |_|_| - |_|_| - |_|_| Age: _____

Living: Yes / No

If NO, Year of Death: |_|_|_|

Cause of Death: _____

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

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SECTION G - CHILDREN

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

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

(City) (State) (Zip Code)

Also Known As: _____
(Prefix) (First) (MI) (Last)

Telephone number: |_|_|_|_| - |_|_|_|_| - |_|_|_|_|_|

(Please Circle one)

Gender: Male / Female

Relationship: Full / Step / Adopted

Date of Birth: |_|_|_|_| - |_|_|_|_| - |_|_|_|_| Age: _____

Living: Yes / No

If NO, Year of Death: |_|_|_|_|_|

Cause of Death: _____

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

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SECTION G - CHILDREN

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

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

(City) (State) (Zip Code)

Also Known As: _____
(Prefix) (First) (MI) (Last)

Telephone number: |_|_|_| - |_|_|_| - |_|_|_|_|_|

(Please Circle one)

Gender: Male / Female

Relationship: Full / Step / Adopted

Date of Birth: |_|_|_| - |_|_|_| - |_|_|_| Age: _____

Living: Yes / No

If NO, Year of Death: |_|_|_|_|

Cause of Death: _____

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

For Administrative Purposes Only

SECTION G - CHILDREN

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

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

(City) (State) (Zip Code)

Also Known As: _____
(Prefix) (First) (MI) (Last)

Telephone number: |_|_|_| - |_|_|_| - |_|_|_|

(Please Circle one)

Gender: Male / Female

Relationship: Full / Step / Adopted

Date of Birth: |_|_|_| - |_|_|_| - |_|_|_| Age: _____

Living: Yes / No

If NO, Year of Death: |_|_|_|_|

Cause of Death: _____

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

More than 6 children? Yes _____ No _____

If YES, attach additional sheets!!!

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17. e. Consent Form /
Exam Form



Boston University
School of Medicine

IRB Protocol#1910G

Title: THE FRAMINGHAM HEART STUDY

GENERATION III - Exam 1.5

Page 1 of 6



The Framingham Heart Study
Framingham, MA

NAME: _____

PERMISSION FOR INTERVIEW, EXAMINATION, TESTS AND RECORD REVIEWS
(One signed copy for participant, one signed copy for chart)

I. PRINCIPAL INVESTIGATOR:

_____, Medical Director, FHS
National Heart, Lung, and Blood Institute, NIH

_____- BOSTON UNIVERSITY SCHOOL OF MEDICINE

II. OTHER INVESTIGATORS:

III. INTRODUCTION: The Framingham Heart Study is an observational study designed to identify the relationship between risk factors, genetics, cardiovascular disease, and other health conditions over three generations. As a person who has at least one parent in the Framingham Heart Study, you are invited to participate.

IV. PURPOSE: The specific 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, cancer, and other health conditions; and to 2) examine DNA and its relationship to risk of developing these diseases and health conditions. This examination does not take place of a routine medical check up by your physician.

V. WHAT HAPPENS IN THIS RESEARCH STUDY:

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: Past and present heart and lung illnesses; Hospitalizations; Reproductive history; Personal and family history; General 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, and blood pressure, electrocardiogram, and lung function. You will also be asked to have procedures such as an echocardiogram and vascular testing. (See below for further descriptions)

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.

Echocardiogram: This is a picture of your heart using ultrasound waves instead of radiation.

| | |
|-------------|---------|
| IRB# | 19104 |
| VALID THRU: | 6/22/04 |
| PER IRB: | M |
| AUTH. INIT. | |

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Boston University
School of Medicine

IRB Protocol#1910G
Title: THE FRAMINGHAM HEART STUDY
GENERATION III - Exam 1.5 Page 2 of 6



The Framingham Heart Study
Framingham, MA

NAME: _____

PERMISSION FOR INTERVIEW, EXAMINATION, TESTS AND RECORD REVIEWS
(One signed copy for participant, one signed copy for chart)

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 the urine samples will be used for the testing of potential risk factors for the diseases and health conditions that are 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) can be used for the preparation of DNA and for the creation of a living tissue sample (cell line). A cell line provides an unlimited supply of DNA and would allow researchers in the future to test your blood without the need to obtain more blood from you if you are unable. 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.

Data and DNA will be distributed to researchers conducting the Framingham Heart Study and other qualified researchers interested in the genetics of heart, lung and blood diseases and other diseases and health conditions. The scientists from these laboratories 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 anyone or to institutions or companies for financial gain or commercial profit without your consent. 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 tests of vascular function, which will take about 30-40 minutes:

- a. **Brachial ultrasound** measures the ability of a blood vessel in your arm (brachial artery) to get bigger (dilate) when exposed to increased blood flow; this measures the health of the blood vessel lining. A technician will perform brachial ultrasound before, during and after 5 minutes of blood pressure cuff inflation on your lower arm.
- b. **Fingertip pulse test.** While the technician is performing the ultrasound test, he/she will also measure your pulse at a fingertip on each hand.
- c. **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.

| | |
|-------------|-------------|
| IRB# | 19104 |
| VALID THRU: | 6/22/04 |
| PER IRB: | HC |
| 6/23/03 | AUTH. INIT. |

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The Framingham Heart Study
Framingham, MA

NAME: _____

PERMISSION FOR INTERVIEW, EXAMINATION, TESTS AND RECORD REVIEWS
(One signed copy for participant, one signed copy for chart)

5) Medical Records.

You will be asked to sign three additional medical release forms to allow the Framingham Heart Study Medical Records staff to obtain and review copies of your hospital, cancer registry, and medical records for Framingham Heart Study Physician Review. These medical release forms will be considered as valid to obtain these records, and these authorizations will remain valid until canceled by you.

You may be contacted later to obtain additional health information, or 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. You may be asked to come back for another exam in the future, 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.

VI. RISKS, DISCOMFORTS AND RESEARCH-RELATED INJURY: Each of the test procedures and their risks and discomforts have been listed below:

The Brachial Ultrasound Test: The main risks are tingling, or mild pain and painless red spots (petechiae). About 0.5% of participants who have the brachial ultrasound test develop painless red spots after the test on the same arm; the red spots go away after a few days without any treatment.

The Fingertip Pulse Test: The fingertip device is made of latex and may cause a reaction if you have an allergy to latex. Please tell us if you have a latex allergy and we will not apply the fingertip device.

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.

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

We do not expect an unusual risk or injury to occur as a result of participation. In the unlikely event that, during examination procedures, you should require medical care, first aid will be available. There may also be some risks that are unforeseeable. Framingham Heart Study Investigators will tell you if new information becomes available that may affect your willingness to participate.

VII. BENEFITS: You may not receive any direct benefit from this research, but if FHS investigators identify the causes of heart, vascular and other diseases, those who develop these illnesses in the future may benefit. These studies may lead to the development of new methods of prevention and treatment of these diseases.

A summary letter of routine test results from this exam will be sent to you and your physician.

| | |
|--------------------------|---------|
| IRB# | 19106 |
| VALID THRU: | 6/22/04 |
| PER IRB: | MC |
| L. J. COLE, M.D., M.P.H. | |

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The Framingham Heart Study
Framingham, MA

NAME: _____

PERMISSION FOR INTERVIEW, EXAMINATION, TESTS AND RECORD REVIEWS
(One signed copy for participant, one signed copy for chart)

VIII. POSSIBLE COST TO YOU FOR PARTICIPATING: 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 for compensation or for payment of treatment solely because of your participation in this study. This does not waive any of your legal rights.

IX. PAYMENT TO YOU FOR PARTICIPATING: You will not receive payment for your participation.

X. ALTERNATIVE TO PARTICIPATION: You may choose not to participate. If at any point during the testing you are uncomfortable and would like to terminate any of the tests, please tell the study staff.

XI. 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 potentially identifying information will not be used on any samples you provide.

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.

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.

No other individuals, including your spouse, children, physician or employer 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 based on your information are published, your name and any other potentially identifying information (i.e., code numbers) will not be revealed. You will be kept informed, through periodic publications from the Framingham Heart Study, of any new information of findings about genetics or genetic testing for cardiovascular disease or other health conditions generated from the DNA analyses that may be of importance to you or your family.

| | |
|-------------|------------|
| IRB# | 19/04 |
| VALID THRU: | 6/22/04 |
| PER IRB: | dc |
| 6/22/03 | ALITH INIT |

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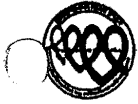
Boston University
School of Medicine

IRB Protocol#1910G

Title: THE FRAMINGHAM HEART STUDY

GENERATION III - Exam 1.5

Page 5 of 6



The Framingham Heart Study
Framingham, MA

NAME: _____

PERMISSION FOR INTERVIEW, EXAMINATION, TESTS AND RECORD REVIEWS
(One signed copy for participant, one signed copy for chart)

The Boston University Medical Center Institutional Review Board may examine the study records to assure adherence to regulations and protocol.

XII. COMPENSATION FOR RESEARCH-RELATED INJURY: In the unlikely event of injury from your participation in the research, emergency medical treatment will be provided at no cost to you. In the event of injury while you are at the Framingham Heart Study premises, someone who is capable of dealing with emergencies will stay with you.

However, no additional medical care or compensation is offered to participants in this study.

XIII. YOUR RIGHTS TO PARTICIPATE, NOT PARTICIPATE, OR TO WITHDRAW FROM THE STUDY:

Taking part in this study is voluntary. You have the right to refuse to take part in all of the study and/or certain measurements and procedures. If you choose to fully take part, you have the right to stop at any time. Refusal to participate will involve no penalty, and you may also choose to discontinue participation at any time without any penalty.

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 [redacted] and ask for the lab manager.

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

The investigators may decide to discontinue your participation without your permission in the event that future funding is not obtained.

You are welcome to ask questions at any time during the examination and throughout the course of the Study. If you have any questions concerning the research and procedures of this study or if a research-related injury occurs, please contact [redacted], Boston University/Framingham Heart Study [redacted] or [redacted] at the Framingham Heart Study, [redacted]. 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 617- 638-7207. 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, Vol. 60, No. 13, Friday, January 20, 1995, pages 4264-4266.

If you have any unanswered questions, please ask and obtain answers before signing this form. A signed copy of this form will be given to you.

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|---------------------|------------|
| IRB# | 19104 |
| VALID THRU: | 6/22/04 |
| PER IRB: | [initials] |
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Boston University School of Medicine



The Framingham Heart Study Framingham, MA

NAME: _____

PERMISSION FOR INTERVIEW, EXAMINATION, TESTS AND RECORD REVIEWS
(One signed copy for participant, one signed copy for chart)

Please check the appropriate box beside each statement:

YES NO

I agree to participate in the physical examination and genetic studies of factors contributing to heart, lung and blood diseases, stroke, dementia, osteoarthritis, osteoporosis, deafness, cancer, and other major diseases and health conditions.

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.

YES NO

I agree to allow the creation of a cell line from my blood sample.

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.)

YES NO

I authorize (give my permission) to the Framingham Heart Study to release the results of this exam to:

(List the name(s) of your current physician(s))

PARTICIPANT AUTHORIZATION

DATE PARTICIPANT SIGNATURE / PRINTED NAME

I have explained this research study to the participant. I am available to answer any questions now or in the future regarding the study and the participant's rights. You may call _____

DATE SIGNATURE OF PERSON OBTAINING CONSENT / PRINTED NAME

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Boston University
School of Medicine



The Framingham Heart Study
Framingham, MA

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| CONSENT BY SUBSTITUTED JUDGMENT | |
| IRB Protocol#1910G Title: THE FRAMINGHAM HEART STUDY GENERATION III - Exam 1.5b | Page 1 of 7 |

NAME: _____

PERMISSION FOR INTERVIEW, EXAMINATION, TESTS AND RECORD REVIEWS
(One signed copy for participant, one signed copy for chart)

I. PRINCIPAL INVESTIGATOR:

_____, Medical Director, FHS
National Heart, Lung, and Blood Institute, NIH

_____ - BOSTON UNIVERSITY SCHOOL OF MEDICINE

II. OTHER INVESTIGATORS:

III. INTRODUCTION: The Framingham Heart Study is an observational study designed to identify the relationship between risk factors, genetics, cardiovascular disease, and other health conditions over three generations. As a person who has at least one parent in the Framingham Heart Study, you are invited to participate.

IV. PURPOSE: The specific 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, cancer, and other health conditions; and to 2) examine DNA and its relationship to risk of developing these diseases and health conditions. This examination does not take place of a routine medical check up by your physician.

V. WHAT HAPPENS IN THIS RESEARCH STUDY:

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: Past and present heart and lung illnesses; Hospitalizations; Reproductive history; Personal and family history; General 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, and blood pressure, electrocardiogram, and lung function. You will also be asked to have procedures such as an echocardiogram and vascular testing. (See below for further descriptions)

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.

Echocardiogram: This is a picture of your heart using ultrasound waves instead of radiation.

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Boston University
School of Medicine



The Framingham Heart Study
Framingham, MA

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GENERATION III - Exam 1.5b

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NAME: _____

PERMISSION FOR INTERVIEW, EXAMINATION, TESTS AND RECORD REVIEWS
(One signed copy for participant, one signed copy for chart)

3) Blood and urine specimens.

A technician will draw a sample of your blood (112.5cc or about 7.5 tablespoons) and you will be asked to give a sample of your urine. Both the blood and the urine samples will be used for the testing of potential risk factors for the diseases and health conditions that are 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) can be used for the preparation of DNA and for the creation of a living tissue sample (**cell line**). A cell line provides an unlimited supply of DNA and would allow researchers in the future to test your blood without the need to obtain more blood from you if you are unable. 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.

Data and DNA will be distributed to researchers conducting the Framingham Heart Study and other qualified researchers interested in the genetics of heart, lung and blood diseases and other diseases and health conditions. The scientists from these laboratories 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 anyone or to institutions or companies for financial gain or commercial profit without your consent. 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 tests of vascular function, which will take about 30-40 minutes:

- a. **Brachial ultrasound** measures the ability of a blood vessel in your arm (brachial artery) to get bigger (dilate) when exposed to increased blood flow; this measures the health of the blood vessel lining. A technician will perform brachial ultrasound before, during and after 5 minutes of blood pressure cuff inflation on your lower arm.
- b. **Fingertip pulse test.** While the technician is performing the ultrasound test, he/she will also measure your pulse at a fingertip on each hand.
- c. **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.

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THRU:
PER IRB: [signature]
6/23/04 AUTH. INIT.

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Boston University
School of Medicine



The Framingham Heart Study
Framingham, MA

CONSENT BY SUBSTITUTED JUDGMENT

IRB Protocol#1910G
Title: THE FRAMINGHAM HEART STUDY
GENERATION III - Exam 1.5b

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NAME: _____

PERMISSION FOR INTERVIEW, EXAMINATION, TESTS AND RECORD REVIEWS
(One signed copy for participant, one signed copy for chart)

5) Medical Records.

You will be asked to sign three additional medical release forms to allow the Framingham Heart Study Medical Records staff to obtain and review copies of your hospital, cancer registry, and medical records for Framingham Heart Study Physician Review. These medical release forms will be considered as valid to obtain these records, and these authorizations will remain valid until canceled by you.

You may be contacted later to obtain additional health information, or 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. You may be asked to come back for another exam in the future, 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.

VI. RISKS, DISCOMFORTS AND RESEARCH-RELATED INJURY: Each of the test procedures and their risks and discomforts have been listed below:

- The Brachial Ultrasound Test: The main risks are tingling, or mild pain and painless red spots (petechiae). About 0.5% of participants who have the brachial ultrasound test develop painless red spots after the test on the same arm; the red spots go away after a few days without any treatment.
- The Fingertip Pulse Test: The fingertip device is made of latex and may cause a reaction if you have an allergy to latex. Please tell us if you have a latex allergy and we will not apply the fingertip device.
- 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.
- The Blood Draw: Minimal bruising may occur as a result of the blood draw. A latex allergy can occur from the gloves worn by the technicians. If you have a known latex allergy, inform the technician and he/she will use another form of protection.

We do not expect an unusual risk or injury to occur as a result of participation. In the unlikely event that, during examination procedures, you should require medical care, first aid will be available. There may also be some risks that are unforeseeable. Framingham Heart Study Investigators will tell you if new information becomes available that may affect your willingness to participate.

VII. BENEFITS: You may not receive any direct benefit from this research, but if FHS investigators identify the causes of heart, vascular and other diseases, those who develop these illnesses in the future may benefit. These studies may lead to the development of new methods of prevention and treatment of these diseases.

A summary letter of routine test results from this exam will be sent to you and your physician.

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Boston University
School of Medicine



The Framingham Heart Study
Framingham, MA

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| CONSENT BY SUBSTITUTED JUDGMENT | |
| IRB Protocol#1910G | |
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| GENERATION III - Exam 1.5b | Page 4 of 7 |

NAME: _____

PERMISSION FOR INTERVIEW, EXAMINATION, TESTS AND RECORD REVIEWS
(One signed copy for participant, one signed copy for chart)

VIII. POSSIBLE COST TO YOU FOR PARTICIPATING: 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 for compensation or for payment of treatment solely because of your participation in this study. This does not waive any of your legal rights.

IX. PAYMENT TO YOU FOR PARTICIPATING: You will not receive payment for your participation.

X. ALTERNATIVE TO PARTICIPATION: You may choose not to participate. If at any point during the testing you are uncomfortable and would like to terminate any of the tests, please tell the study staff.

XI. 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 potentially identifying information will not be used on any samples you provide.

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.

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.

No other individuals, including your spouse, children, physician or employer 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 based on your information are published, your name and any other potentially identifying information (i.e., code numbers) will not be revealed. You will be kept informed, through

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Boston University
School of Medicine



The Framingham Heart Study
Framingham, MA

CONSENT BY SUBSTITUTED JUDGMENT

IRB Protocol#1910G
Title: THE FRAMINGHAM HEART STUDY
GENERATION III - Exam 1.5b

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NAME: _____

PERMISSION FOR INTERVIEW, EXAMINATION, TESTS AND RECORD REVIEWS
(One signed copy for participant, one signed copy for chart)

periodic publications from the Framingham Heart Study, of any new information of findings about genetics or genetic testing for cardiovascular disease or other health conditions generated from the DNA analyses that may be of importance to you or your family.

The Boston University Medical Center Institutional Review Board may examine the study records to assure adherence to regulations and protocol.

XII. COMPENSATION FOR RESEARCH-RELATED INJURY: In the unlikely event of injury from your participation in the research, emergency medical treatment will be provided at no cost to you. In the event of injury while you are at the Framingham Heart Study premises, someone who is capable of dealing with emergencies will stay with you.

However, no additional medical care or compensation is offered to participants in this study.

XIII. YOUR RIGHTS TO PARTICIPATE, NOT PARTICIPATE, OR TO WITHDRAW FROM THE STUDY:

Taking part in this study is voluntary. You have the right to refuse to take part in all of the study and/or certain measurements and procedures. If you choose to fully take part, you have the right to stop at any time. Refusal to participate will involve no penalty, and you may also choose to discontinue participation at any time without any penalty.

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 [redacted] and ask for the lab manager.

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

The investigators may decide to discontinue your participation without your permission in the event that future funding is not obtained.

You are welcome to ask questions at any time during the examination and throughout the course of the Study. If you have any questions concerning the research and procedures of this study or if a research-related injury occurs, please contact [redacted], Boston University/Framingham Heart Study [redacted] or [redacted] at the Framingham Heart Study, [redacted]. 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 617- 638-7207. 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, Vol. 60, No. 13, Friday, January 20, 1995, pages 4264-4266.

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| IRB# | 1910G |
| VALID THRU: | 6/22/04 |
| PER IRB: | [signature] |
| | 6/23/04 AUTH. INIT. |

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Boston University
School of Medicine



The Framingham Heart Study
Framingham, MA

CONSENT BY SUBSTITUTED JUDGMENT

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Title: THE FRAMINGHAM HEART STUDY
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NAME: _____

PERMISSION FOR INTERVIEW, EXAMINATION, TESTS AND RECORD REVIEWS
(One signed copy for participant, one signed copy for chart)

system of records which applies to the Framingham Heart Study is documented in the Federal Register, Vol. 60, No. 13, Friday, January 20, 1995, pages 4264-4266.

If you have any unanswered questions, please ask and obtain answers before signing this form. A signed copy of this form will be given to you.

Please check the appropriate box beside each statement:

YES NO

I agree to participate in the physical examination and genetic studies of factors contributing to heart, lung and blood diseases, stroke, dementia, osteoarthritis, osteoporosis, deafness, cancer, and other major diseases and health conditions.

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.

YES NO

I agree to allow the creation of a cell line from my blood sample.

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.)

YES NO

I authorize (give my permission) the Framingham Heart Study to release the results of this exam to:

(List the name(s) of your current physician(s))

Signer's initials: _____

IRB# 19104
VALID
THRU: 6/22/04
PER IRB: mu
6/23/07 AUTH. INIT.

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Boston University School of Medicine



The Framingham Heart Study Framingham, MA

CONSENT BY SUBSTITUTED JUDGMENT

IRB Protocol#1910G Title: THE FRAMINGHAM HEART STUDY GENERATION III - Exam 1.5b

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NAME: _____

PERMISSION FOR INTERVIEW, EXAMINATION, TESTS AND RECORD REVIEWS (One signed copy for participant, one signed copy for chart)

I have been asked to grant consent for participation of my _____ in this study, on his/her behalf. In my judgment and/or the judgment of the Framingham Heart Study staff or health care professional(s) involved with treating _____ he/she is unable to adequately understand the Informed Consent Form, due to severity of illness, and/or is otherwise unable to sign the form.

I have read this Informed Consent Form and the above paragraph. The decision to grant consent for this study is that which I believe the participant would have made were he/she able to make such a decision. I have been informed of the risks and benefits involved, and all of my questions have been answered to my satisfaction. Furthermore, I have been assured that any future questions I may have will also be answered by a member of the research team.

I hereby give consent for _____ to participate in this research.

AUTHORIZATION SIGNATURES

Signature lines for participant and witness, including fields for DATE, SIGNATURE, PRINTED NAME, and WITNESS SIGNATURE.

I have explained this research study to the participant. I am available to answer any questions now or in the future regarding the study and the participant's rights. You may call _____

Signature line for person obtaining consent, including fields for DATE, SIGNATURE OF PERSON OBTAINING CONSENT, and PRINTED NAME.

IRB# 19106 VALID THRU: 6/22/04 PER IRB: [initials] 6/12/04 AUTH. INIT.

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Numerical Data--Part I

|7|0|2|0|1| FORM NUMBER OMB NO=0925-0216

| Basic Information | | | |
|--|---|---|--|
| _ _ _ | Examiner's Number for weight and height. | | |
| _ | Sex of Participant (1=Male, 2=Female) | | |
| _ - _ - _ _ _ | Date of Birth (mo/day/year). | | |
| _ _ _ | Weight (to nearest pound) | _ | Protocol modification 0=No 1=Yes |
| _ _ * _ _ | Height (inches, to next lower 1/4 inch) | _ | Protocol modification |
| Regional Anthropometry | | | |
| (Code boxes below with 9's if not done or unknown) | | | |
| _ _ _ | Examiner's Number for anthropometry, fasting and hand preference. | | |
| _ _ * _ _ | Neck Circumference (inches, to next lower 1/4 inch) | _ | Protocol modification 0=No 1=Yes |
| _ _ * _ _ | Waist Girth (inches, to next lower 1/4 inch) | _ | Protocol modification |
| _ _ | Number of Hours Fasting (99=Don't know) | | |
| _ | Hand preferred for writing (1=right, 2=left) | | |

| Technician's Number for Blood Pressure (to nearest 2 mm Hg) | | | |
|---|-----------|---|-----------------------|
| _ _ _ | | | |
| Systolic | Diastolic | BP cuff size | Protocol modification |
| _ _ _ | _ _ _ | _ | _ |
| | | 0=pediatric, 1=regular, 2=large ad., 3=thigh | 0=No, 1=Yes |

Comments on all protocol modifications:

(113)

Exam 1 Procedures Sheet

- Informed Consent Signed
 - Anthropometry
 - Sociodemographic Questions
 - SF-12 Health Survey 0=No,
 - CES-D Scale
 - Exercise Questionnaire 1=Yes,
 - Pedigree Verification
 - Urine Specimen
 - Blood Draw
 - ECG
 - Tonometry /Brachial /ECHO
 - Spirometry
 - Diffusion Capacity
- Reason Spirometry not done 1=Major Surgery, 2=Heart Attack
3=Stroke, 4=Aneurysm, 5=BP>210/110
- Reason Diffusion not done 6=Refused, 7=Test Aborted, 8=Other,
10=equipment problems

Exit Interview

- Procedure sheet reviewed
 - Check for Id on Pedigree Verification Form
 - Referral sheet reviewed 0=No
 - Willett dietary questionnaire provided 1=Yes
 - Left clinic w/ belongings
 - Coronary Ca CT test brochure given
 - Feedback 0=No feedback, 1=Positive feedback,
2=Negative feedback, 3=Other
- Comments _____

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Respiratory Disease Questionnaire. Technician Administered.

7|0|2|0|3| FORM NUMBER OMB NO=0925-0216

Respiratory Diagnoses

Examiner ID

1. Have you ever had asthma? 0=No, 1=Yes

if yes
fill Do you still have it?

Was it diagnosed by a doctor or other health professional? 0=No
1=Yes

At what age did it start? (Age in years)

If you no longer have it, at what age did it stop? (Age in years) ←88=N/A

Have you received medical treatment for this in the past 12 months?

2. Have you ever had hay fever (allergy involving the nose and/or eyes)?

3. Have you ever had bronchitis? 0=No
1=Yes

4. Have you ever had pneumonia (including bronchopneumonia)?

5. Have you ever had

| | Have condition? | Health professional DX? | Age condition began |
|---|--------------------------|--------------------------|---|
| | (0=No, 1=Yes) | | 99=Unk |
| Chronic Bronchitis | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> |
| Emphysema | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> |
| COPD <small>Chronic obstructive pulmonary disease</small> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> |
| Sleep Apnea | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> |
| Pulmonary Fibrosis | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> |

6. Have you ever had ...

Any other chest illnesses? If yes, please specify: _____ 0=No
1=Yes

Any chest operations? If yes, please specify: _____

Any chest injuries? If yes, please specify: _____

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Respiratory Disease Questionnaire. Technician Administered.

|7|0|2|0|4| FORM NUMBER OMB NO=0925-0216

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

- Start to cough?
- Start to wheeze?
- Get a feeling of tightness in your chest? 0=No
- Start to feel short of breath? 1=Yes
- Get a runny or stuffy nose or start to sneeze?
- 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

- Start to cough?
- Start to wheeze?
- Get a feeling of tightness in your chest? 0=No
- Start to feel short of breath? 1=Yes
- Get a runny or stuffy nose or start to sneeze?
- Get itching or watering eyes?

3. When you are at your current job, do you ever

- Start to cough?
- Start to wheeze?
- Get a feeling of tightness in your chest? 0=No
- Start to feel short of breath? 1=Yes
- Get a runny or stuffy nose or start to sneeze?
- Get itching or watering eyes?

4. When you are near strong odors such as perfume or bleach, do you ever

- Start to cough?
- Start to wheeze?
- Get a feeling of tightness in your chest? 0=No
- Start to feel short of breath? 1=Yes

5. When you exercise or exert yourself or when the air is cold, do you ever

- Start to cough?
- Start to wheeze?
- Get a feeling of tightness in your chest? 0=No
- Start to feel short of breath? 1=Yes

6. Do you currently have a cat, dog, or other furry pets living in your home?

7. Have you ever been exposed at work to vapors, gas, dust or fumes? 0=No, 1=Yes

9=Don't know

99=Don't know

if yes Total years exposed (01=1 year or less)

fill 0

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Sociodemographic questions. Part I Self-administered

7|0|2|0|7| FORM NUMBER OMB NO=0925-0216

| | | |
|---|--|---|
| | | 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? (check ALL that apply) |
| _ | | 1=Caucasian or white |
| _ | | 2=Spanish/Hispanic/Latino |
| _ | | 3=African-American or black |
| _ | | 4=Asian |
| _ | | 5=Native Hawaiian or other Pacific Islander |
| _ | | 6=American Indian or Alaska native |
| _ | | 8=Other, specify _____ |
| _ | | 9=prefer not to answer |
| _ | | 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 (12 th 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 |
| _ | | 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 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 |

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Sociodemographic questions. Part II. Self-administered

|7|0|2|0|8| FORM NUMBER OMB NO=0925-0216

What is your current occupation? Write in _____

|_|_| Using the occupation coding sheet choose the code that best describes your occupation.

What is the occupation you have worked in longest? Write in _____

|_|_| Using the occupation coding sheet choose the code that best describes the occupation you have worked in longest.

|_|_| Please select which income group best represents your combined family income for the past 12 months.

- 1=under \$12,000
- 2 =\$12,000 – \$24,999
- 3 =\$25,000 – \$49,999
- 4 =\$50,000 – \$74,999
- 5 =\$75,000 – \$100,000
- 6 =over \$100,000
- 99=prefer not to answer

|_|_| How many people are supported by this income?

To help you pay your medical care, do you have
Please, circle one on every line

- | | | |
|-----|----|--|
| YES | NO | HMO or other private insurance such as Blue Cross, Aetna, Harvard-Pilgrim, etc |
| YES | NO | Medicare |
| YES | NO | Medicaid |
| YES | NO | Military or Veteran's administration sponsored |
| YES | NO | Other |
| YES | NO | None |
| YES | NO | Prefer not to answer |

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SF-12® Health Survey (Standard) Self-administered

|7|0|2|0|9| FORM NUMBER OMB NO=0925-0216

This questionnaire asks for your views about your health. This information will help you keep track of how you feel and how well you are able to do your usual activities.

Please answer every question by marking one box. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is:

| | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Excellent | Very good | Good | Fair | Poor |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

| | Yes, limited a lot | Yes, limited a little | No, not limited at all |
|--|-----------------------------------|--------------------------------------|---------------------------------------|
| 2. Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Climbing several flights of stairs | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

| | Yes | No |
|--|--------------------------|--------------------------|
| 4. Accomplished less than you would like | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Were limited in the kind of work or other activities | <input type="checkbox"/> | <input type="checkbox"/> |

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

| | Yes | No |
|--|--------------------------|--------------------------|
| 6. Accomplished less than you would like | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Didn't do work or other activities as carefully as usual | <input type="checkbox"/> | <input type="checkbox"/> |

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SF-12® Health Survey (Standard) Self-administered

|7|0|2|1|0| FORM NUMBER OMB NO=0925-0216

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 |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks...

| | All of the time | Most of the time | A good bit of the time | Some of the time | A little of the time | None of the time |
|---|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 9. Have you felt calm and peaceful? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. Did you have a lot of energy? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. Have you felt downhearted and blue? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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 |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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CES-D Scale (Self-administered)

|7|0|2|1|1| FORM NUMBER

OMB NO=0925-0216

Circle the number for each statement which best describes how often you felt or behaved this way DURING THE PAST WEEK.

| <p>Circle best answer for each question</p> <p>DURING THE PAST WEEK</p> | <p>Rarely or none of the time</p> <p>(less than 1 day)</p> | <p>Some or a little of the time</p> <p>(1-2 days)</p> | <p>Occasionally or moderate amount of time</p> <p>(3-4 days)</p> | <p>Most or all of the time</p> <p>(5-7 days)</p> |
|--|--|---|--|--|
| 1. I was bothered by things that usually don't bother me. | 0 | 1 | 2 | 3 |
| 2. I did not feel like eating; my appetite was poor. | 0 | 1 | 2 | 3 |
| 3. I felt that I could not shake off the blues, even with help from my family and friends. | 0 | 1 | 2 | 3 |
| 4. I felt that I was just as good as other people. | 0 | 1 | 2 | 3 |
| 5. I had trouble keeping my mind on what I was doing. | 0 | 1 | 2 | 3 |
| 6. I felt depressed. | 0 | 1 | 2 | 3 |
| 7. I felt that everything I did was an effort. | 0 | 1 | 2 | 3 |
| 8. I felt hopeful about the future. | 0 | 1 | 2 | 3 |
| 9. I thought my life had been a failure. | 0 | 1 | 2 | 3 |
| 10. I felt fearful. | 0 | 1 | 2 | 3 |
| 11. My sleep was restless. | 0 | 1 | 2 | 3 |
| 12. I was happy. | 0 | 1 | 2 | 3 |
| 13. I talked less than usual. | 0 | 1 | 2 | 3 |
| 14. I felt lonely. | 0 | 1 | 2 | 3 |
| 15. People were unfriendly. | 0 | 1 | 2 | 3 |
| 16. I enjoyed life. | 0 | 1 | 2 | 3 |
| 17. I had crying spells. | 0 | 1 | 2 | 3 |
| 18. I felt sad. | 0 | 1 | 2 | 3 |
| 19. I felt that people disliked me | 0 | 1 | 2 | 3 |
| 20. I could not "get going" | 0 | 1 | 2 | 3 |

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Physical Activity Questionnaire--Framingham Heart Study

Tech-administered

|7|0|2|0|5| FORM NUMBER OMB NO=0925-0216

| Examiner ID | |
|---|-----------------|
| Rest and Activity for a Typical Day (Activities must equal 24 hours) | Number of hours |
| Sleep --Number of hours that you typically sleep? | _____ |
| Sedentary --Number of hours typically sitting? | _____ |
| Slight Activity --Number of hours with activities such as standing, walking? | _____ |
| Moderate Activity --Number of hours with activities such as housework (vacuum, dust, yard chores, climbing stairs; light sports such as bowling, golf)? | _____ |
| Heavy Activity --Number of hours with activities such as heavy household work, heavy yard work such as stacking or chopping wood, exercise such as intensive sports--jogging, swimming etc.? | _____ |
| Total number of hours (should be the total of above items) | 24 |

| __ 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 |
| __ 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 |

(123)

Physical Activity Questionnaire--Framingham Heart Study Tech-administered

17|0|2|0|6| FORM NUMBER OMB NO=0925-0216

| DURING THE PAST YEAR, what was your average time PER WEEK spent in each of the following recreational activities? | zero | 1-4 min | 5-19 min | 20-59 min | 1 hr | 1-1.5 hr | 2-3 hr | 4-6 hr | 7-10 hr | 11+ hr |
|---|------|---------|----------|-----------|------|----------|--------|--------|---------|--------|
| Walking for exercise or walking to work | | | | | | | | | | |
| Jogging (slower than 10 minute mile) | | | | | | | | | | |
| Running (10 minutes/mile or faster) | | | | | | | | | | |
| Bicycling (include stationary bike) | | | | | | | | | | |
| Tennis, squash, racquetball | | | | | | | | | | |
| Lap swimming | | | | | | | | | | |
| Other aerobic exercise (aerobic dance, ski or stair machine, etc) | | | | | | | | | | |
| Lower intensity exercise (yoga, stretching, toning) | | | | | | | | | | |
| Other vigorous exercise (lawn mowing) | | | | | | | | | | |
| Weight training including free weights or machines such as nautilus | | | | | | | | | | |

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Pedigree Verification. Part II. Tech-administered

|7|0|2|1|3| FORM NUMBER OMB NO=0925-0216

If the parent is not in study, please fill in "Parent History" below

| Health History of nonparticipating biological parent. | |
|---|---------------------------------------|
| First Name <input type="text"/> | Last Name <input type="text"/> |
| <input type="checkbox"/> Is your parent living? | 0=No, 1=Yes, 2=Don't know |
| if no fill <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> | Date of death |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | Cause of death |

| Medical History | | |
|--|---|--------------|
| HEART PROBLEMS, such as: | | |
| <input type="checkbox"/> | Chest pain, angina or angina pectoris | |
| <input type="checkbox"/> | Heart attack or myocardial infarction or MI | |
| <input type="checkbox"/> | Heart failure or congestive heart failure or CHF | 0=No |
| <input type="checkbox"/> | Heart catheterization or cardiac catheterization | 1=Yes |
| <input type="checkbox"/> | Heart bypass operation or coronary bypass surgery or CABG | 2=Don't know |
| <input type="checkbox"/> | Procedure to unblock vessels to the heart muscle (PTCA, stent, angioplasty) | know |
| <input type="checkbox"/> | Other heart problem (pacemaker, valve, aorta, etc.) write in _____ | |
| CIRCULATORY PROBLEMS, such as: | | |
| <input type="checkbox"/> | Stroke, TIA, sudden paralysis, vision, speech loss | |
| <input type="checkbox"/> | Procedure to unblock blood vessels in the neck (such as carotid endarterectomy) | 0=No |
| <input type="checkbox"/> | Poor blood circulation or blockage to legs/feet | 1=Yes |
| <input type="checkbox"/> | Amputation of leg or toes, due to poor circulation/gangrene | 2=Don't know |
| <input type="checkbox"/> | Blood clot or embolism in leg or lung | know |
| <input type="checkbox"/> | Other circulation problem write in _____ | |
| OTHER NEUROLOGICAL PROBLEMS, such as: | | |
| <input type="checkbox"/> | Memory problems or dementia | 0=No, 1=Yes |
| <input type="checkbox"/> | Other neurological problems such as Parkinson's | 2=Don't know |
| <input type="checkbox"/> | Have this parent ever had an MRI scan of the head? | know |
| HAS YOUR PARENT OTHER PROBLEMS | | |
| <input type="checkbox"/> | Cancer, specify site/type _____ | 0=No, 1=Yes |
| <input type="checkbox"/> | Fracture, broken bone | 2=Don't know |
| <input type="checkbox"/> | Other write in _____ | know |
| <input type="checkbox"/> | High blood cholesterol | 0=No, 1=Yes |
| <input type="checkbox"/> | Hypertension (high blood pressure) | 2=Don't know |
| <input type="checkbox"/> | Diabetes (high blood sugar) | know. |

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Brachial Scan

|7|0|2|1|5| FORM NUMBER OMB NO=0925-0216

Keyer 1: _____

Keyer 2: _____

|_|_|/|_|_|/|_|_|

Date of brachial scan? (mo/day/yr)

|_|_|-|_|_|

Brachial Video CD number

|_|_|

Brachial Sonographer ID

|_|_|.|_|

Room temperature (Celsius)

|_|_|_|

Mean systolic baseline blood pressure

|_|_|_|

Cuff inflation pressure (Baseline SBP + 50 or 250)

0 1 9

Was brachial scan completed? (Baseline, Doppler, Deflation)
(0=No, 1=Yes, 9=Unk)

If no (0)

Brachial scan deviations: circle ALL that apply

- 1: Subject refusal
- 2: Subject discomfort
- 3: Time constraint
- 4: Equipment problem (if not #5 or #6), specify _____
- 5: Foot pedal problem/cuff sequence problem
- 6: Doppler problem
- 7: Other, specify _____

|_|_|

Interpreter ID (mo/day/yr)

|_|_|/|_|_|/|_|_|

Interpretation date

0 1 2 9

Baseline measurable? (0=No, 1=Yes, 2=Suboptimal, 9=Unknown)

0 1 9

Do you see occlusion? (0=No, 1=Yes, 9=Unknown)

0 1 9

Do you see normal release? (0=No, 1=Yes, 9=Unknown)

0 1 2 9

Deflation measurable? (0=No, 1=Yes, 2=Suboptimal, 9=Unknown)

0 1 2 9

OK to calculate FMD? (0=No, 1=Yes, 2=Suboptimal, 9=Unknown)

0 1 9

Significant rhythm disturbance (0=No, 1=Yes, 9=Unknown)

|_|_|-|_|_|

Measurement Video CD#

|_|_|-|_|_|

Brachial data floppy #

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17|0|2|1|6| FORM NUMBER OMB NO=0925-0216

FHS ECHOCARDIOGRAPHY ULTRASONOGRAPHER WORKSHEET

Study Date ___/___/___ Study type 0 1 2 (0=exam, 1=repeat study, 2=other) EXAM ___

Data entry date ___/___/___ ; ___/___/___ Data entry ID _____ 1st _____ 2nd

ECHO done? Yes=1 No=0 Room # 108 110

Tech ID ___ Height (inches) ___ Sex M F

Video MOD # _____ if no video MOD, code 0 SVHS # _____ if no SVHS#, code 0 SVHS location _____

STUDY QUALITY

| <u>OD</u> | <u>Good</u> | <u>Fair</u> | <u>Poor</u> | <u>Inadequate</u> |
|------------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|
| M-mode Ao/LA | <input type="checkbox"/> =1 | <input type="checkbox"/> =2 | <input type="checkbox"/> =3 | <input type="checkbox"/> =4 |
| M-mode LV | <input type="checkbox"/> =1 | <input type="checkbox"/> =2 | <input type="checkbox"/> =3 | <input type="checkbox"/> =4 |
| PW mitral inflow | <input type="checkbox"/> =1 | <input type="checkbox"/> =2 | <input type="checkbox"/> =3 | <input type="checkbox"/> =4 |
| <u>VHS</u> | | | | |
| 2-D study | <input type="checkbox"/> =1 | <input type="checkbox"/> =2 | <input type="checkbox"/> =3 | <input type="checkbox"/> =4 |
| CW AV | <input type="checkbox"/> =1 | <input type="checkbox"/> =2 | <input type="checkbox"/> =3 | <input type="checkbox"/> =4 |
| Color Doppler | <input type="checkbox"/> =1 | <input type="checkbox"/> =2 | <input type="checkbox"/> =3 | <input type="checkbox"/> =4 |
| <u>Overall study quality</u> | <input type="checkbox"/> =1 | <input type="checkbox"/> =2 | <input type="checkbox"/> =3 | <input type="checkbox"/> =4 |

Comments: _____

Priority MD overread:

- Severe AS
- Severe MS
- Mod-severe _____ regurgitation
- Thrombus
- Vegetation
- Mass
- Large pericardial effusion
- Significant LV dysfunction
- Other _____

Called Dr. _____ Date/time: _____

MD overread, other:

- > Mild LAE
- > Mild AoR dil.
- RA/RV abnormality
- Any LVH
- Any LVE
- LV WMA
- ↓ LVEF
- MS
- > Mild MAC
- Any MVP
- AS
- Bicuspid AV
- Valve prosthesis
- > Mild _____ regurgitation
- Other _____

Requested by:

_____ For Dr. _____ Date: _____

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Reader _____

Reading 1 2

Date interpreted ___/___/___ (mo/day/yr) (

LA enlargement 0=no 1=borderln. 2=mild 3=moderate 4=severe 9=unknown
Other LA comment

Mitral Valve 0=normal 1=prob nl 2=abnormal 4=prosth. 9=unknown
 MV thickening 0=no 1=minimal 2=mild 3=moderate 4=severe 9=unknown
 MS 0=normal 1=possible 2=likely 9=unknown
 MAC 0=no 1=minimal 2=mild 3=moderate 4=severe 9=unknown
 MVP 0=no 1=min.sup.disp 2=mild 3=moderate 4=severe 9=unknown
Other MV comment

Aortic Valve 0=normal 1=prob nl 2=abnormal 4=prosth. 9=unknown
 AV thickening 0=no 1=minimal 2=mild 3=moderate 4=severe 9=unknown
 AV cusp excursion 0=normal 1=minimal 2=mild 3=moderate 4=severe 9=unknown
Aortic Root 0=normal 1=prob nl 2=abnormal 9=unknown
 Aortic root dilation 0=no 2=present 9=unknown
 Aortic root calcium 0=no 1=minimal 2=mild 3=moderate 4=severe 9=unknown
Other AV/AR comment

LV Structure 0=normal 1=prob nl 2=abnormal 9=unknown
 LV enlargement 0=no 1=borderline 2=mild 3=moderate 4=severe 9=unknown
 LVWT, concentric 0=no 1=borderline 2=mild 3=moderate 4=severe 9=unknown
 LVWT, other 0=no 1=DUSK 2=ASH 3=ISH 4=oth_____ 9=unknown

Regional WMA 0=normal 1=prob nl 2=abnormal 9=unknown
 Septum 0=normal 1=paradoxical 2=hypokinetic 3=akinetik 4=dyskinetic 9=unknown
 Anterior 0=normal 2=hypokinetic 3=akinetik 4=dyskinetic 9=unknown
 Anterior/Anterolateral 0=normal 2=hypokinetic 3=akinetik 4=dyskinetic 9=unknown
 Posterior 0=normal 2=hypokinetic 3=akinetik 4=dyskinetic 9=unknown
 Inferior 0=normal 2=hypokinetic 3=akinetik 4=dyskinetic 9=unknown
 Apex 0=normal 2=hypokinetic 3=akinetik 4=dyskinetic 9=unknown

LV Systolic Function 0=normal 1=prob nl 2=regional 4=global 9=unknown
 LV ejection fraction 0=normal 1=borderline 2=mild 3=moderate 4=severe 9=unknown
Other LV comment LVEF ___%

Right Heart/Pericardium 0=normal 1=prob nl 2=abnormal 9=unknown
 RA enlargement 0=no 2=mild 3=moderate 4=severe 9=unknown
 RV enlargement 0=no 2=mild 3=moderate 4=severe 9=unknown
 RV hypertrophy 0=no 2=mild 3=moderate 4=severe 9=unknown
 Pericardial fluid 0=no/syst. 2=small 3=medium 4=large 9=unknown
Other right v/pericardium

Valve Regurgitation 0=none 2=present 9=unknown
 Mitral 0=none 1=trace 2=mild 3=moderate 4=m-s 5=sev 9=unknown
 Aortic 0=none 1=trace 2=mild 3=moderate 4=m-s 5=sev 9=unknown
 Tricuspid 0=none 1=trace 2=mild 3=moderate 4=m-s 5=sev 9=unknown

Mitral Stenosis 0=none 1=trivial 2=mild 3=moderate 4=severe 9=unknown
Aortic Stenosis 0=none 1=trivial 2=mild 3=moderate 4=severe 9=unknown
Other Doppler comment

Comments: _____

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GENERATION 3 EXAM 1 LOG BOOK SHEET FOR
TONOMETRY, BRACHIAL AND ECHO TESTS

|7|0|2|1|7| FORM NUMBER OMB NO=0925-0216

Date of Clinic Visit ____ - ____ - ____
Mo Day Yr

Room # 108 110

TONOMETRY

| | | | | | |
|-------------------|---|-------------------------------------|-----------------------------|--|-------------------------------|
| Test done? | <input type="checkbox"/> yes | <input type="checkbox"/> incomplete | <input type="checkbox"/> no | If no or incomplete, why: | Circle all that apply |
| _____ | Sonographer ID# | | | | 1. Subject refusal |
| _ _ _ - _ _ _ | Video CD# | | | | 2. Subject discomfort |
| ___/___/___ | TONOMETRY test date if different from Clinic Date above. | | | | 3. Time constraint |
| | | | | | 4. Equipment problem, specify |
| | | | | | 7. Other, specify |

ECHO

| | | | | | |
|------------------------------|--|-------------------------------------|-----------------------------|--|-------------------------------|
| Test done? | <input type="checkbox"/> yes | <input type="checkbox"/> incomplete | <input type="checkbox"/> no | If no or incomplete, why: | Circle all that apply |
| _____ | Sonographer ID# | | | | 1. Subject refusal |
| _ _ _ - _ _ _ | SVHS# | | | | 2. Subject discomfort |
| ___/___/___ | ECHO test date if different from Clinic Date above. | | | | 3. Time constraint |
| | | | | | 4. Equipment problem, specify |
| | | | | | 7. Other, specify |
| MD overread required: | <input type="checkbox"/> yes | <input type="checkbox"/> no | | | |

BRACHIAL

| | | | | | |
|-------------------|--|-------------------------------------|-----------------------------|--|-------------------------------|
| Test done? | <input type="checkbox"/> yes | <input type="checkbox"/> incomplete | <input type="checkbox"/> no | If no or incomplete, why: | Circle all that apply |
| _____ | Sonographer ID# | | | | 1. Subject refusal |
| _ _ _ - _ _ _ | Video CD# | | | | 2. Subject discomfort |
| ___/___/___ | BRACHIAL test date if different from Clinic Date above. | | | | 3. Time constraint |
| | | | | | 4. Equipment problem, specify |
| | | | | | 5. test contraindication |
| | | | | | 7. Other, specify |

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Date of exam

____/____/____

**Framingham Heart Study
Gen 3 Exam 1**

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 abnormal**.

Summary of Findings _____

1.No clinical evidence of 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.

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The Framingham Heart Study

Letter Date _____

Exam Date _____

OMB No = 0925-0216

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 cooperation makes possible further progress in the determination of causes and ways of preventing heart disease.

Thank you for your continuing support.

Sincerely,

Examiner _____

Medical Director
Framingham Heart Study

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()

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Referral Tracking

[7|0|2|1|5| FORM NUMBER OMB NO=0925-0216

| | |
|--|---|
| <input type="checkbox"/> if yes fill <input type="checkbox"/> 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 | |
| <input type="checkbox"/> | Blood Pressure result ___/___ mmHg Phone call > 200/110 Expedite > 180/100 Elevated > 140/90 |
| <input type="checkbox"/> | Abnormal Urine result _____ <i>Write in abnormality</i> |
| <input type="checkbox"/> | ECG abnormality _____ |
| <input type="checkbox"/> | Clinic Physician _____ identified medical problem |
| <input type="checkbox"/> | Other _____ _____ _____ |

| | |
|--------------------------|--|
| <input type="checkbox"/> | Was there an adverse event in clinic that does not require further medical evaluation? (0=No, 1=Yes, 9=Unknown) Comments: _____ _____ _____ |
|--------------------------|--|

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|7|0|2|1|6| FORM NUMBER OMB NO=0925-0216

| Method used to inform participant of need for further medical evaluation (circle ALL that apply) | |
|---|------------------------|
| 1 | Face-to-face in clinic |
| 2 | Phone call |
| 3 | Result letter |
| 4 | Other |

| Method used to inform participant's personal physician of need for further medical evaluation (circle ALL that apply) | |
|--|----------------------|
| 1 | Phone call |
| 2 | Result letter mailed |
| 3 | Result letter FAX'd |
| 4 | Other |

Date referral made: ___ / ___ / ___

ID number of person completing the referral: _____

Notes documenting conversation with participant or participant's personal physician: _____

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Medical History—Hospitalizations, ER Visits, MD Visits

GEN 3 EXAM 1

DATE _____

|7|0|3|0|1| FORM NUMBER OMB NO=0925-0216

(SCREEN 1)

| Health Care | |
|---|---|
| _ _ _ | 1st Examiner ID _____ 1st Examiner Name |
| _ | Hospitalization (not just E.R.) ever (0=No; 1=yes, hospitalization, 2=yes, more than 1 hospitalization, 9=Unknown) |
| _ | E.R. Visit ever (0=No; 1=Yes, 1 or more Emergency Room visit, 9=Unknown) |
| _ | Day Surgery (0=No, 1=Yes, 9=Unknown) |
| _ | Major illness with visit to doctor (0=No, 1=Yes, 1 visit; 2=Yes, more than 1 visit; 9=Unk) |
| _ | Check up by doctor in past 5 years (0=No, 1=Yes, 9=Unknown) |
| Date of this FHS exam (Today's date - See above) | |
| ____ | MM DD YYYY |

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

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Medical History—Medications

|7|0|3|0|2| FORM NUMBER OMB NO=0925-0216

(SCREEN2)

| | | |
|---|---|---|
| <input type="checkbox"/> If yes, fill | Take aspirin regularly? (0=No, 1=Yes, 9=Unk) | |
| | <input type="checkbox"/> | Number aspirins taken regularly (99=Unknown) |
| | <input type="checkbox"/> | Frequency per (1=Day, 2=Week 3=Month, 4=Year, 9=Unk) |
| | <input type="checkbox"/> | Usual dose (081=baby,160=half dose, 325=nl, 500=extra or larger,999=unk) |

| | | |
|---|--|---|
| <input type="checkbox"/> If yes, fill | Do you take medication for hypertension/high blood pressure? (0=no, 1=yes,now, 2=yes,not now, 9=unk) | |
| | <input type="checkbox"/> | At what age did you begin taking medicine for this (99=unk) |

| | | |
|---|---|---|
| <input type="checkbox"/> If yes, fill | Do you take medication for high blood cholesterol? (0=no, 1=yes, now, 2=yes,not now, 9=unk) | |
| | <input type="checkbox"/> | At what age did you begin taking medicine for this (99=unk) |

| | | |
|---|--|--|
| <input type="checkbox"/> If yes, fill | Do you take medication for high blood sugar or diabetes? (0=no, 1=yes,now, 2=yes,not now, 9=unk) | |
| | <input type="checkbox"/> | At what age did you begin taking medicine for this (99=unk) |
| | <input type="checkbox"/> | Was insulin your first diabetes medication? (0=no, 1=yes, 9=unk) |
| | <input type="checkbox"/> | Did diabetes occur in pregnancy only (0=no, 1=yes, 9=unk) |

| | | |
|---|---|---|
| <input type="checkbox"/> If yes, fill | Do you take 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) | |
| | <input type="checkbox"/> | At what age did you begin taking medicine for this (99=unk) |

140

Medical History-Female Reproductive History. Part 1.

17|0|3|0|5| FORM NUMBER OMB NO=0925-0216

(SCREEN 5)

If participant is male, leave questions blank

| | |
|-----------------|--|
| _ _ | <p>1. How old were you when you had your first menstrual period (menses)? (0=never, 9 or less, 10, 11, 12, 13, 14, 15, 16, 17, or older, 99=unknown)</p> |
| _ | <p>2. Have you ever 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)</p> |
| If yes, fill | <p>What is the name of the current or most recent oral contraceptive, shot or implant used?</p> <p>_____ Name</p> <p>_____ Strength</p> <p> _ Form (1=pill, 2=shot, 3=patch, 4=implant)</p> <p>___/___/___ Duration of use (mo/yr began, mo/yr ended, year - 4 digits) 99/9999=Unknown, 88/8888=current user</p> <p> _ _ What is the total number of years over your lifetime that you used oral contraceptive pills, shots, or hormone implants?</p> |
| _ | <p>3. Have you ever been pregnant? (0=no, 1=yes, 9=Unkn)</p> |
| If yes, fill | <p> _ _ Number of pregnancies?</p> <p> _ _ Number of live births?</p> <p> _ _ How old were you at the end of your first term pregnancy? 99=unknown</p> <p> _ _ How old were you at the end of your last term pregnancy? 99=unknown</p> <p> _ During any of these pregnancies, were you told you had hypertension (high blood pressure)? (0=no, 1=yes, 1st pregnancy only, 2=yes, not 1st pregnancy, 3=yes, 1st & subsequent pregnancy, 9=unknown)</p> |
| _ | <p>4. Have you had a hysterectomy (uterus/womb removed)? (0=no, 1=yes, 9=unknown)</p> |
| If yes, fill | <p> _ _ Age at hysterectomy?</p> <p>/ Date of surgery (mo/yr)</p> |
| _ | <p>5. Have you ever 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)</p> |
| If yes, fill | <p> _ _ Age when ovaries removed? If more than one surgery, use age at last surgery</p> |

143

Medical History--Female Reproductive History. Part 2.

17|0|3|0|6| FORM NUMBER OMB NO=0925-0216

(SCREEN 6)

| | |
|-----|--|
| _ _ | <p>6. Have your periods stopped (for one year or more)? (Have you reached menopause?) (0=not stopped, 1=stopped but now have periods induced by hormones, 2=yes stopped > 1 year, 3=yes stopped < 1 year, 9=unknown)</p> |
|-----|--|

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

| | |
|---|---|
| IF PERIODS NOT STOPPED (pre-menopausal!) | |
| _ _ | When was the first day of your last menstrual period? |
| _ _ | Normally how many days are there between your periods (start to start)? |
| _ _ | 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.)

| | |
|---------------------|--|
| _ _ | <p>a) Age when periods stopped (00=not stopped, 99=unknown) ! If periods now induced by hormones, cod age when periods naturally stopped.</p> |
| _ | <p>b) Was your menopause natural or the result of surgery, chemotherapy, or radiation? (1=natural, 2=surgical, 3=chemo/radiation, 4=other, 9=unknown)</p> |
| _ | <p>c) Have you ever taken hormone replacement therapy? (estrogen/progesterone) (0=no, 1=yes, now, 2=yes, not now, 9=unknown)</p> |
| If yes, fill | <p> _ _ What age did you begin hormone replacement therapy? 99=unknown</p> |
| | <p> _ _ For how long did you take hormones? 99/99=unknown</p> <p>years</p> <p> _ _ </p> <p>months</p> |
| | <p> _ Estrogen use ever? (0=no, 1=yes, now, 2=yes, not now, 9=unknown)</p> <p>If yes, fill</p> <p>_____ Name of most recent estrogen preparation</p> <p>_____ Strength</p> <p> _ _ Number of days per month taken</p> |
| | <p> _ Progesterone use ever? (0=no, 1=yes, now, 2=yes, not now, 9=unknown)</p> <p>If yes, fill</p> <p>_____ Name of most recent progesterone preparation</p> <p> _ _ . _ _ Strength</p> <p> _ _ Number of days per month taken</p> |
| If yes, fill | <p>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)</p> |
| fill | <p> _ _ _ Number of months used?</p> <p> _ Current use? (0=no, 1=yes, raloxifene, 2=yes, tamoxifen, 3=yes, other, 9=unknown)</p> |
| If yes, fill | <p>e) Do you take over-the-counter alternative, herbal, or natural soy-based preparations to treat menopausal symptoms? (0=no, 1=yes, 9=unknown)</p> <p>Specify preparation</p> |

144

Medical History--Smoking**Cigarettes****Have you ever smoked cigarettes regularly?** (No means less than 20 packs of cigarettes or 12 oz of tobacco in a lifetime or less than 1 cigarette a day for 1 year.) (0=no, 1=yes, 9=unk)If yes,
fill

Have you smoked cigarettes regularly in the last year?

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

How many cigarettes do you smoke per day now?

On the average of the entire time you smoked, how many cigarettes did you smoke per day?

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

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

When you were smoking, did you ever stop smoking for >6 months?

If yes,
fill For how many years in total did you stop smoking cigarettes (00=never stopped)**Pipes****Have you ever smoked a pipe regularly?** (Yes means more than 12oz of tobacco in a lifetime.) (0=no, 1=yes, 9=unk)If yes,
fill

Have you smoked a pipe regularly in the last year?

Do you now smoke a pipe (as of 1 month ago)?

How much pipe tobacco do you smoke per day now? (oz. Per week)

On the average of the entire time you smoked a pipe how much pipe tobacco did you smoke per week? (oz./week, a standard pouch of tobacco contains 1 1/2 oz.)

How old were you when you first started to smoke a pipe? (99=Unk.)

If you have stopped smoking a pipe completely, how old were you when you stopped? (Age stopped, 00=not stopped, 99=Unk)

When you were smoking a pipe, did you ever stop smoking for >6 months?

If yes,
fill For how many years in total did you stop smoking a pipe?(00=never stopped)

145

Medical History--Smoking

Cigars

| **Have you ever smoked cigars regularly? (Yes means more than 1 cigar/week for a year)**
(0=no, 1=yes, 9=unk)

If yes,
fill

| Have you smoked cigars regularly in the last year?

| Do you now smoke cigars (as of 1 month ago)?

| | How many cigars do you smoke per week now?

| | On the average of the entire time you smoked cigars, how many cigars did you smoke per week?

| | How old were you when you first started to smoke cigars regularly? (99=Unk.)

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

| When you were smoking cigars, did you ever stop smoking for > 6 months?

If yes,
fill

| | For how many years in total did you stop smoking cigars (00=never stopped)

Passive smoking exposure.

| **In your childhood, did you live with a regular cigarette smoker who smoked in your home?** (0=no, 1=yes, 9=unk)

If yes,
fill

| Mother smoked?

| Father smoked?

| Others in Household smoked?

If yes
to OTHERS,
fill | | How many others?

| **As an adult, now or in the past, have you ever lived with a regular cigarette smoker who smoked in your home?** (0=no, 1=yes, 9=unk)

If yes,
fill

| Spouse or Partner? | | Years of exposure

| Others in household? | | Years of exposure

| **Currently, when you are not at home, do you regularly spend time indoors where there are people smoking cigarettes?** (0=no, 1=yes, 9=unk)

If yes,
fill

| At Work? | | Years of exposure

| Other than work? | | Years of exposure

146

Medical History -Alcohol Consumption.

7|0|3|0|9| FORM NUMBER OMB NO=0925-0216

(SCREEN 9)

| | | |
|-----------------------|--|---|
| __ if yes fill | Have you ever consumed alcoholic beverages (beer, wine, liquor/spirits)? (0=no,1=yes,9=unknown) | |
| | __ __ | How old were you when you first started drinking alcoholic beverages? (99=unknown) |

| Do you drink any of the following beverages at least once a month? | | | | | |
|--|----------------|--|--------------|-------------|--------------------|
| Drink? | 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. | | | Usually with meals |
| | | Number of drinks | | 0=No, 1=Yes | |
| | | Per week | OR Per month | | |
| 0=No, 1=Yes, 9=Ukn | | | 999=Unk | | 0=No, 1=Yes |
| __ | Beer | 12oz bottle, glass, can | _ _ _ _ | _ _ _ _ | __ |
| __ | White wine | 4oz glass | _ _ _ _ | _ _ _ _ | __ |
| __ | Red wine | 4oz glass | _ _ _ _ | _ _ _ _ | __ |
| __ | Liquor/spirits | 1 ¼ oz jigger | _ _ _ _ | _ _ _ _ | __ |
| __ | Other | Specify | _ _ _ _ | _ _ _ _ | __ |

| | |
|-------|--|
| __ __ | At what age did you stop drinking alcohol? (00= not stopped, 99=Unknown) |
|-------|--|

| | |
|-------|--|
| __ __ | Over the past year, on average on how many days per week did you drink an alcoholic beverage of any type? (1=1or less, 99=Unknown) |
| __ __ | Over the past year, on a typical day when you drink, how many drinks do you have? (99=Unknown) |
| __ __ | What was the maximum number of drinks you had in 24 hr. period during the past month? (99=Unknown) |
| __ | 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) |

147

Medical History—Respiratory Symptoms

|7|0|3|1|0| FORM NUMBER OMB NO=0925-0216

(SCREEN 10)

Cough

- During the past 12 months, have you had a cough apart from colds? (Count a cough when you first go outdoors or first smoke. Exclude clearing of throat) 0=No
1=Yes
- During the past 12 month, have you had a cough on getting up or first thing in the morning? 9=Don't know

If YES to either question above answer the following:

- Do you cough on most days (4 or more days/week) for three months or more during the past 12 months? 0=No
1=Yes
9=Don't know
- How many years have you had this cough? (99=Unk.) # of years

Phlegm

- During the past 12 months, have you brought up phlegm from your chest apart from colds? (Exclude phlegm from the nose) 0=No
1=Yes
- During the past 12 month, have you brought up phlegm from your chest on getting up or first thing in the morning? 9=Don't know

If YES to either question above answer the following:

- Do you bring up phlegm from your chest on most days (4 or more days/week) for three months or more during the past 12 months? 0=No
1=Yes
9=Don't know
- How many years have you brought phlegm up from your chest on most days? (99=Unk.) # of years

Wheeze

- Have you ever had wheezing or whistling in your chest? 0=No
1=Yes
9=Don't know
- In the last 12 months, have you had wheezing or whistling in your chest at any time? 9=Don't know
- 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
- In the past 12 months, have you had this wheezing or whistling in the chest when you did NOT HAVE A COLD? 0=No
1=Yes
- 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? 9=Don't know

if yes, fill all

148

Medical History—Respiratory Symptoms. Part II

7|0|3|1|1| FORM NUMBER OMB NO=0925-0216

(SCREEN 11)

Sleep Related Symptoms

- In the past 12 months, on average how many nights a week did you snore? 0=Never
1=Rarely(1-2 nights/week)
2=Occasionally(3-4 nights/week)
3=Frequently(5/more nights/week)
9=Unknown
- In the past 12 months, on average how many nights a week do you snort, gasp, or stop breathing while you are asleep?
- In the past 12 months, on average how many days a week have you had excessive (too much) daytime sleepiness?

Nocturnal chest symptoms

- In the last 12 months, have you been awakened by shortness of breath? 0=No
1=Yes
9=Don't know
 - In the last 12 months, have you been awakened by a wheezing/whistling in your chest? 9=Don't know
 - In the last 12 months, have you been awakened by coughing? 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
- if yes, fill all In the last 12 months, how often have you been awakened by coughing?

Shortness of breath

- Are you troubled by shortness of breath when hurrying on level ground or walking up a slight hill? 0=No
1=Yes
9=Don't know
- if yes, fill all Do you have to walk slower than people of your age on level ground because of shortness of breath?
- Do you ever have to stop for breath when walking at your own pace on level ground?
- Do you ever have to stop for breath after walking 100 yards (or after a few minutes) on level ground?
- Do you/have you needed to sleep on two or more pillows to help you breath? (Orthopnea)
- Have you ever had swelling in both your ankles (ankle edema)?
- Have you been told you had heart failure or congestive heart failure?
- Have you been hospitalized for heart failure?

Examiner's opinion:

- First examiner believes CHF 0=No, 1=Yes
2=Maybe, 9=Unkn

Comments _____

149

Medical History—Chest pain

| | | |
|---|--|--|
| <input type="checkbox"/> | 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 | <input type="checkbox"/> | Chest discomfort with exertion or excitement (0=No, 1=Yes, 2=Maybe, 9=Unknown) |
| | <input type="checkbox"/> | Chest discomfort when quiet or resting |
| Chest Discomfort Characteristics (must have checked box at top of table) | | |
| <input type="checkbox"/> | <input type="checkbox"/> * <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | Date of onset mo/yr, 99/9999=Unknown) |
| <input type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | Usual duration (minutes, 999=Unknown) |
| <input type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | Longest duration (minutes: 1=1 min or less, 900=15 hrs or more, 999=Unknown) |
| <input type="checkbox"/> | <input type="checkbox"/> | 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) |
| <input type="checkbox"/> | <input type="checkbox"/> | 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) |
| <input type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | Frequency (number in past month) 999=Unknown |
| <input type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | Frequency (number in past year) 999=Unknown |
| <input type="checkbox"/> | <input type="checkbox"/> | Type (1=Pressure, heavy, vise, 2=Sharp, 3=Dull, 4=Other, 9=Unk) |
| <input type="checkbox"/> | <input type="checkbox"/> | Relief by Nitroglycerine in < 15 minutes 0=No |
| <input type="checkbox"/> | <input type="checkbox"/> | Relief by Rest in < 15 minutes 1=Yes, |
| <input type="checkbox"/> | <input type="checkbox"/> | Relief Spontaneously in < 15 minutes 8=Not tried |
| <input type="checkbox"/> | <input type="checkbox"/> | Relief by Other cause in < 15 minutes 9=Unknown |

| | | |
|--------------------------|---|-----------------------------------|
| <input type="checkbox"/> | Have you ever been told by a doctor you had a heart attack or myocardial infarction? | 0=No, 1=Yes, 2=Maybe 9=Unknown |
|--------------------------|---|-----------------------------------|

| CHD First Opinions | |
|--------------------------|---|
| <input type="checkbox"/> | Angina pectoris |
| <input type="checkbox"/> | Angina pectoris since revascularization procedure |
| <input type="checkbox"/> | Coronary insufficiency |
| <input type="checkbox"/> | Myocardial infarct |

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

Comments _____

150

| | | | | | | | | | |
|---|--|---|--|---|--|----|----|------|--|
| <input type="checkbox"/> | Have you been told you have/had atrial fibrillation? (0=No, 1=Yes, 2=Maybe,, 9=Unknown) | | | | | | | | |
| if yes, fill <input type="checkbox"/> | <table border="0"> <tr> <td><input type="checkbox"/><input type="checkbox"/>*</td> <td><input type="checkbox"/><input type="checkbox"/>*</td> <td><input type="checkbox"/><input type="checkbox"/><input type="checkbox"/><input type="checkbox"/></td> <td>Date of first episode (99/99/9999=unk) code year as 4 digits, example: Year 1999=1999</td> </tr> <tr> <td>mm</td> <td>dd</td> <td>yyyy</td> <td></td> </tr> </table> | <input type="checkbox"/> <input type="checkbox"/> * | <input type="checkbox"/> <input type="checkbox"/> * | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | Date of first episode (99/99/9999=unk) code year as 4 digits, example: Year 1999=1999 | mm | dd | yyyy | |
| <input type="checkbox"/> <input type="checkbox"/> * | <input type="checkbox"/> <input type="checkbox"/> * | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | Date of first episode (99/99/9999=unk) code year as 4 digits, example: Year 1999=1999 | | | | | | |
| mm | dd | yyyy | | | | | | | |
| <input type="checkbox"/> | ER/hospitalized or saw M.D. (0=Nc, 1=Hosp/ER, 2=Saw M.D., 9=Unkn) | | | | | | | | |
| | Hospitalized at: _____ | | | | | | | | |
| | M.D. seen: _____ | | | | | | | | |

| | | |
|---|---|---|
| <input type="checkbox"/> | Have you ever 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 |
| if yes, fill all <input type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | Number of episodes in the past two years (999=Unknown) |
| | <input type="checkbox"/> <input type="checkbox"/> * | Date of first episode (use 4 digits for year, i.e. 1998) (mo/yr, 99/9999=Unknown) |
| | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | Usual duration of loss of consciousness (minutes, 999=Unkn) 1=1 min or less |
| <input type="checkbox"/> | Did you have any injury caused by the event? (0=No,1=Yes, 2=Maybe,9=Unkn) | |
| if yes, fill <input type="checkbox"/> | <input type="checkbox"/> | ER/hospitalized or saw M.D. (0=No, 1=Hosp/ER, 2=Saw M.D., 9=Unkn) |
| | | Hospitalized at: _____ |
| | | M.D. seen: _____ |

| | | | | | | | | | |
|---|--|---|---|---|---|----|----|------|--|
| <input type="checkbox"/> | History of ever having a head injury with loss of consciousness (0=No, 1=Yes, 2=Maybe, 9=Unknown) | | | | | | | | |
| if yes, fill <input type="checkbox"/> | <table border="0"> <tr> <td><input type="checkbox"/><input type="checkbox"/>*</td> <td><input type="checkbox"/><input type="checkbox"/>*</td> <td><input type="checkbox"/><input type="checkbox"/><input type="checkbox"/><input type="checkbox"/></td> <td>Date of serious head injury with loss of consciousness (00/00/0000 =none, 99/99/9999=unk)</td> </tr> <tr> <td>mm</td> <td>dd</td> <td>yyyy</td> <td></td> </tr> </table> | <input type="checkbox"/> <input type="checkbox"/> * | <input type="checkbox"/> <input type="checkbox"/> * | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | Date of serious head injury with loss of consciousness (00/00/0000 =none, 99/99/9999=unk) | mm | dd | yyyy | |
| <input type="checkbox"/> <input type="checkbox"/> * | <input type="checkbox"/> <input type="checkbox"/> * | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | Date of serious head injury with loss of consciousness (00/00/0000 =none, 99/99/9999=unk) | | | | | | |
| mm | dd | yyyy | | | | | | | |

| | | | | | | | | | |
|---|--|---|---|---|---|----|----|------|--|
| <input type="checkbox"/> | History of a seizure disorder (0=No, 1=Yes, 2=Maybe,, 9=Unknown) | | | | | | | | |
| if yes, fill <input type="checkbox"/> | <table border="0"> <tr> <td><input type="checkbox"/><input type="checkbox"/>*</td> <td><input type="checkbox"/><input type="checkbox"/>*</td> <td><input type="checkbox"/><input type="checkbox"/><input type="checkbox"/><input type="checkbox"/></td> <td>Date of most recent seizure (99/99/9999=unk) code four digit year</td> </tr> <tr> <td>mm</td> <td>dd</td> <td>yyyy</td> <td></td> </tr> </table> | <input type="checkbox"/> <input type="checkbox"/> * | <input type="checkbox"/> <input type="checkbox"/> * | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | Date of most recent seizure (99/99/9999=unk) code four digit year | mm | dd | yyyy | |
| <input type="checkbox"/> <input type="checkbox"/> * | <input type="checkbox"/> <input type="checkbox"/> * | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | Date of most recent seizure (99/99/9999=unk) code four digit year | | | | | | |
| mm | dd | yyyy | | | | | | | |
| <input type="checkbox"/> | Are you being treated for a seizure disorder? (0=No, 1=Yes, 2=Maybe, 9=Unknown) | | | | | | | | |

| Syncope First Opinions | |
|-------------------------------|---|
| <input type="checkbox"/> | Syncope (0=No, 1=Yes, 2=Maybe, 3=Presyncope, 9=Unknown) needs second opinion |
| <input type="checkbox"/> | Cardiac syncope |
| <input type="checkbox"/> | Vasovagal syncope |
| <input type="checkbox"/> | Other-Specify: _____ |
| | (0=No, 1=Yes, 2=Maybe, 9=Unknown) |

Comments: _____

Medical History—Cerebrovascular Disease

|7|0|3|1|4| FORM NUMBER OMB NO=0925-0216

(SCREEN14)

| Cerebrovascular Episodes | | | | | | | | | | | | | |
|---------------------------------|--|-----------------|-----------------------------------|-----------------|--------------------------|---|--|---|---|--|------------|--|---------------|
| <input type="checkbox"/> | Sudden muscular weakness | | | | | | | | | | | | |
| <input type="checkbox"/> | Sudden speech difficulty | | | | | | | | | | | | |
| <input type="checkbox"/> | Sudden visual defect | | | | | | | | | | | | |
| <input type="checkbox"/> | Double vision | | | | | | | | | | | | |
| <input type="checkbox"/> | Loss of vision in one eye | | | | | | | | | | | | |
| <input type="checkbox"/> | Numbness, tingling | | | | | | | | | | | | |
| if yes, fill ☞ | <input type="checkbox"/> Numbness and tingling is positional | | | | | | | | | | | | |
| <input type="checkbox"/> | Head CT or MRI scan (date/place _____) (0=No, 1=CT, 2=MRI, 3=both, 9=Unknown) | | | | | | | | | | | | |
| <input type="checkbox"/> | Seen by neurologist (write in who and when below) | | | | | | | | | | | | |
| Neurology First Opinions | | | | | | | | | | | | | |
| <input type="checkbox"/> | TIA or stroke took place (0=No, 1=Yes, 2=Maybe, 9=Unknown) | | | | | | | | | | | | |
| if yes or maybe fill ☞ | <table style="width: 100%; border: none;"> <tr> <td style="width: 30%; text-align: center;"> _ _ * _ _ _ _ _ </td> <td style="padding: 5px;">Date (mo/yr, 99/9999=Unkn)</td> </tr> <tr> <td style="width: 30%; text-align: center;"> _ _ * _ _ * _ _ </td> <td style="padding: 5px;">Observed by _____</td> </tr> <tr> <td style="width: 30%; text-align: center;"> _ </td> <td style="padding: 5px;">Duration (use format days/hours/mins, 99/99/99=Unknown)</td> </tr> <tr> <td style="width: 30%; text-align: center;"> _ </td> <td style="padding: 5px;">Hospitalized or saw M.D. (0=No, 1=Hosp.2=Saw M.D, 9=Unk)</td> </tr> <tr> <td></td> <td style="padding: 5px;">Name _____</td> </tr> <tr> <td></td> <td style="padding: 5px;">Address _____</td> </tr> </table> | _ _ * _ _ _ _ _ | Date (mo/yr, 99/9999=Unkn) | _ _ * _ _ * _ _ | Observed by _____ | _ | Duration (use format days/hours/mins, 99/99/99=Unknown) | _ | Hospitalized or saw M.D. (0=No, 1=Hosp.2=Saw M.D, 9=Unk) | | Name _____ | | Address _____ |
| _ _ * _ _ _ _ _ | Date (mo/yr, 99/9999=Unkn) | | | | | | | | | | | | |
| _ _ * _ _ * _ _ | Observed by _____ | | | | | | | | | | | | |
| _ | Duration (use format days/hours/mins, 99/99/99=Unknown) | | | | | | | | | | | | |
| _ | Hospitalized or saw M.D. (0=No, 1=Hosp.2=Saw M.D, 9=Unk) | | | | | | | | | | | | |
| | Name _____ | | | | | | | | | | | | |
| | Address _____ | | | | | | | | | | | | |

Neurology
Comments

152

Medical History-- CVD Procedures

17101311161 FORM NUMBER OMB NO=0925-0216

(SCREEN 16)

| | |
|--|---|
| 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) |
| <input type="checkbox"/> if yes fill | Heart Valvular Surgery _ _ _ _ Year done (9999-Unk) Location and description _____ |
| <input type="checkbox"/> if yes fill | Exercise Tolerance Test _ _ _ _ Year done (9999-Unk) Location _____ |
| <input type="checkbox"/> if yes fill | Coronary arteriogram _ _ _ _ Year done (9999-Unk) |
| <input type="checkbox"/> if yes fill | Coronary artery angioplasty _ _ _ _ Year done (9999-Unk) _ Type of procedure (0=none, 1=balloon, 2=stent, 3=other, 9=unkn) |
| <input type="checkbox"/> if yes fill | Coronary bypass surgery _ _ _ _ Year done (9999-Unk) |
| <input type="checkbox"/> if yes fill | Permanent pacemaker insertion _ _ _ _ Year done (9999-Unk) |
| <input type="checkbox"/> if yes fill | Carotid artery surgery _ _ _ _ Year done (9999-Unk) |
| <input type="checkbox"/> if yes fill | Thoracic aorta surgery _ _ _ _ Year done (9999-Unk) |
| <input type="checkbox"/> if yes fill | Abdominal aorta surgery _ _ _ _ Year done (9999-Unk) |
| <input type="checkbox"/> if yes fill | Femoral or lower extremity surgery _ _ _ _ Year done (9999-Unk) |
| <input type="checkbox"/> if yes fill | Lower extremity amputation _ _ _ _ Year done (9999-Unk) |
| <input type="checkbox"/> if yes fill | Other Cardiovascular Procedure (write in below) _ _ _ _ Year done (9999-Unk) Description _____ |

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

154

Cancer Site or Type

710131171 FORM NUMBER OMB NO=0925-0216

(SCREEN17)

| <input type="checkbox"/> Have you ever 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. |
| <input type="checkbox"/> | Esophagus | | | |
| <input type="checkbox"/> | Stomach | | | |
| <input type="checkbox"/> | Colon | | | |
| <input type="checkbox"/> | Rectum | | | |
| <input type="checkbox"/> | Pancreas | | | |
| <input type="checkbox"/> | Larynx | | | |
| <input type="checkbox"/> | Trachea/Bronchus/Lung | | | |
| <input type="checkbox"/> | Leukemia | | | |
| <input type="checkbox"/> | Skin | | | |
| <input type="checkbox"/> | Breast | | | |
| <input type="checkbox"/> | Cervix/Uterus | | | |
| <input type="checkbox"/> | Ovary | | | |
| <input type="checkbox"/> | Prostate | | | |
| <input type="checkbox"/> | Bladder | | | |
| <input type="checkbox"/> | Kidney | | | |
| <input type="checkbox"/> | Brain | | | |
| <input type="checkbox"/> | Lymphoma | | | |
| <input type="checkbox"/> | Other/Unknown | | | |

Comment (If participant has more details concerning tissue diagnosis, other hospitalization, procedures, treatments)

153

Physical Exam--Head, Neck and Respiratory

1710131181 FORM NUMBER OMB NO=0925-0216

(SCREEN18)

| Physician Blood Pressure (first reading) | | | |
|--|--|---|---|
| Systolic | Diastolic | BP cuff size | Protocol modification |
| <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> to nearest 2 mm Hg | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> to nearest 2 mm Hg | <input type="text"/> 0=pedi, 1=reg. adult, 2=large adult, 3= thigh, 9=unknown | <input type="text"/> <input type="text"/> 0=No, 1=Yes, 9=Unknown |

| Respiratory | | |
|--------------------------|---------------------------------|-----------------|
| <input type="checkbox"/> | Wheezing on auscultation | 0=No, 1=Yes, |
| <input type="checkbox"/> | Rales | 2=Maybe, |
| <input type="checkbox"/> | Abnormal breath sounds | 9=Unknown |

Comments about Respiratory _____

156

Physical Exam—Heart and Abdomen

1710131191 FORM NUMBER OMB NO=0925-0216

(SCREEN19)

| Heart | | |
|--------------------------|--|---------------------------------------|
| <input type="checkbox"/> | Left Heart Enlargement | 0=No 1=Yes 9=Unknown |
| <input type="checkbox"/> | Right Heart Enlargement | |
| <input type="checkbox"/> | S3 Gallop | |
| <input type="checkbox"/> | S4 Gallop | |
| <input type="checkbox"/> | Systolic Click | 0=No 1=Yes 2=Maybe 9=Unknown |
| <input type="checkbox"/> | Neck vein distention at 90 degrees (sitting upright) | |
| <input type="checkbox"/> | Other--Specify _____ | |

| Systolic murmur(s) (0=No, 1=Yes, 2=Maybe, 9=Unknown) | | | | | |
|--|--|---|--|---|--|
| Murmur Location | Grade | Type | Radiation | Valsalva | Origin |
| | 0=No sound 1 to 6 for grade of sound heard 9=Unknown | 0=None 1=Ejection 2=Regurgitant 3=Other 9=Unknown | 0=None 1=Axilla 2=Neck 3=Back 4=Rt. chest 9=Unknown | 0=Nochange 1=Increase 2=Decrease 9=Unknown | 0=None, indet. 1=Mitral 2=Aortic 3=Tricuspid 4=Pulm 9=Unknown |
| Apex | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Left Sternum | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Base | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

| | |
|--------------------------|---|
| <input type="checkbox"/> | Diastolic murmur(s) (0=No, 1=Yes, 2=Maybe, 9=Unknown) |
| if yes, fill | <input type="checkbox"/> Valve of origin for diastolic murmur(s) (0=No, 1=Mitral, 2=Aortic, 3=Both, 4=Other, 8=N/A, 9=Unk) |

Comments _____

| Abdominal Abnormalities | |
|--------------------------|--------------------|
| <input type="checkbox"/> | Liver enlarged |
| <input type="checkbox"/> | Surgical scar |
| <input type="checkbox"/> | Abdominal aneurysm |
| <input type="checkbox"/> | Abdominal bruit |

0=No
1=Yes
2=Maybe
9=Unknown

157

Physical Exam--Peripheral Vessels--Part I

[7|0|3|2|0|] FORM NUMBER

OMB NO=0925-0216

(SCREEN 20)

| Left | Right | Varicosities | |
|--------------------------|--------------------------|--|---|
| <input type="checkbox"/> | <input type="checkbox"/> | Stem varicose veins (Do not code reticular or spider varicosities) | 0=No abnormality 1=Uncomplicated 2=With skin changes 3=With ulcer 9=Unknown |
| Left | Right | Lower Extremity Abnormalities | |
| <input type="checkbox"/> | <input type="checkbox"/> | Ankle edema | (0=No, 1=Yes, 2=Maybe, 8=absent due to amputation 9=Unknown) |
| <input type="checkbox"/> | <input type="checkbox"/> | Amputation level | (0=No, 1=Toes only, 2=Ankle, 3=Knee, 4=Hip, 8=Not applicable, 9=Unknown) |

Comments _____

Physical Exam--Peripheral Vessels--Part II

| Artery | Pulse | | Bruit | |
|-----------------------|-----------------------------------|--------------------------|-----------------------------------|--------------------------|
| | (0=Normal, 1=Abnormal, 9=Unknown) | | (0=Normal, 1=Abnormal, 9=Unknown) | |
| | Left | Right | Left | Right |
| Femoral | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Popliteal | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Post Tibial | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Dorsalis Pedis | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Comments _____

158

Physical Exam--Neurological Diseases and Final Blood Pressure

|7|0|3|2|1| FORM NUMBER OMB NO=0925-0216

(SCREEN21)

| Neurological Exam | | | |
|-------------------|--------------|--|--|
| Left | Right | | |
| _ | _ | Carotid Bruit | Coding (0=No, 1=Yes, 2=Maybe, 9=Unknown) |
| | _ | Speech disturbance | |
| | _ | Disturbance in gait | |
| | _ | Other neurological abnormalities on exam Specify _____ | |

| Physician Blood Pressure (second reading) | | | |
|--|-----------------------------------|---|------------------------------|
| Systolic | Diastolic | BP cuff size | Protocol modification |
| _ _ _ | _ _ _ | _ | _ |
| 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 _____

159

Electrocardiograph--Part I

|7|0|3|2|2| FORM NUMBER OMB NO=0925-0216

(SCREEN22)

| | |
|---|---|
| __ if Yes, fill out rest of form | ECG done (0=No, 1=Yes) |
| Rates and Intervals | |
| __ __ __ | Ventricular rate per minute (999=Unknown) |
| __ __ | P-R Interval (hundredths of a second) (99=Fully Paced, Atrial Fib, or Unknown) |
| __ __ | QRS interval (hundredths of second) (99=Fully Paced, Unknown) |
| __ __ | Q-T interval (hundredths of second) (99=Fully Paced, Unknown) |
| __ __ __ | QRS angle (put plus or minus as needed) (e.g. -045 for minus 45 degrees, +090 for plus 90, 999= Fully paced or Unknown) |
| Rhythm--predominant | |
| __ | 0 or 1 = Normal sinus, (including s.tach, s.brady, s arrhy, 1 degree AV block) 3 = 2nd degree AV block, Mobitz I (Wenckebach) 4 = 2nd degree AV block, Mobitz II 5 = 3rd degree AV block / AV dissociation 6 = Atrial fibrillation / atrial flutter 7 = Nodal 8 = Paced 9 = Other or combination of above (list) _____ |
| Ventricular conduction abnormalities | |
| __ | IV Block (0=No, 1=Yes, 9=Fully paced or Unknown) |
| if yes, fill | __ Pattern (1=Left, 2=Right, 3=Indeterminate, 9=Unknown) |
| __ | Complete (QRS interval = .12 sec or greater)(0=No, 1=Yes, 9=Unknown) |
| __ | Incomplete (QRS interval = .10 or .11 sec) (0=No, 1=Yes, 9=Unknown) |
| __ | Hemiblock (0=No, 1=Left Ant, 2=Left Post, 9=Fully paced or Unknown) |
| __ | WPW Syndrome (0=No, 1=Yes, 2=Maybe, 9=Fully paced or Unknown) |
| Arrhythmias | |
| __ | Atrial premature beats (0=No, 1=Atr, 2=Atr Aber, 9=Unknown) |
| __ | Ventricular premature beats (0=No, 1=Simple, 2=Multifoc, 3=Pairs, 4=Run, 5=R on T, 9=Unk) |
| __ __ | Number of ventricular premature beats in 10 seconds (see 10 second rhythm strip) |

(60)

Electrocardiograph-Part II

17101312131 FORM NUMBER OMB NO=0925-0216

(SCREEN23)

Myocardial Infarction Location

- | | | |
|--------------------------|----------------|---------------------------|
| <input type="checkbox"/> | Anterior | (0=No, |
| <input type="checkbox"/> | Inferior | 1=Yes, |
| <input type="checkbox"/> | True Posterior | 2=Maybe, |
| | | 9=Fully paced or Unknown) |

Left Ventricular Hypertrophy Criteria

- | | | |
|--------------------------|---------------------------------------|--------------------------------------|
| <input type="checkbox"/> | R > 20mm in any limb lead | (0=No, |
| <input type="checkbox"/> | R > 11mm in AVL | 1=Yes, |
| <input type="checkbox"/> | R in lead I plus S ≥ 25mm in lead III | 9=Fully paced, Complete LBBB or Unk) |

Measured Voltage

- | | | | |
|---|--------------------------|--------------------------|---|
| * | <input type="checkbox"/> | <input type="checkbox"/> | R AVL in mm (at 1 mv = 10 mm standard) Be sure to code these voltages |
| * | <input type="checkbox"/> | <input type="checkbox"/> | 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

- | | | |
|--------------------------|-----------------------------------|--------------------------------------|
| <input type="checkbox"/> | R ≥ 25mm | |
| <input type="checkbox"/> | S ≥ 25mm | |
| <input type="checkbox"/> | R or S ≥ 30mm | (0=No, |
| <input type="checkbox"/> | R + S ≥ 35mm | 1=Yes, |
| | | 9=Fully paced, Complete LBBB or Unk) |
| <input type="checkbox"/> | Intrinsicoid deflection ≥ .05 sec | |
| <input type="checkbox"/> | S-T depression (strain pattern) | |

Hypertrophy, enlargement, and other ECG Diagnoses

- | | |
|--------------------------|---|
| <input type="checkbox"/> | Nonspecific S-T segment abnormality (0=No, 1=S-T depression, 2=S-T flattening, 3=Other, 9=Fully paced or unknown) |
| <input type="checkbox"/> | Nonspecific T-wave abnormality (0=No, 1=T inversion, 2=T flattening, 3=Other, 9=Fully paced or unknown) |
| <input type="checkbox"/> | U-wave present (0=No, 1=Yes, 2=Maybe, 9=Paced or Unknown) |
| <input type="checkbox"/> | Atrial enlargement (0=None, 1=Left, 2=Right, 3=Both, 9=Atrial fib. or Unknown) |
| <input type="checkbox"/> | RVH (0=No, 1=Yes, 2=Maybe, 9=Fully paced or Unknown; If complete RBBB present, RVH=9) |
| <input type="checkbox"/> | 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 _____

161

Clinical Diagnostic Impression--Part II
Non Cardiovascular Diagnoses First Examiner Opinions

7|0|3|2|5| FORM NUMBER

OMB NO=0925-0216

(SCREEN 25)

Endocrine

- Thyroid Disease
 - Diabetes Mellitus
 - Other endocrine disorders, specify _____
- 0=No, 1=Yes,
2=Maybe,
9=Unknown

GU/GYN

- Renal disease, specify _____
 - Prostate disease
 - Gynecologic problems, specify _____
- 0=No, 1=Yes,
2=Maybe,
9=Unknown

Pulmonary

- Emphysema
 - Pneumonia
 - Asthma
 - Other pulmonary disease, specify _____
- 0=No,
1=Yes,
2=Maybe,
9=Unknown

Rheumatologic Disorders

- Gout
 - Degenerative joint disease
 - Rheumatoid arthritis
 - Other musculoskeletal or connective tissue disease,specify _____
- 0=No,
1=Yes,
2=Maybe,
9=Unknown

GI

- Gallbladder disease
 - GERD/ulcer disease
 - Liver disease
 - Other GI disease, specify _____
- 0=No,
1=Yes,
2=Maybe,
9=Unknown

Blood

- Hematologic disorder
 - Bleeding disorder
- 0=No, 1=Yes,
2=Maybe, 9=Unk

Other

- Eye
 - ENT
 - Skin
 - Other, specify _____
- 0=No, 1=Yes,
2=Maybe,
9=Unknown

Infectious Disease

- HIV
 - TB
 - Other, specify _____
- 0=No, 1=Yes,
2=Maybe,
9=Unknown

Mental Health

- Depression
 - Anxiety
 - Psychosis
 - Other, specify _____
- 0=No,
1=Yes,
2=Maybe,
9=Unknown

Comments CDI Diagnoses _____

163

| | | |
|---|-------------------------------|-------------------------------|
| <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | 2nd Examiner ID Number | 2nd Examiner Last Name |
|---|-------------------------------|-------------------------------|

| Coronary Heart Disease Second Examiner Opinions (Provide initiators, qualities, radiation, severity, timing, presence after procedures done) | |
|--|---------------------------------|
| <input type="checkbox"/> | Congestive Heart Failure |
| <input type="checkbox"/> | Cardiac Syncope |
| <input type="checkbox"/> | Angina Pectoris |
| <input type="checkbox"/> | Coronary Insufficiency |
| <input type="checkbox"/> | Myocardial Infarct |

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

Comments about chest and heart disease

| Intermittent Claudication Second Examiner Opinions (Provide initiators, qualities, radiation, severity, timing, presence after procedures done) | |
|---|----------------------------------|
| <input type="checkbox"/> | 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) | |
|--|---------------|
| <input type="checkbox"/> | Stroke |
| <input type="checkbox"/> | TIA |

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

Comments about possible Cerebrovascular Disease

164

PLEASE USE PENCIL 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 B₆? 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 51 mg. 51 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 Cod liver Oil Iodine Beta-Carotene Other (please specify): _____
 Vitamin D Copper Brewer's Yeast
 B-Complex Vitamins Omega-3 Fatty-acids Magnesium

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 | 2-4 per week | 5-6 per week | 1 per day | 2-3 per day | 4-5 per day | 6+ per day |
| Skim or low fat milk (8 oz. glass) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Whole milk (8 oz. glass) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Cream, e.g. coffee, whipped (Tbs) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Sour cream (Tbs) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Non-dairy coffee whitener (tsp.) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Sherbet or ice milk (1/2 cup) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Ice cream (1/2 cup) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Yogurt (1 cup) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Cottage or ricotta cheese (1/2 cup) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Cream cheese (1 oz.) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Other cheese, e.g. American, cheddar, etc., plain or as part of a dish (1 slice or 1 oz. serving) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Margarine (pat), added to food or bread; exclude use in cooking | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Butter (pat), added to food or bread; exclude use in cooking | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

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 | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Prunes (1/2 cup) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Bananas (1) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Cantaloupe (1/4 melon) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Watermelon (1 slice) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Fresh apples or pears (1) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Apple juice or cider (small glass) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Oranges (1) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Orange juice (small glass) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Grapefruit (1/2) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Grapefruit juice (small glass) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Other fruit juices (small glass) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Strawberries, fresh, frozen or canned (1/2 cup) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Blueberries, fresh, frozen or canned (1/2 cup) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Peaches, apricots or plums (1 fresh, or 1/2 cup canned) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

| 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) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Tomato juice (small glass) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Tomato sauce (1/2 cup) e.g. spaghetti sauce | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Red chili sauce (1 Tbs) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Tofu or soybeans (3-4 oz.) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| String beans (1/2 cup) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Broccoli (1/2 cup) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Cabbage or cole slaw (1/2 cup) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Cauliflower (1/2 cup) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Brussels sprouts (1/2 cup) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Carrots, raw (1/2 carrot or 2-4 sticks) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Carrots, cooked (1/2 cup) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Corn (1 ear or 1/2 cup frozen or canned) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Peas, or lima beans (1/2 cup fresh, frozen, canned) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Mixed vegetables (1/2 cup) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Beans or lentils, baked or dried (1/2 cup) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Yellow (winter) squash (1/2 cup) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Eggplant, zucchini, or other summer squash (1/2 cup) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Yams or sweet potatoes (1/2 cup) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Spinach, cooked (1/2 cup) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Spinach, raw as in salad | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Kale, mustard or chard greens (1/2 cup) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Iceberg or head lettuce (serving) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Romaine or leaf lettuce (serving) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Celery (4" stick) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Beets (1/2 cup) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Alfalfa sprouts (1/2 cup) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Garlic, fresh or powdered (1 clove or shake) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

| 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) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Chicken or turkey, with skin (4-6 oz.) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Chicken or turkey, without skin (4-6 oz.) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Bacon (2 slices) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Hot dogs (1) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

3. (Continued) Please fill in your average use, during the past year, of each specified food.

| | | 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 |
|--------------------------|--|------------------------------------|-----------------------|----------------------------------|-----------------------|-----------------------|----------------------------------|-----------------------|-----------------------|-----------------------|
| MEATS (CONTINUED) | | | | | | | | | | |
| | Processed meats, e.g. sausage, salami, bologna, etc. (piece or slice) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | Liver (3-4 oz.) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | Hamburger (1 patty) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | Beef, pork, or lamb as a sandwich or mixed dish, e.g. stew, casserole, lasagne, etc. | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | Beef, pork, or lamb as a main dish, e.g. steak, roast, ham, etc. (4-6 oz.) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | Canned tuna fish (3-4 oz.) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | Dark meat fish, e.g. mackerel, salmon, sardines, bluefish, swordfish (3-5 oz.) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | Other fish (3-5 oz.) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | Shrimp, lobster, scallops as a main dish | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

| | | 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 |
|----------------------------------|--|------------------------------------|-----------------------|----------------------------------|-----------------------|-----------------------|----------------------------------|-----------------------|-----------------------|-----------------------|
| BREADS, CEREALS, STARCHES | | | | | | | | | | |
| | Cold breakfast cereal (1 cup) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | Cooked oatmeal (1 cup) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | Other cooked breakfast cereal (1 cup) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | White bread (slice), including pita bread | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | Dark bread (slice) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | English muffins, bagels, or rolls (1) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | Muffins or biscuits (1) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | Brown rice (1 cup) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | White rice (1 cup) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | Pasta, e.g. spaghetti, noodles, etc. (1 cup) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | Other grains, e.g. bulgar, kasha, couscous, etc. (1 cup) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | Pancakes or waffles (serving) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | French fried potatoes (4 oz.) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | Potatoes, baked, boiled (1) or mashed (1 cup) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | Potato chips or corn chips (small bag or 1 oz.) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | Crackers, Triskets, Wheat Thins (1) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | Pizza (2 slices) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

| | | 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 |
|---|---|------------------------------------|----------------------------------|----------------------------------|-----------------------|----------------------------------|----------------------------------|-----------------------|-----------------------|-----------------------|
| BEVERAGES | | | | | | | | | | |
| CARBONATED BEVERAGES | Low Calorie (sugar-free) types | | | | | | | | | |
| | Low calorie cola, e.g. Tab with caffeine | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | Low calorie caffeine-free cola, e.g. Pepsi Free | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | Other low calorie carbonated beverage, e.g. Fresca, Diet 7-Up, diet ginger ale | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Consider the serving size as 1 glass, bottle or can for these carbonated beverages. | Regular types (not sugar-free) | | | | | | | | | |
| | Coke, Pepsi, or other cola with sugar | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | Caffeine Free Coke, Pepsi, or other cola with sugar | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | Other carbonated beverage with sugar, e.g. 7-Up, ginger ale | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| OTHER BEVERAGES | Hawaiian Punch, lemonade, or other non-carbonated fruit drinks (1 glass, bottle, can) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | Decaffeinated coffee (1 cup) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | Coffee (1 cup) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | Tea (1 cup), not herbal teas | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | Beer (1 glass, bottle, can) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | Red wine (4 oz. glass) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | White wine (4 oz. glass) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Liquor, e.g. whiskey, gin, etc. (1 drink or shot) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | |

ID: _____

(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 | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Candy bars, e.g. Snickers, Milky Way, Reeses | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Candy without chocolate (1 oz.) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Cookies, home baked (1) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Cookies, ready made (1) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Brownies (1) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Doughnuts (1) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Cake, home baked (slice) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Cake, ready made (slice) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Sweet roll, coffee cake or other pastry, home baked (serving) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Sweet roll, coffee cake or other pastry, ready made (serving) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Pie, homemade (slice) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Pie, ready made (slice) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Jams, jellies, preserves, syrup, or honey (1 Tbs) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Peanut butter (Tbs) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Popcorn (1 cup) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Nuts (small packet or 1 oz.) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Bran, added to food (1 Tbs) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Wheat germ (1 Tbs) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Chowder or cream soup (1 cup) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Oil and vinegar dressing, e.g. Italian (1 Tbs) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Mayonnaise or other creamy salad dressing (1 Tbs) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Mustard, dry or prepared (1 tsp) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Pepper (1 shake) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Salt (1 shake) | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

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) | | | 168 |

17. f. Inter-tech Form

For Administrative Purposes Only

**Framingham Heart Study
Intertech Quality Control Measurements**

Date: _____ Pt Label: _____

First Tech ID: _____ Second Tech ID: _____ Test Tech ID: _____

Height/Weight Measurement

Each technician, paired with a second technician and out of each other's view, measures height and weight on the same participant. If the difference in weight is greater than **0.5** pounds (or the average of 1 pound), or the difference in height is more than **0.25** inches, the measurement is repeated.

Height Measurement: _____ Repeat Height Measurement: _____

Weight Measurement: _____ Repeat Weight Measurement: _____

Keyer: _____

Anthropometric Measurements

Neck Circumference and Waist Girth

Each technician, paired with a second technician and out of each other's view, performs anthropometric measurements on the same participant. If the neck circumference differs by more than **0.25** inches, or the waist girth measurement differs by more than **0.50** inches the measurement is repeated.

Neck Circumference: _____ Repeat Neck Circumference: _____
(inches, round down to the next lower 1/4 inch)

Waist Girth: _____ Repeat Waist Girth: _____
(inches, round down to the next lower 1/4 inch)

Keyer: _____

Blood Pressure Measurement

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 is SBP and/or DBP is greater than **4mmHg**, or if the average of the readings for each technician differs by more than **3mmHg**, the measurement is repeated.

Cuff Size: _____

Cuff Size:

Palpated Systolic Pressure: _____

0= Pedi

Systolic Blood Pressure (SBP): _____

1= Regular

Diastolic Blood Pressure (DBP): _____

2= Large

Repeat SBP: _____

3= Thigh

Repeat DBP: _____

Keyer: _____

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**INTERTECH MEASUREMENTS
MONTHLY REPORTS**

DATE:

| | Number of Sets Completed | Number of Sets With Acceptable Difference | Number of Sets <u>Not</u> Acceptable | Absolute Difference (Interpretation of Non-Acceptable Sets) | Acceptable Difference (QC Guidelines) |
|--------------------------------------|--------------------------|---|--------------------------------------|---|---|
| Blood Pressure | | | | | No greater than 4mm Hg |
| Height/ Weight | | | | | No greater than (Hgt) 0.25 inch (Wt) 0.5 lb or average 1 lb |
| Anthro. Neck Circ. Waist Girth | | | | | No greater than (Neck) 0.25 inch (Waist) 0.50 inch |

For Administrative Purposes Only

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17. g. Supervisor
Observation Forms

For Administrative
Purposes Only

**Blood Pressure
Supervisor Checklist**

Date: _____

Technician #: _____

Supervisor: _____

Participant name & ID #: _____

Instruction: Check that each procedure is carried out correctly. If incorrect, circle **n** (*no*) and provide an explanation in the comment section. Items are presented in the sequence of the examination procedure, but may require confirmation after the examination

The following items apply throughout the exam:

Comments:

y n Participants is kept warm, relaxed, and comfortable.

y n Participant is discouraged from talking, except to voice discomfort or confusion about instructions.

Standard blood pressure examination:

y n Technician greets and informs participant appropriately.

y n Tech bares participant's arm to allow proper placement of cuff.

y n Tech assesses participant's arm for correct cuff size.

y n Tech palpates brachial artery.

y n Tech wraps cuff center of bladder over brachial artery.

y n Tech instructs participant on posture with feet flat on the ground.

y n Tech finds palpated systolic pressure using standard manometer.

y n Tech calculates maximal inflation level, standard manometer.

y n Tech waits at least 30 seconds before proceeding.

y n Tech places stethoscope in ears, earpiece forward.

y n Tech places bell on brachial pulse.

y n Tech inflates rapidly to maximal inflation.

y n Tech deflates cuff 2 mmHg per second.

y n Tech deflates cuff 10 mmHg below diastolic.

y n Tech opens thumb valve or disconnects tubing

y n Tech records readings.

Overall Comments of Supervisor:

Instructions to technician/corrective action:

Signature, Supervisor 3/02

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For Administrative
Purposes Only

**ECG
Supervisor Checklist**

Date: _____

Technician #: _____

Supervisor: _____

Participant name & ID #: _____

Instruction: Check that each procedure is carried out correctly. Circle **y** (*yes*) if correct. If incorrect, circle **n** (*no*) and provide an explanation in the comment section following the item. Items are presented in the sequence of the examination procedure, but may require confirmation before or after the examination.

Comments:

- | | | |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | Participant is informed that ECG is going to be done. Procedure is explained. Participant is asked to lie on bed, get comfortable. |
| <input type="checkbox"/> | <input type="checkbox"/> | Tech establishes a rapport with participant so participant is at ease with procedure. Answers any questions participant may have. |
| <input type="checkbox"/> | <input type="checkbox"/> | Electrode location V2 is located in the 4 th intercostal space at the left sternal border, a mark is made with pencil. |
| <input type="checkbox"/> | <input type="checkbox"/> | V1 is found at the same level as V2 but at the right sternal border, a mark is made. |
| <input type="checkbox"/> | <input type="checkbox"/> | The E point is located at the intersection of the 5 th intercostal space and the mid-clavicular line, a mark is made. |
| <input type="checkbox"/> | <input type="checkbox"/> | A line is drawn at mid axillary in exact vertical center plane of the thorax. |
| <input type="checkbox"/> | <input type="checkbox"/> | 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). |
| <input type="checkbox"/> | <input type="checkbox"/> | The difference between the E0 measurement and V6 measurement is calculated. |
| <input type="checkbox"/> | <input type="checkbox"/> | The difference from the above calculation is located in the heart square and V4 is located on the chest, a mark is made. |
| <input type="checkbox"/> | <input type="checkbox"/> | V3 is located midway between V2 and V4, a mark is made. |
| <input type="checkbox"/> | <input type="checkbox"/> | V5 is located midway between V4 and V6, a mark is made. |
| <input type="checkbox"/> | <input type="checkbox"/> | Alcohol wipe is used to clean each area, V1, V2, V3, V4, V5, V6 and RA, LA, RL, LL |

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Comments:

- y n 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.
- y n RA electrode is located on the upper (dorsal) surface of right forearm, placed with tab extending away from body.
- y n LA electrode is located on the upper (dorsal) surface of left forearm, placed with tab extending away from body.
- y n RL electrode is located on the inside surface of the right lower leg, placed with tab extending away from body.
- y n LL electrode is located on the inside surface left lower leg, placed with tab extending away from body.
- y n Leads are connected to electrodes in the following order: RL, LL, RA, LA, V1, V2, V3, V4, V5, V6.
- y n All leads are rechecked for proper placement.
- y n The participant's identifying information is typed into the MAC.
- y n Participant is requested to relax and lie quietly while ECG recording is in process.
- y n When tracing appears acceptable, the ECG is printed and reviewed for errors.
- y n Leads are disconnected and electrodes gently removed.

Rarely, lead placement varies depending on physical condition of participant, such as limb amputation, current skin infections/conditions, hand tremors causing unclear tracings, etc: (note if lead position(s) has to be altered)

Overall Comments of Supervisor:

Instructions to Technician/Corrective Action:

Supervisor, Signature

03/02

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For Administrative Purposes Only
**Physical Activities Questionnaire/Pedigree Verification
Supervisor Checklist**

Date: _____

Technician #: _____

Supervisor: _____

Participant name & ID #: _____

Instruction: Check that each procedure is carried out correctly. If incorrect, circle **n** and provide an explanation in the comment section following the item. Items are presented in the sequence of the examination procedure, but may require confirmation before or after the examination

The following items apply throughout the exam: **Comments:**

PHYSICAL ACTIVITIES QUESTIONNAIRE:

- y n The exam forms are explained to participant.
- y n Answer sheets are provided for assistance.
- y n Participant seems at ease.
If not, tech speaks with participant to relax him/her.
- y n Speaks slowly and distinctly, reading at neutral even pace.
- y n Maintains focus of exam but allows participants to express thoughts.
- y n Follows instructions, read questions as they are written.
- y n Initiates appropriate nonleading questions.
- y n Records answers correctly.
- y n Tech Id# filled in on exam form.

PEDIGREE VERIFICATION FORM:

- y n Information is gathered accurately.
- y n Skip patterns are followed.
- y n ID # for both parents obtained.
- y n Non participating parent information is obtained.
- y n Date of death and cause of death is asked and filled in properly.
- y n Health History on non participating parent obtained.

Overall Comments of Supervisor:

Instruction to technician/corrective action:

Signature, Supervisor 3/02

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For Administrative Purposes Only

**Waist/Neck
Supervisor Checklist**

Date: _____

Technician #: _____

Supervisor: _____

Participant name & ID #: _____

Instruction: Check that each procedure is carried out correctly. Circle **y** (yes) if correct. If incorrect, circle **n** (no) and provide an explanation in the comment section following the item. Items are presented in the sequence of the examination procedure, but may require confirmation before or after the examination.

Waist Circumference Measurements:

Comments:

- | | | | |
|---|---|--|--|
| y | n | Participant is standing erect and facing straight ahead, arms hanging loosely at sides and weight equally distributed on both feet. | |
| y | n | The tape is applied at the level of the umbilicus, if needed the top of the underwear should be lowered, just enough so that proper placement of the tape may be made. | |
| y | n | The tape is neither too loose nor too tight and is horizontal. | |
| y | n | The tape is level all the way around the waist. | |
| y | n | The measurement is recorded to the nearest 1/4 inch, rounding down. | |

Neck Circumference Measurement:

- | | | | |
|---|---|---|--|
| y | n | Participant is standing erect, hands at sides, head positioned in the Frankfort Horizontal plane. | |
| y | n | Technician stands to the left side of the participant. | |
| y | n | Participant is asked to swallow, two fingers placed on Adams apple and slight depression felt. | |
| y | n | Tape measure placed in proper position. | |
| y | n | Neck measurement is read, rounding down to the nearest 1/4 inch and recorded accurately. | |

Overall Comments of Supervisor:

Instructions to technician/corrective action:

Signature, Supervisor 3/02

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For Administrative Purposes Only
**Weight and Height
Supervisor Checklist**

Date: _____

Technician #: _____

Supervisor: _____

Participant name & ID #: _____

Instruction: Check that each procedure is carried out correctly. Circle **y** (*yes*) if correct. If incorrect, circle **n** (*no*) and provide an explanation in the comment section. Items are presented in the sequence of the examination procedure, but may require confirmation before or after the examination.

Weight Measurements:

Comments:

- y n Scale is positioned at zero.
- y n Participant is not wearing shoes.
- y n Participant's weight is equally distributed on both feet
- y n The measurement is recorded, rounding down to the nearest pound.

Height Measurements:

- y n Participant is not wearing shoes.
- y n Participant is standing erect with his/her back to stadiometer.
- y n Participant's heels are together and against the stadiometer.
- y n Participant faces straight ahead.
- y n Participant is asked to take a deep breath in
- y n Examiner's eyes are level with the point of measurement.
- y n The measurement is recorded to the nearest quarter inch, rounding down.

Overall Comments of Supervisor:

Instructions to technician/corrective action:

Signature, Supervisor 3/02

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For Administrative Purposes Only

Spirometry
Supervisor Checklist for DLCO

Date: _____

Technician #: _____

Supervisor: _____

Participant name & ID #: _____

Instruction: Check that each procedure is carried out correctly. Circle y (yes) if correct. If incorrect, circle n (no) and provide an explanation in the comment section following the item. Items are presented in the sequence of the examination procedure, but may require confirmation before or after the examination.

DLCO Preparation:

Comments:

- y n The participant is still seated in the chair.
- y n The technician clicks on the 'Spirometry' tab and selects 'Diffusion' and clicks on 'Start Test' to start the machine prep.

DLCO Testing Procedure:

- y n While the machine preps for the diffusion maneuver, the tech explains the testing procedure. The participant is instructed that s/he will still use the noseclip and the mouthpiece and that s/he will still start the test by breathing normally into the machine. The tech explains that at a point during the normal breathing, the participant will be asked to "Blow everything out" or to "Empty out your lungs". The participant is told that s/he will then be instructed to take in a **fast, deep** breath and then to hold the breath for 12 seconds. S/he is told that a valve will be closed to help hold the breath. The participant is told that after 12 seconds s/he will be asked to "Blow out all the air" and coached to keep blowing out until asked to stop.
- y n The breathing technique for diffusion is then demonstrated by the tech. At some point during instructions, the tech will explain that 2 reproducible maneuvers are needed and that it may be necessary to do 3 trials to achieve this.
- y n When the tech sees the prompt on the screen, the participant is instructed to place the mouthpiece in his/her mouth and to start breathing normally. The tech checks the mouthpiece placement and also checks for a tight lip seal.
- y n The tech watches the participant and the screen for normal breathing patterns. After 2-3 normal breathes in and out, the tech explains that after the next breath in, the participant can blow all of the air out of his/her lungs. The tech watches for normal inhalation wave and then prompts with "Now push all the air out, keep going, keep going, keep going."

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- y n The tech watches the participant and then checks the screen for the plateau indicating maximum exhalation. The tech prompts the participant to "Take a fast, deep breath in and hold it!" Coaching with "Hold it, hold it, good job, keep holding your breath" (etc), the tech watches for the timing line to intersect the line marking 12 seconds. The tech then prompts the participant to "Blow the air out, blow all of the air out, keep going..." until the tech can again see a bottom plateau indicating the participant has fully exhaled. The participant is then instructed to take the mouthpiece out and that the maneuver is complete.
- y n The tech looks at the grades for this maneuver (as with the FVC) and, if all positive, continues with the participant for another DLCO maneuver. If the grades are not all positive, then the tech reviews whatever improvement is needed.
- y n The tech waits at least 4 minutes between DLCO maneuvers.
- y n There must be 2 reproducible (within 10%) DLCO maneuvers. The maximum number of DLCO maneuvers does not exceed 3.
- y n The tech picks the best DLCO maneuver and clicks on that box to highlight and choose it. The tech saves this portion of the spirometry exam.
- y n The tech clicks on 'Notes' tab if there is any pertinent information that should be included with this participant's testing.
- y n The tech prints out 2 copies of this test and initials both copies in the lower left corner.

Overall Comments of Supervisor:

Instructions to technician/corrective action:

Signature, Supervisor 8/02

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For Administrative Purposes Only

Spirometry

Supervisor Checklist for FVC

Date: _____

Technician #: _____

Supervisor: _____

Participant name & ID #: _____

Instruction: Check that each procedure is carried out correctly. Circle **y** (*yes*) if correct. If incorrect, circle **n** (*no*) and provide an explanation in the comment section following the item. Items are presented in the sequence of the examination procedure, but may require confirmation before or after the examination.

FVC Preparation:

Comments:

- y n The participant is seated in the chair.
- y n Participant is asked if s/he has, within the past three months, had any major surgery, a heart attack, stroke or aneurysm, or if s/he has had any recent procedures that would be adversely affected by inhaling and exhaling strenuously.
- y n Participant's blood pressure is <210/120
- y n Participant's name, ID#, birthdate, height, weight, and gender are correctly entered. Technician's initials are entered in the 'Administrator's' box. This screen is saved and the participant's name appears in the 'Cache' at the top of the screen.
- y n The technician clicks on the 'Spirometry' tab and then onto the FVC screen and starts the PFT machine prep. (Spirometry bell fills up.)

FVC Testing Procedure:

- y n The participant is given a kit with a mouthpiece and filter and shown how to put it together. Tech helps if necessary.
- y n The tech explains the procedure for testing, explaining to breathe normally and, when prompted, take in as deep a breath as possible and then blow out, into the mouthpiece, as hard and fast as possible, maintaining the exhale for 6 seconds or until told to stop. The tech demonstrates the correct technique, including how to use the mouthpiece.
- y n The participant is advised to stop blowing if s/he feels light-headed or dizzy or if s/he feels any discomfort.
- y n Participant is made aware that 3 matches are needed, and that it may take more than three trials to achieve this goal.

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- y n When prompted by the screen message, the tech tells participant to place the mouthpiece into her/his mouth. The tech checks correct placement of the mouthpiece and makes sure a noseclip is in place.
- y n Examiner instructs participant to breathe in and out normally and watches the graph screen. At the appropriate time, tech instructs the participant to "Take a deep breath in!" followed by "Blast it out!".
- y n The tech *watches the participant* to make sure s/he follows instructions.
- y n The tech *continuously coaches* the participant to "Keep pushing!", "Keep going!", "Empty out all the air!" or uses similar commands.
- y n When the 'Good Effort' message appears on the screen, (which will be after at least 6 seconds of continuous exhalation) tech instructs the participant to stop and take the mouthpiece out of his/her mouth.
- y n The tech saves each maneuver by clicking on the 'Save' tab on the toolbar.
- y n The tech makes sure the participant is feeling well and repeats the procedure until 3 acceptable maneuvers (2 of which must be reproducible within 5%) are obtained. The tech stops if the participant wants to quit testing. The tech stops testing after 8 unsuccessful (unacceptable by protocol) maneuvers for FVC have been completed.
- y n The tech selects the trial with the highest sum of FVC and FEV1 for printing by clicking on the top row of that selected trial and then clicking on the 'Choose' tab on the toolbar. The selected trial number appears with a check mark under the 'Choose' tab.

Overall Comments of Supervisor:

Instructions to technician/corrective action:

Signature, Supervisor 8/02

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17. h. Corrective Log

For Administrative Purposes Only

Problems/Corrective Action Log

Anthropometrics

| Date | Problem | Date | Corrective Action |
|------|---------|------|-------------------|
|------|---------|------|-------------------|

For Administrative Purposes Only

Problems/Corrective Action Log

Blood Pressures

| Date | Problem | Date | Corrective Action |
|------|---------|------|-------------------|
|------|---------|------|-------------------|

For Administrative Purposes Only

Problems/Corrective Action Log

ECGs

| Date | Problem | Date | Corrective Action |
|------|---------|------|-------------------|
|------|---------|------|-------------------|

For Administrative Purposes Only

Problems/Corrective Action Log

Physical Activity Questionnaires

| Date | Problem | Date | Corrective Action |
|------|---------|------|-------------------|
|------|---------|------|-------------------|

17. i. Non-Participant Form

For Administrative Purposes Only

SCRIPT 3: For 3rd Gen who have not returned postcards

Name of Gen 3 _____

ID# 3- _____

Phone # _____

| | | | | | |
|-----------|------|--|--------------|--------------|------------|
| Attempt 1 | Date | | made contact | left message | no machine |
| | Time | | | | |
| Attempt 2 | Date | | made contact | left message | no machine |
| | Time | | | | |
| Attempt 3 | Date | | made contact | left message | no machine |
| | Time | | | | |

Hello, this is _____ calling from the Framingham Heart Study. As you probably know, you have family who are participants in this study. We are currently in the process of inviting the next generation of participants to the study, which includes you! Some time ago, we sent information to you about the study. Did you receive this information?

I'm not interested

Non-Participant Form (see back of sheet)

YES, I received the info.

Included in that packet of information was a postcard for you to return to us by mail. We use the postcard as a way of knowing if you are interested in participating. If you are interested, or if you'd like more information about the Framingham Heart Study, I can fill out a postcard here with you on the phone. Is this okay?

Yes Dummy Card

No If the person doesn't have time now

1. ask for a better time/day to call: _____
2. ask them to call us back @ 508.935.3440
3. ask if they still have the postcard to mail back to us – if not, verify address on Dummy Card

NO, I did not receive the info.

Included in that packet of information was a postcard for you to return to us by mail. We use the postcard as a way of knowing if you are interested in participating. If you are interested, or if you'd like more information about the Framingham Heart Study, I can fill out a postcard here with you on the phone and I can be sure to update your address. Is this okay?

Yes Dummy Card

No Non-Participant Form (see back of sheet)

Need to leave a message?

The message is for: _____. This is _____ calling from the Framingham Heart Study. I have a couple of questions for you so that we can complete our records. If you could please call me back at 508.935.3440 at your earliest convenience I'd greatly appreciate it. If you need to leave a message, please let me know the best time to return call. Thank you, and I look forward to speaking with you!

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For Administrative Purposes Only

DUMMY CARD:

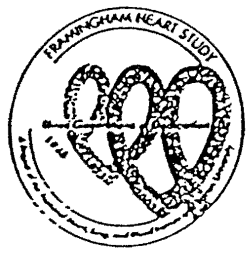
Are you interested in participating in the study? (If not, check MORE INFO)

I need you to give me your current address:

Do you have a work # at which we can reach you?

Please send me more information

I would like to participate



Name/Address Correction, Please

PHONE (H)
(W)

WILLING PARTICIPANTS:

Within the next two years, you'll receive more detailed information and an invitation to officially enroll in the study if you are eligible.

If applicable: Since you are from out-of-town, please give us a call if you are planning to be in the area and would like to schedule a visit.

We appreciate your interest in the study. You'll hear from us soon; have a great day!

NEED MORE INFO

Thanks for showing interest in the study. We hope that you'll decide to join us in the future. Have a great day!



NON-PARTICIPANT FORM

Because this study is based on research about families, it's important to know some basic information about those family members who are unable to participate. Would you have a few minutes to answer some questions? All your answers will be kept strictly confidential.

- YES Non-Participant Form
- NO Okay. Thank you for your time, and have a great day!

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Data entry 1 Date: ___ / ___ / ___

Data entry 2 Date: ___ / ___ / ___

Interviewer: _____

Interviewer ID: _____

Date: ___ / ___ / ___

GEN 3 EXAM 1 NON-PARTICIPANT FORM

1. ID #: ___ - _____

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

3. Date of Birth: ___ / ___ / ___

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

(City) (State) (Zip Code)

Home Telephone Number: (_____) _____ - _____

5. Why have you chosen not to participate in the Gen 3 study?

- 1 = Lives too far away
- 2 = Unable to make time commitment
- 3 = Other write in _____
- 9 = Prefers not to answer

6. Would you say, in general, your health is: (read responses)

- 1 = Excellent
- 2 = Very Good
- 3 = Good
- 4 = Fair
- 5 = Poor
- 9 = Prefer not to answer

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7. **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
8. **Which of the following best describes you? (Check All that apply)**
 1 = Caucasian or white
 2 = Spanish / Hispanic / Latino
 3 = African-American or black
 4 = Asian
 5 = Native Hawaiian or other Pacific Islander
 6 = American Indian or Alaska native
 8 = Other, specify _____
 9 = Prefer not to answer
9. **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
10. **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
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

For Administrative Purposes Only

Medical History Questions

| | Circle one: | No | Yes | Prefer not to answer | Don't know not sure |
|---|-------------|----|-----|----------------------|---------------------|
| <u>Heart Problems</u> | | | | | |
| 11. Chest pain, angina or angina pectoris | | 0 | 1 | 8 | 9 |
| 12. Heart attack or myocardial infarction or MI | | 0 | 1 | 8 | 9 |
| 13. Heart failure or congestive heart failure or CHF | | 0 | 1 | 8 | 9 |
| 14. Heart catheterization or cardiac catheterization | | 0 | 1 | 8 | 9 |
| 15. Heart bypass operation or coronary bypass surgery or CABG | | 0 | 1 | 8 | 9 |
| 16. Procedure to unblock vessels to your heart muscle (PTCA, stent, angioplasty) | | 0 | 1 | 8 | 9 |
| 17. Other heart problem (atrial fibrillation, pacemaker, valve, aorta, etc.) Write in: _____ | | 0 | 1 | 8 | 9 |
| <u>Circulatory Problems</u> | | | | | |
| 18. Stroke, TIA, sudden paralysis, vision, speech loss | | 0 | 1 | 8 | 9 |
| 19. Procedure to unblock blood vessels to your neck (such as carotid endarterectomy) | | 0 | 1 | 8 | 9 |
| 20. Poor blood circulation or blockage to legs/feet | | 0 | 1 | 8 | 9 |
| 21. Amputation of leg or toes, due to poor circulation/gangrene | | 0 | 1 | 8 | 9 |
| 22. Blood clot or embolism in leg or lung | | 0 | 1 | 8 | 9 |
| 23. Other circulation problem Write in: _____ | | 0 | 1 | 8 | 9 |

17. j. CT Scan Brochure

Directions

**40 Second Avenue
The PARC Center**

**Suite 120 (CT/MRI Services)
Waltham, MA 02451**

**Exit 27B off Route 95/128
Telephone: 800-697-8296**

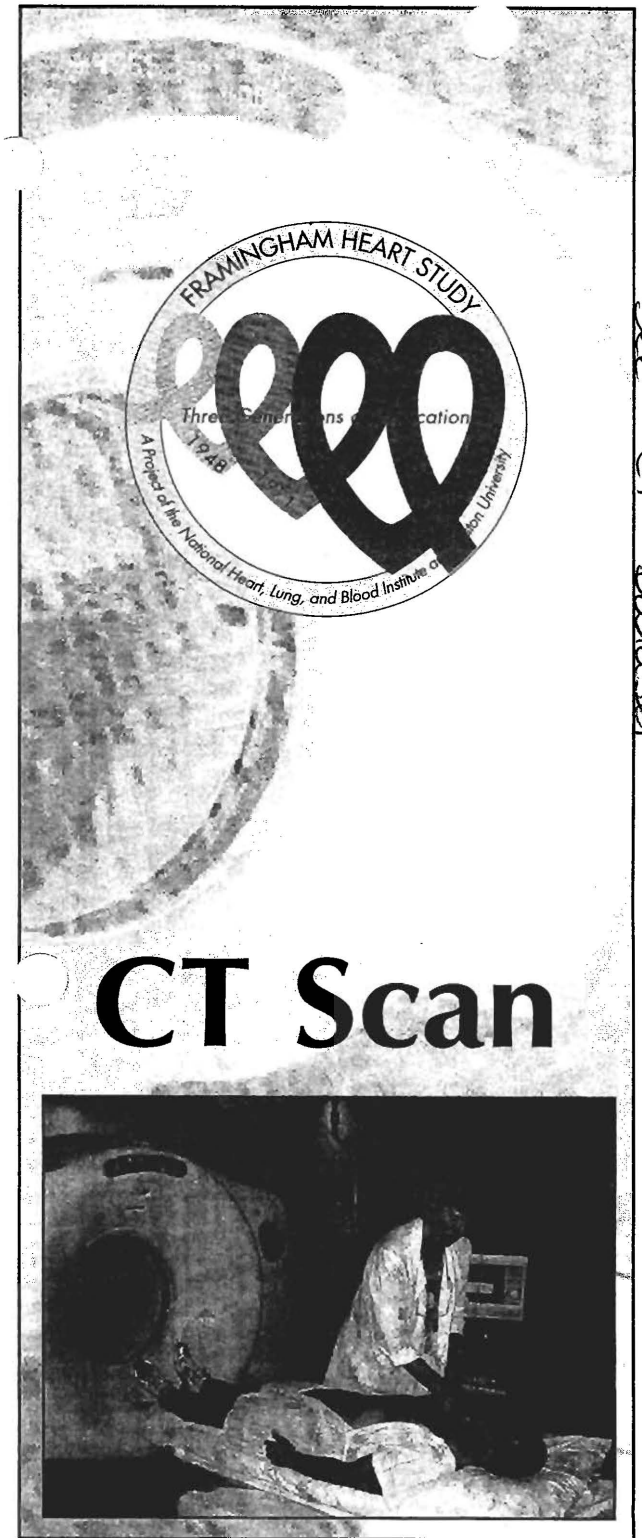
From Route 95/128 Northbound:

Take Exit 27B (Winter St. Waltham) passing the brick and white P.A.R.C. Building on the left of the highway. Bear right off the exit, then right over the highway. Stay in the middle lane. Proceed straight through the first lights. Bear left (from the middle lane) at the sign: Second Ave/Bear Hill Road. The DoubleTree Hotel should now be on your right. Stay in the right lane and follow the signs that state: Second Ave/Bear Hill Rd. Turn right and then left into the parking lot of the P.A.R.C. Building.

From Route 95/128 Southbound:

Take Exit 27B (Winter St. Waltham) and bear right off the exit. Get into the middle lane. Proceed straight through the first lights. Bear left at the sign: Second Ave/Bear Hill Road. The DoubleTree Hotel should now be on your right. Stay in the right lane and follow the signs that state: Second Ave/ Bear Hill Rd. Turn right and then left into the parking lot of the P.A.R.C. Building.

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See CT Dataset

CT Scan

What is a CT scan?

A CT (Computed Tomography) or CAT (Computed Axial Tomography) scan is a type of X-ray that uses a computer to produce detailed cross-sectional images, or "slices," of parts of the body. In this particular scan we will be obtaining pictures of the heart and the aorta (the main artery that carries blood from the heart to the rest of the body). The goal of this test is to measure how much hardened or calcified plaque has built up in these arteries. This hardened plaque could represent the degree of "hardening of the arteries" (atherosclerosis) is present in the coronary arteries of the heart and in the aorta.

Who is eligible to have a CT scan?

Men aged 35 and older and women aged 40 and older who are enrolled in either the Third Generation or Offspring study groups are eligible to participate. Because our recruitment is limited to about half the study participants some participants will not be chosen to have a CT scan.

Is it safe?

A CT scan is a painless type of X-ray. For your safety the radiation is kept to the minimum needed to do the test. Because x-rays might harm a developing fetus, premenopausal women will be asked to take a pregnancy test prior to the scan. Because this test will be used for research purposes, CT scans will not be performed on women who are pregnant, planning to become pregnant within the next year, or nursing.

Where is the CT scan done?

All CT scans will be performed at [REDACTED]

How long will it take?

The actual scan takes less than 15 minutes. However, we do ask that you arrive 15 minutes prior to the test to register and complete the necessary forms.

How do I prepare for a CT scan?

How is a CT scan done?

No outside preparation is necessary before your CT scan. When you arrive you will be asked to change into a hospital gown and lie down on a scanner bed. Special wires, called electrodes, will be placed on your skin to monitor your heart-beat. Once the scan begins you will be asked to hold your breath several times while pictures of your heart and aorta are being taken. The scan is very rapid and the actual image-taking time may take only one or two minutes to complete.

What happens after I have my CT scan?

Once finished with your CT scan you may go home and resume your normal daily activities without restriction.

Will my physician receive the results of my CT scan?

This test is being performed for research purposes only and the clinical significance of this test is not yet known. Therefore, your doctor will only receive a report if you have a highly elevated calcium score. Because this is a research study, a complete clinical evaluation of the CT scan images for all possible abnormalities in the chest and abdomen will not be performed. It is possible that some clinically important findings may not be discovered.



See CT Dataset

| | |
|--------------------|------------|
| Contacts | |
| Offspring Study | [REDACTED] |
| Third Generation | [REDACTED] |
| Family Heart Study | [REDACTED] |

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