Persons using assistive technology may not be able to fully access information in this file. For assistance, e-mail biolincc@imsweb.com. Include the Web site and filename in your message.

Exam 28 Table of Contents

Cohort Exam 28 Clinic Components

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   b. Creatinine
   c. Glucose
   d. Cell Line (if not already collected)

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5. Standing Height and Weight Measurement

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   d. CES-D
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   b. Medication documentation

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   a. Brachial Ultrasound
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11. Foot Study- [redacted], Principal Investigator
This is completed on a subset of participants who did not have a Foot Study Exam during Cohort Exam 27.

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Cohort Exam 28 Offsite Components

1. Obtain Informed Consent or Complete Waiver of Informed Consent document

2. Update of Socio-demographic Data and Family History Information (Salmon Sheet)

3. No phlebotomy

4. Electrocardiogram

5. Weight Measurement (no Height Measurement)

6. Technician Obtained Resting Blood Pressure (2)

7. Technician Administered Questionnaires

   a. Marital status
   b. MMSE
   c. End of Life Preferences questionnaire
   d. CES-D
   e. Socio-demographics
   f. Subjective Health
   g. Activities of Daily Living
   h. Use of Nursing Home & Community Service
   i. Rosow-Breslau
   j. Falls/Fractures
   k. Nagi
   l. Berkman Social Network
   m. Leisure Time Cognitive & Physical Activities questionnaire

8. Technician Obtained Measures of Observed Physical Performance

   a. Repeated Chair Stands
   b. Measured Walks
   c. Hand Grip Strength
   d. Stands

9. Technician Administered Medical Questionnaire (same as physician-administered Medical Questionnaire for on-site exam)

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i. Chest Pain
j. Syncope History
k. Cerebrovascular Symptoms
l. Peripheral Arterial and Venous Disease
m. Cardiovascular Procedures
n. Cancer History

10. No Vascular Function Testing

11. Foot Study- [redacted] Principal Investigator
This is completed on a subset of participants who did not have a Foot Study Exam during Cohort Exam 27.

Equipment For Exam Procedures

1. A. Clinic: Detecto Scale
Worcester Scale Co., Inc.
228 Brooks Street
Worcester, MA
[redacted]
Room 102

FU252

Detecto Scale
Halliday Medical
Walpole, MA 02081
[redacted]
Room 101

FU252

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

FU252

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

FU252

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

Tech support: [redacted]
[redacted] ext [redacted] (voice mail)
Sales Rep: [redacted]
Applications: [redacted]

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

5. Marquette Mac5000 – Offsite Visits

ECG

FU201 - FU235

6. Portable standard mercury column sphygmomanometer:
Baumanometer 300 model
W.A. Baum Co., Inc.
620 Oak Street
Copiague, NY 11726
[redacted]

FU270, FU271
FU019, FU020
FU195, FU196

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

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

   FU270, FU271
   FU019, FU020
   FU195, FU196

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

9. Bauman latex free blood pressure cuffs in four sizes: regular adult, large adult, pediatric, thigh (clinic only).

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

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

    FU516-FU523

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

    FU524-FU532
    FU534-FU548

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

    FU201-FU235

13. Adjusted stool, 18"
    United Chair
    P.O. Box 96
    114 Churchill Ave. NW
    Leeds, AL 35094

    FU534-FU538A

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

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

FU258

Equipment Calibration Time Table

Activity	Daily	Weekly	Monthly	Yearly
Scale				
Detecto Scale (Clinic)				
Zero Reading	X			
50 lb. Weight		X		
Professionally Calibrated				X
Seca Scale (Offsite)				
Zero Reading		X		
50 lb. Weight			X	
Sphygmomanometer				
Mercury Manometer				
Zero Reading	X			
Check Inflation System			X	
Aneroid–Gauge Type				
Check Inflation System			X	
Stadiometer (Check level)			X	
Dynamometer (Professional Calibrated)				X

Guidelines For Coding Accuracy

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

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

2. Make sure all numerals are unmistakably clear.

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

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

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

Informed Consent

An informed consent is administered to each participant by a trained interviewer prior to the collection of any research examination study data. The "consent form" is a two-part document. The first part is a narrative description of the studies goals, the content of the exam, the risks and benefits of participating, the studies confidentiality policies, each persons right to withdraw from the study, and what compensation is provided in the unlikely event that participation results in the need for medical care. The second part is the participants authorization page, which the participant signs. This documents them agreeing to (1) participate in an interview and clinical examination, including collection and storage of blood samples and DNA (blood draws are not done offsite), (2) be contacted by study personnel in the future, (3) obtain medical records concerning information relevant to the study, and (4) release their clinically relevant study data to their medical care provider. The documents core content complies with guidelines from the National Heart, Lung, and Blood Institute and is approved by BU Medical Center IRB.

I. Overview

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

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

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

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

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

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

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

II. Administration

As the FHS staff person obtaining informed consent for cohort exam 28, one must provide ample time for the participant to read the consent and answer any questions the participant may have. During the consent process the consenter must "...minimize the

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

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

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

Completing the Physician Checkbox

A participant should check **yes** in the following situations:
-If the participant has a doctor and would like us to send results to their doctor;
-If the participant does not have a doctor, but will be getting one within the next 4-6 weeks and would like us to send results to their new physician.

A participant should check **no** in the following situations:
-If the participant does not want their research exam results sent to their personal physician
-If the participant does not have a doctor and will not be getting one within 4-6 weeks

Visual Impaired Participants

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

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

consenter must also document on the consent the way he/she communicated this information and also have the witness sign and date.

Photocopying Consents

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

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

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

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Cohort Exam 28.1

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Background

You are asked to participate in the 28th Framingham Heart Study examination. This is an observational research study designed to identify the relationship between risk factors, genetics, cardiovascular disease, and other health conditions.

Purpose

The purpose of this research study is to 1) investigate factors related to the development of heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, 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 560 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 2.5 hours and includes the following:

1) History

An interview about your medical history since your last exam or health history update including heart and lung illnesses, hospitalizations, emergency room visits, day surgeries, physicals, 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 standardized measurements routinely done in your physician's office such as height, weight, and blood pressure. You will also be asked to have an electrocardiogram and tests of memory and mood. The electrocardiogram measures the rate and regularity of your heartbeats.

You will also be asked to perform tasks to assess your walk, balance, and hand grip strength, called Observed Performance. A technician will ask you questions about your feet and briefly examine them. If you are able to, you will also be asked to walk across a pressure-sensitive mat in your bare feet.

You will be asked questions to assess your ability to perform activities of daily living, general daily functioning, and social support. You will also be asked questions about your leisure and end of life preferences.

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.

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3) Blood Specimen
A technician will draw a sample of your blood (35 mL or about 2.3 tablespoons) and use currently obtained or previously frozen samples (if applicable) of blood for 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: If you have not done so in the past, 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 also be asked to participate in two experimental tests of vascular function, which will take about 15 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.

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

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

You 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. It is expected that this exam will be done approximately every 1-2 years at which time you will be asked to sign a new consent form. If an exam is not possible, you may be asked to complete a medical history update over the phone.

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

Any questions you have regarding your rights as a research subject can be directed to the Office of the Institutional Review Board for Human Research of Boston University Medical Center at [redacted]
The Framingham Heart Study is a medical research project sponsored by the National Institutes of Health. It is authorized under 42USC 285b-3. The system of records which applies to the Framingham Heart Study is documented in the Federal Register, 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 2% of older participants who have the brachial ultrasound test develop painless red spots or bruising 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.
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.
Observed Performance: This test involves a very low level of risk. The primary risk involved is injury from falling.

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 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.

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Alternatives

There are no alternative treatments or procedures to participating in this study. You may, however, choose not to participate.

Subject Costs and Payments

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

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

You will not receive payment for your participation. However, if necessary, we will provide transportation to the clinic and your return home at no cost. If you reside in a nursing home or are unable to come to the clinic, we will arrange for a technician to go to you.

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

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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:

_____ 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 signing this form you do not waive any of your legal rights. Signing this consent form 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 signed form to keep.

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

The investigator and/or his/her designee 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 related to the research, contact [redacted]

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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.

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.

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

Subject Signature and Printed Name _____ Date _____

Person Obtaining Consent Signature and Printed Name _____ Date _____

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Cohort Exam 28.0 Offsite

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Background

You are asked to participate in the 28th Framingham Heart Study examination. This is an observational research study designed to identify the relationship between risk factors, genetics, cardiovascular disease, and other health conditions.

Purpose

The purpose of this research study is to 1) investigate factors related to the development of heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, 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 560 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 2 hours and includes the following:

1) History

An interview about your medical history since your last exam or health history update including heart and lung illnesses, hospitalizations, emergency room visits, day surgeries, physicals, and medical health habits (including diet, prescription, and non-prescription drug use).

2) Measurements and Procedures

You will be asked to participate in standardized measurements routinely done in your physician's office such as height, weight, and blood pressure. You will also be asked to have an electrocardiogram and tests of memory and mood. The electrocardiogram measures the rate and regularity of your heartbeats.

You will also be asked to perform tasks to assess your walk, balance, and hand grip strength, called Observed Performance. A technician will ask you questions about your feet and briefly examine them. If you are able to, you will also be asked to walk across a pressure-sensitive mat in your bare feet.

You will be asked questions to assess your ability to perform activities of daily living, general daily functioning, and social support. You will also be asked questions about your leisure and end of life preferences.

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 Specimen

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You will not be asked to provide a blood sample at this visit, although we will use previously frozen blood samples for testing of potential risk factors for the diseases and health conditions under investigation. The blood samples will also be tested for genetic studies.

Genetic Studies: Data and DNA will be distributed to Framingham Heart Study researchers and other qualified researchers interested in the genetics of heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, joint disease, bone loss, deafness, cancer, and other 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) Medical Records
You will be asked to sign a medical release form to allow the Framingham Heart Study Medical Records staff to obtain and review copies of your hospital, cancer registry, and medical records for Framingham Heart Study Physician Review. This medical release form will be considered valid to obtain these records and this authorization will be valid until canceled by you.

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

You 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. It is expected that this exam will be done approximately every 1-2 years at which time you will be asked to sign a new consent form. If an exam is not possible, you may be asked to complete a medical history update over the phone.

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

Any questions you have regarding your rights as a research subject can be directed to the Office of the Institutional Review Board for Human Research of Boston University Medical Center at [redacted]
The Framingham Heart Study is a medical research project sponsored by the National Institutes of Health. It is authorized under 42USC 285b-3. The system of records which applies to the Framingham Heart Study is documented in the Federal Register, 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:

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

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Cohort Exam 28.0 Offsite

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

Potential Benefits
You will receive no direct benefit from your participation in this study. However, your participation may help the investigators better understand the precursors, etiology, and prevention of cardiovascular disease and other health conditions, including the possibility of genetic linkages

Alternatives

Your alternative is to not participate in the study.

Subject Costs and Payments
You will not be charged for any part of the examination. If the examination uncovers any medical problems that require medical diagnosis or treatment, you will be so advised and that information will be provided to the physician or clinic that you choose.

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

You will not receive payment for your participation. However, if necessary, we will provide transportation to the clinic and your return home at no cost. If you reside in a nursing home or are unable to come to the clinic, we will arrange for a technician to go to you.

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

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

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

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 the statement if you agree:

_____ 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 [redacted] If this study is being done outside the United States you can ask the investigator for contact information for the local Ethics Board.

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

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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.

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.

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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 _____

Waiver of Informed Consent-Original Cohort

On January 8, 2004, the Boston Medical Center IRB approved a new protocol for cognitively impaired original cohort participants allowing a Waiver of Consent. Original cohorts with moderate or severe dementia as determined by the Dementia Study will sign a consent form for the sole purpose documenting assent to the exam, providing the participant is physically able to do so. The participant will not be asked to check the consent boxes on the consent form. If the participant checks the consent boxes, those choices will not be considered the priority, rather the choices made on the last exam where their cognitive status was not an issue will be used. The Consent by Substituted Judgment form will no longer be used for the Original Cohort participants.

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

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

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

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

and/or

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

2=Moderate Dementia
3=Severe Dementia

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

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

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

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

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

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

Hello, this is _____ (staff name) from the Framingham Heart Study. I am calling to let you know that we will be arranging an appointment to visit with your mother/father/relative for his/her 28th Heart Study exam. As you may know, your mother/father/relative has been participating in the Heart Study over the past 50 years. The current exam includes questions regarding his/her medical history since his/her last exam, two blood pressure measurements, an ECG and personal history questionnaires (add a nursing home chart review if applicable). The exam will not involve any invasive testing or blood samples (if offsite). I'd like to visit with _____ (participant name) on _____ (date). Would you like to be present at the exam?

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

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

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

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

1. Healthcare Preferences
2. Berkman Questions 1-4 and 8-12
3. Nagi
4. Rosow-Breslau questions

The remaining questions should be answered by a proxy and/or through a nursing home chart review (if offsite).

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

The Proxy may answer all questions except:

1. Mini-Mental State Exam (MMSE)
2. Healthcare Preferences
3. CES-D
4. Health assessment questions (2)

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

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

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

1. The MMSE should be scored by [redacted] (offsite and clinic). (If [redacted] is out, notify [redacted]

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

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

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

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

   and

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

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

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

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

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

1. Date of Exam and Exam Number
2. FHS ID and Participant Name
3. Event (0=Clinic Exam, 1=Nursing Home, 2=Residence, 3=Blood draw only (clinic), 4=Other_____ (write in)).
4. Informed Consent Status (1=Informed Consent, 2= Waiver Only, 3= Consent Form signed may qualify for Waiver, 4=Other_____(write in)).

5. Clinical Dementia Rating Scale (CDR) & date evaluated
6. Dementia Review Outcome/Severity Score† & date evaluated
7. Consent Status & date evaluated
8. MMSE Score from last exam & date administered
9. MMSE Score from current exam & date administered
10. Comments

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

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

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

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

1. Review the Consent Form Waiver that has been completed by [redacted]
2. Review the participant's MMSE;
3. Determine if the Informed Consent should be used or Waived
4. Complete page two of the Waiver within 2 days and return the chart to [redacted] (Room [redacted]).

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

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

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

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

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

1. Review Waiver to ensure everything is properly documented and stamped
2. She will make sure the Consent form is stapled to the Waiver and NOT keyed
3. Key the Waiver

4. Document the Waiver Status in the roster comments, date waived and exam number
5. File the Waiver & Consent form in the chart

If the Consent is not waived, she will:

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

The Waiver will be keyed by [redacted] under abf heart Waiver key and she will file the Waiver in front and stapled to the Informed Consent in the chart

Once a month [redacted] will send all of the Waivers for the Original Cohort (tracked in an Excel spreadsheet) to [redacted]

Contact Information:

Clinic:

[redacted]	[redacted]	Room 228 Room 103 Room 103	[redacted]

Dementia Study/Neuropsychology:

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

Other:

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

Boston University
Medical Center

January 12, 2004

Office of the
Institutional
Review Board
715 Albany Street (560-300)
Boston, Massachusetts
02118-2526
Tel: [redacted]
Fax: [redacted]

[redacted]
Neurology
B 608
Boston, MA 02118

Re: **1910G The Framingham Heart Study N01-HC-25195**

Dear [redacted]

Review Date: **1/8/2004**
Action: **Approved, Waiver of Consent per 45 CFR 46.116**

The Amendment to the above-referenced protocol was reviewed and Approved by the Full Board on January 8, 2004.

AMENDMENT DESCRIPTION: A December 19, 2003 letter to the IRB requested a "Waiver of Informed Consent: Original cohort" to replace "Consent by Substituted Judgment for the Original Cohort" for exam 28 in order to accommodate aging participants. The reasoning, based on the criteria for 45CFR46.116 (d), for the requested waiver of consent was outlined in attached documentation.

NOTE: This amendment does not change the due date of your next continuing review report.
If you have any questions regarding this amendment, please contact the Office of the Institutional Review Board at [redacted]

If you have any questions regarding this protocol, please contact the Office of the Institutional Review Board at [redacted]

Thank you for your attention.

Sincerely,

[redacted]
IRB Chair, Panel Green
[redacted]

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

The Framingham Heart Study (FHS) Original Cohort participants have demonstrated their commitment to research by attending biennial research examinations since the beginning of the study in 1948. These research participants comprise a closed cohort of individuals who enrolled in a longitudinal study to be followed for health conditions throughout their lifespan until their death. The 28th biennial exam is scheduled to begin in 2004.

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

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

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

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

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

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

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

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

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

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

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

Consent Form Waiver

On January 8, 2004 the Boston Medical Center IRB approved a new protocol for cognitively impaired original cohort participants allowing a Waiver of Consent. Original cohorts with moderate or severe dementia determined by the Dementia Study will sign a consent form for e sole purpose of documenting assent to the exam, providing the participant is physically able to do so. If the original cohort participant is not known to have moderate or severe dementia as determined by the Dementia Study and a cognitive impairment is evident, the participant will sign an informed consent form document assent for the exam. **The Consent by Substituted Judgment form will no longer be used for Cohort participants.** The consent box answers from the last exam without cognitive impairment will be used. The exam 28 appointment will be arranged with a family member according to established protocols. The family member will be informed regarding the content of exam 28 but will not be required to provide verbal or written consent for the exam under the new waiver. However, should the family member object to a Heart Study visit, this objection will be honored.
For all participants who do not sign a consent form and/or signed a consent but fall under the Waiver, this sheet will be completed by FHS staff and kept with the participant's chart.

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

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

FHS ID:___-_____ Participant Name:_____

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

4= Other:_____ (write in)

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

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

.=Other_____

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

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

Consent Status*:_____ on ___/___/___

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

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

Comments:_____

_____

*Based on Dementia Review Tracking

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

Date sent to Neurology: ___/___/___

Over→

Version #5 10/5/05

To be Completed by Neurology Group Neuro ID: ___ ___-___

Date Reviewed:___/___/___

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

Comments:_____

_____

_____

_____

_____

_____

_____

_____

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

HIPPA

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

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

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

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

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

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

BOSTON MEDICAL CENTER

BOSTON UNIVERSITY MEDICAL CAMPUS

RESEARCH SUBJECT'S AUTHORIZATION

FOR RELEASE OF HEALTH INFORMATION FOR RESEARCH PURPOSES

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

IRB Number: 1910G

Subject's Name: _____ Birth Date: _____

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

Section A:

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

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

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

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

Section B: Description of information:

(1) The researchers need to collect information about you and your health. This will include information collected during the study as well as information from your existing medical records so we can review the health problem(s) you have reported to us. The information disclosed under this authorization will not be redisclosed to anyone but the researchers conducting this study except as required by law.

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

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

Specific description of information we will collect may include:

- Face Sheet
- Discharge Summary
- ER Report
- Admission Notes
- Progress Notes
- Operative Report
- Pathology report
- Chest X-Rays
- EKGs (All)
- CT Scan (Head)
- MRI/MRA (Head/Neck)
- Lab Reports - Cardiac Enzymes
- Consults (Cardiology & Neurology)
- Cardiac Catheterization
- Exercise Tolerance Test
- Nursing Home Notes
- Notes near time of death
- Other: (for example: Echocardiogram, Arteriography, Venous Ultrasound, V/Q Scan, PA gram, etc.)

Section C: General

(1) Expiration:
This authorization expires at the end of the study.

(2) Right To Revoke:
You may revoke (take back) this authorization at any time. To do this, you must ask the Framingham Heart Study for the names of the Privacy Officers at the institutions where we got your health information. You must then notify those Privacy Officers in writing that you want to take back your Authorization. If you do, we will still be permitted to use the information that we obtained before you revoked your authorization but we will only use your information the way the Informed Consent Form says. If it is easier for you, please contact [redacted] head of Medical Records, and she will help you take back your authorization.

(3) Your Access to the Information:
You have the right to see your medical records, but you will not be allowed to review medical records in your research records until after the study is completed.

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

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

Printed name of personal representative: _____

Relationship to research subject: _____

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

ACCEPTED
Date: 4/14/03
Sig: [signature]
Research Privacy Advocate

FHS Follow-up by Proxy

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

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

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

The Framingham Heart Study

Follow-Up by Proxy

One of the most important goals of the Framingham Heart Study (FHS) is to keep track of any major changes in your health through the end of the study. This information is important for answering scientific questions about heart disease and other health conditions. You are the best source of information regarding your health, but there may come a time when you are not able to provide details of your health. We are asking you to provide us with the name of a person that can answer questions about your health if you cannot. This person will be considered your "proxy" for the Framingham Heart Study.

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

Why is a proxy needed?
For over 50 years you have been providing important information about your health to FHS. This information should not be lost, even if you are unable to provide it.

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

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

Am I allowed to change my proxy?
Yes, you may change your proxy at any time by either calling FHS or by indicating your wishes at your FHS examination.

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

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

You will be given a copy of these forms to give to your proxy. This material should be kept by them so they understand your wishes as a participant in the Framingham Heart Study.

If you have any questions call [redacted] Cohort Participant Coordinator at [redacted]

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

IRB# 1910 4
VALID
THRU: 6/22/04
PER IRB: M
1/28/04 AUTH. INIT.

The Framingham Heart Study

FHS ID: ___ - _____

Participant Name:_____

I have named as my proxy:

Proxy Name:_____

Proxy Address:_____

_____

_____

Proxy Phone Number:_____

Relationship:_____

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

_____ _____

Participant's Signature Date

_____ _____

Witness Date

IRB# 1904
VALID THRU: 6/22/04
PER IRB: M
1/28/04 AUTH. INIT.

FU270 – FU271

Technician's Seated Blood Pressure

A. Equipment:

1. One standard Litman stethoscope tubing and earpieces with bell: Classic II 3M
2. One standard mercury column sphygmomanometer: Baumanometer (clinic)
3. Aneroid sphygmomanometer (off-site)
4. BP cuffs in four sizes (all Latex free)

   Thigh adult cuff
   Large adult cuff
   Regular adult cuff
   Pediatric cuff

B. Blood Pressure Cuff Placement:

1. Bare participant's left arm to above the point of the shoulder.
2. Determine correct cuff size using guidelines inside the cuff.
3. Palpate the brachial artery.
4. With participant seated, place the appropriate cuff around the upper left arm. The midpoint of the length of the bladder should lie over the brachial artery. Each cuff has an artery marker. The mid-height of the cuff should be at heart level.
5. Place the lower edge of the cuff, with its tubing connections, about one inch (1") above the natural crease across the inner aspect of the elbow.
6. Wrap the cuff snugly about the arm, with the palm of the participant's hand turned upward.
7. If the subject has had a left-sided mastectomy, the right arm may be used for blood pressure measurement. If right arm is used, note it on the form.

C. Determination of Maximal Inflation Level

For each participant, determine the maximal inflation level, or the pressure to which the cuff is to be inflated for blood pressure measurement. This assures that the cuff pressure

FU270-FU271

at the start of the reading exceeds the systolic blood pressure and thus allows the first Kortokoff sound to be heard.

1. Attach the cuff tubing to the sphygmomanometer.

2. Palpate the radial pulse.

3. Inflate the cuff rapidly until the radial pulse is no longer felt (palpated systolic pressure) by inflating rapidly to 70 mmHg, then inflating by 10mmHg increments.

4. Deflate the cuff quickly and completely.

5. The maximal inflation level is 30 mmHg **above** the palpated systolic pressure.

D. Guidelines for Accurate Blood Pressure Readings:

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

2. All readings are made to the nearest even digit.

3. Any reading which appears to fall exactly between marking on the mercury column should be read to the next higher marking (i.e. 2, 4, 6, 8, or 0).

4. All readings are made to the top of the meniscus, the rounded surface of the mercury column.

5. When the pressure is released quickly from a high level, a vacuum is formed above the mercury and the meniscus is distorted. Allow a few moments for it to reappear before reading the manometer.

For offsite Blood Pressures: Check that the needle is at the zero mark at the start and the end of the measurement. Place the manometer in direct line of sight with the eye on a line perpendicular to the center of the face of the gauge.

E. Blood Pressure Readings:

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

2. By closing the thumb valve and squeezing the bulb, inflate the cuff at a rapid but smooth continuous rate to the maximal inflation level (30 mmHg above palpated systolic pressure).

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3. The examiner's eyes should be level with the mid-range of the manometer scale and focused at the level to which the pressure will be raised.

4. Open the thumb valve slightly. Allow the cuff to deflate, maintaining a constant rate of deflation at approximately 2 mmHg per second.

5. Using the bell of the stethoscope, listen throughout the entire range of deflation, from the maximum pressure past the systolic reading (the pressure where the FIRST regular sound is heard), until 10 mmHg BELOW the level of the diastolic reading (that is, 10 mmHg below the level at which the LAST regular sound is heard).

6. Deflate the cuff fully by opening the thumb valve.

7. Remove the stethoscope. Neatly enter systolic and diastolic readings in the spaces provided on the form.

FH252

Weight Measurement

Clinic

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

2. Prior to asking 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

Offsite

1. The participant should remove slippers or shoes.

2. Prior to asking participant to step on the scale, turn scale on, check to make sure it reads 0.0. The scale should be on a flat, hard surface.

3. Ask the participant to step onto the scale.

4. Instruct the participant to stand in the middle of the scale platform with head erect and eyes looking straight ahead. Weight should be equally distributed on both feet, and participant should not touch or support himself/herself.

5. Read the digital display while participant is on the scale.

6. Have the participant step off the scale.

7. Record the weight to the nearest pound; round up if ≥ 0.5, round down if < 0.5.

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9. If participant is unable to stand for weight measurement at a nursing home, record the last weight in nursing home chart and the date the weight was obtained. If the participant is unable to stand on a scale during a home visit, record the weight measurement as 999.

10. Calibrate the scale monthly

FU258

Standing Height Measurement
(clinic only)

Clinic

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 level 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.**

Note: Measurement is not taken during offsite visits.

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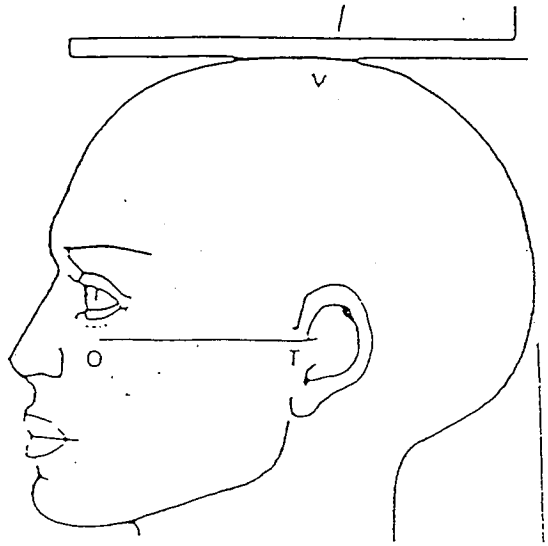
Standing Height Measurement

FRANFORT PLANE FOR MEASURING BODY HEIGHT



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

FU200 – FU235

ECG Lead Placement

1. **V1:** The first intercostal space is palpated just below the clavicle. Count down and identify the 4th intercostal space just below the fourth rib. **Point V1** is just to the right of the sternum in the ***fourth*** intercostal space. Make a small line with a marking pencil here to show where the ECG lead should be placed.

2. **V2:** Should be at the same level as **Point V1** and immediately to the left of the sternum. Make a small line with a marking pencil to show where the ECG lead should be placed.

3. To locate the horizontal reference level for electrodes **(Point E)**, starting from **V2**, locate the **fifth** intercostal space. Move your finger in the **5th** intercostal space laterally to where the midclavicular (center of the chest where you feel a bend in the clavicle) line intersects the **fifth** intercostal space. Make a horizontal line at this point.

   Mark the exact transverse (horizontal) level at this spot with the midsternal line. It should be about one inch (1") below **V1** and **V2** placements.

4. **V6:** Move the participant's elbow laterally away from the body. Mark the midaxillary line in the exact vertical center plane of the thorax down to the intersection of the horizontal plane marked by the location of **E**. This is the exact location of **V6**. (***NOTE:*** It is a common mistake to locate the midaxillary line too far anteriorly, toward the **V5** location).

5. **V4:** Place the # arm of the Heart Square firmly across the lower sternum at the level of **Point E** (as you face the participant, the writing on the Heart Square will appear upside down and backwards). Adjust the **E** and **V6** arms of the Heart Square so they are both perpendicular to the long axis of the thoracic spine at the level of the **E** position. The **E** arm should be exactly horizontal. If the participant is lying flat, the **V6** arm should be exactly vertical.

   Slide the **V6** arm so the **0** point (the *arrow* labeled **V6**) is at the marked location for **V6**. Double check that the **E** arm is still in the correct spot.

   V4: On the **V6** arm (the slide), find the number corresponding to the **E** measurement. Following the corresponding 45 degree line to the surface (e.g. 16) and mark the location following the inside of the square. Place electrodes on ***TOP*** of the breast.

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

6. **V3:** Exactly halfway between **V2** and **V4**.

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

8. Before electrodes are placed on the participant, ask if he/she is known to be allergic to alcohol wipes. If yes, prepare the areas of electrode placement by rubbing with water and drying with a washcloth. If allergies are denied, prepare the areas by wiping with an alcohol wipe and drying with a washcloth.

> *NOTE:* Place the electrodes on the participant and hook up the leads before entering the data in the ECG machine. This will allow ample time for the participant to relax and the machine interference to smooth out.

9. Attach limb leads in the following order: right leg (RL), left leg (LL), right arm (RA), left arm (LA). This will avoid lead reversal.

10. The body of the electrode is placed centrally at the pencil mark with the tab extending downward. Precordial electrodes are attached in the following order: V1, V2, V3, V4, V5, V6. Recheck all leads for proper placement.

11. Ask the participant to lie still and relax. In the computer, enter the participants Name, ID, Age, Height (clinic only), Weight, and Gender. Enter the Exam Cycle, Location (1=clinic 2=offsite), and your Tech ID.

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

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

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

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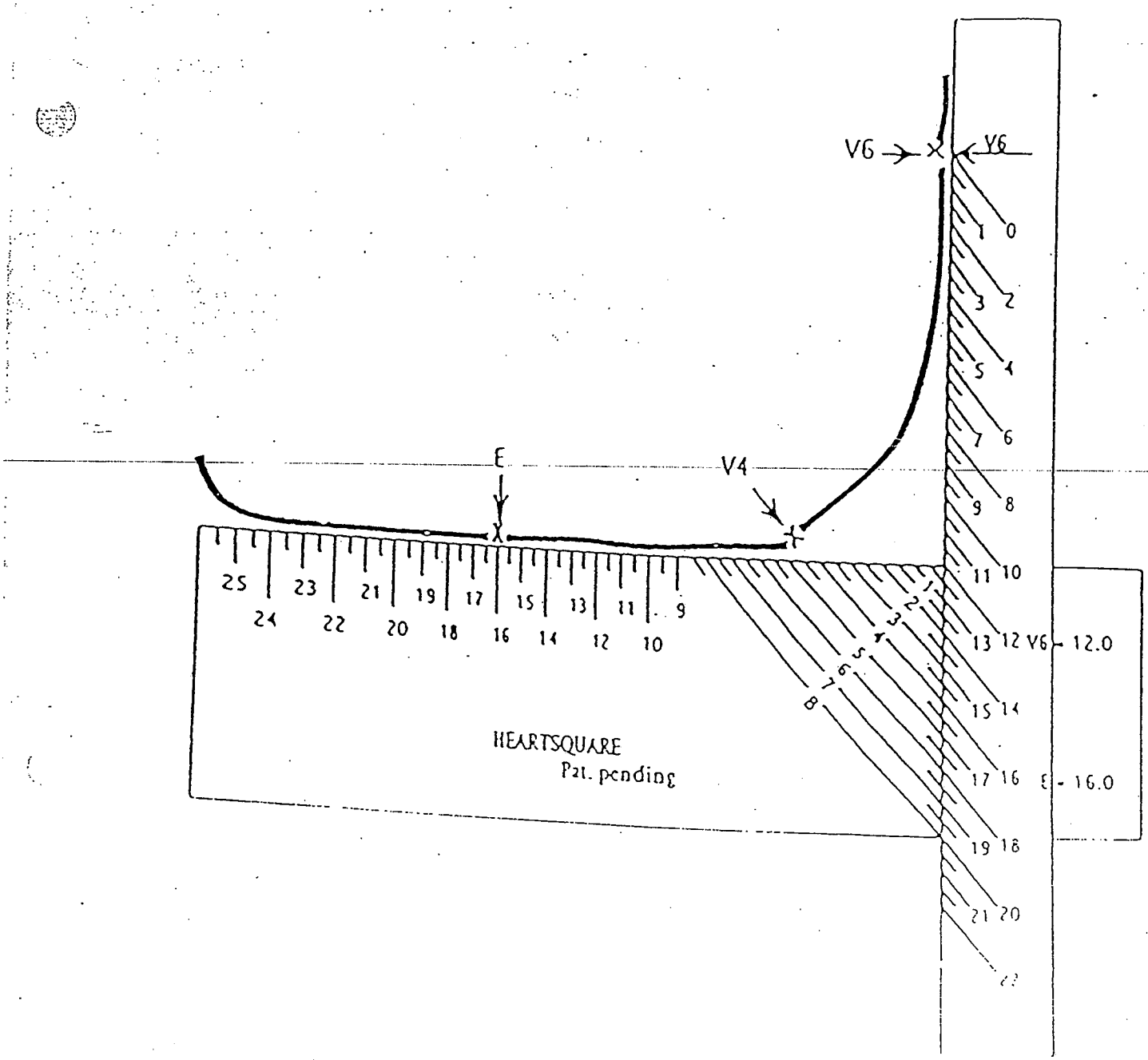
V6
V6
E
V4
25
24
23
22
21
20
19
18
17
16
15
14
13
12
11
10
9
HEARTSQUARE
Pat. pending
V6 - 12.0
E - 16.0

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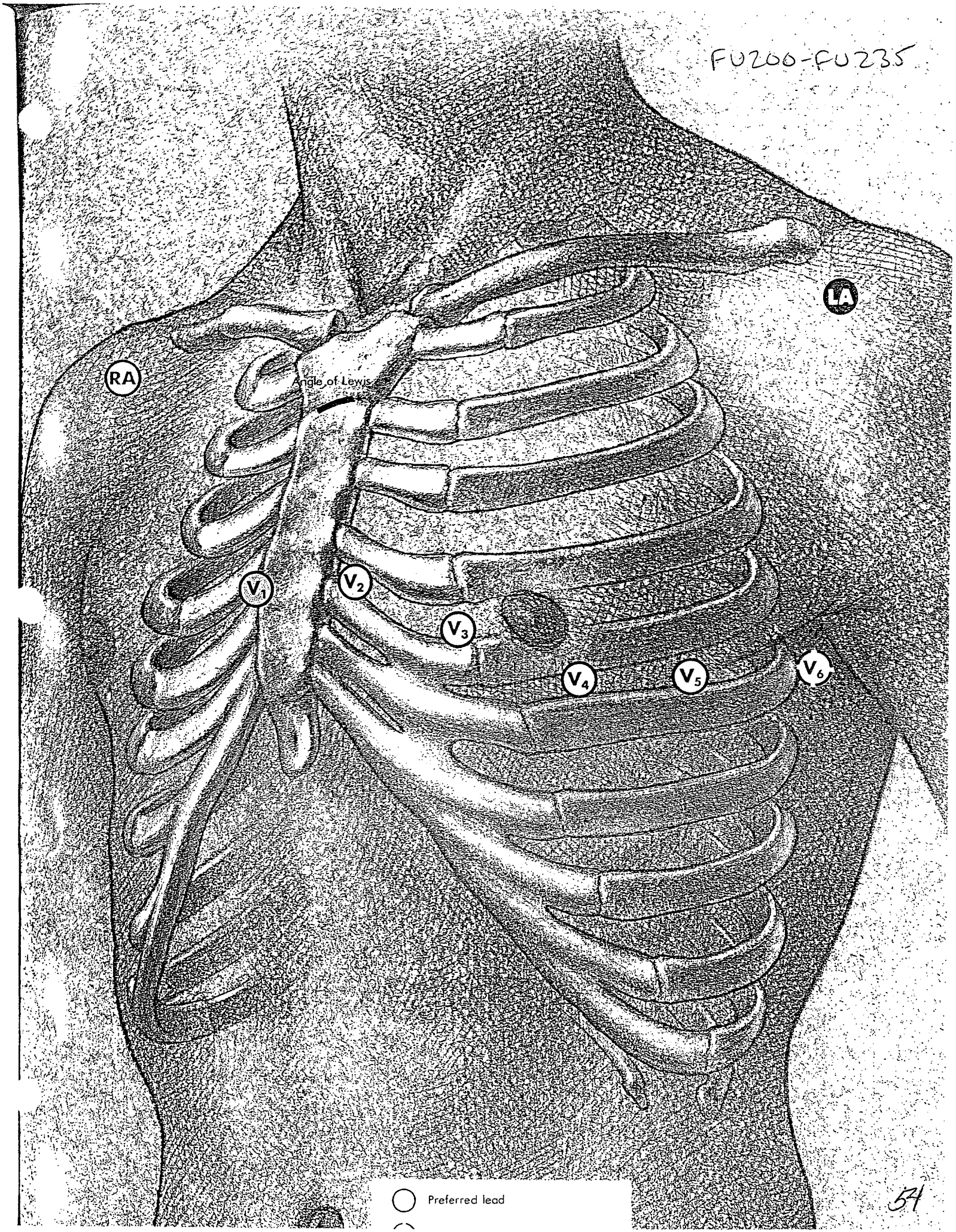

Fu335 → Fu359

Mini-Mental State Exam (MMSE)

A. Background and Rationale:

Cognitive function may decline as a result of certain risk factors (e.g. hypertension, elevated cholesterol, cardiac arrhythmias). This in turn could adversely impact the physical functioning and quality of life of older adults. Dementia is a major illness and cause of disability among the elderly. Cerebrovascular disease or multi infarct dementia is the second leading cause of dementing illness among Caucasians, preceded only by Alzheimer's Disease.

The Mini-Mental State Exam (MMSE) is a widely used test of cognitive function among the elderly; it includes tests of orientation, attention, memory, language and visual-spatial skills.

B. Definitions:

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

MMSE-EDUCATION ADJUSTED CUT-OFF SCORES

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

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

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

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

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

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

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

FU335-FU359

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

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

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

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

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

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

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

C. Methods:

1. The MMSE asks questions to ascertain cognitive status. Responses are scored:
   0=incorrect
   1=correct
   6=item administered, participant does not answer
   9=test item not administered/unknown

2. If a response is ambiguous, the interviewer records the response in the margin so a decision can be made on its appropriateness. Please refer all questionable responses to the neuropsychologists (i.e. [redacted] or [redacted]

3. When a participant is incapacitated by blindness, has a functional disability, is illiterate, or is otherwise unable to respond to a question, the interviewer should specify the problem and questions involved (see "Factors Potentially Affecting Mental Status Testing" later in the section).

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D. Expanded Scoring Instructions for Mini-Mental Exam:

Important note: The single exception to scoring **6** for no response is if a participant is in a coma (this circumstance would be encountered in a nursing home visit) In this instance, administer the first item (to establish no response -- give a **0** to the first item if there is no response). (This exception is made to conform with the stroke protocol.)

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

Important note: Sometimes a participant might produce a response that is not a word (i.e. a neologism) but has been responding with intelligible responses on previous items (right or wrong). In this case the items should be scored **0**. The key to differentiating a **0** or a **9** is consistency within test. If a person has a speech abnormality, such as aphasia or dysarthria, across all items, most (or many) responses will be unintelligible. If a person is, for example, demented, he/she may produce a flow of intelligible responses with occasional unintelligible responses. A "**9**" must represent situations in which the EXAMINER is not sure whether (1) the participant responded correctly (because of slurred speech, severe stuttering, etc.), or (2) if the participant has some other factor that prevents test item administration (such as an inability to administer *copy this figure* test item to a right-handed person who has right-handed paralysis, or to someone who has a visual impairment or inability to hear).

Scoring for Administered Individual Items: (applies only if a test item is administered)

Score **0** for the following reasons:

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

E. Questions: Scripts and Procedures for Each Question:

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

Read each question on the form.
Record the response on the form.

Fu335 1. *What is the date today?* (**3** = correct score for month (1 pt), day (1 pt) and year (1 pt))

a. Ask for the date. Then ask specifically for parts omitted (e.g. *Can you also tell me what month, year it is?*)
b. If participant supplies part or all of the date (e.g. month and day, or month, day, and year), record as appropriate and do not ask those questions again.

Fu336 2. *What is the season?*

Since distinctions between seasons can be difficult during certain months, one week leeway is allowed on either side of the actual date.

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

Fu337 3. *What day of the week is it?*

Fu338 4. *What town, county, and state are we in?*

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

Fu339 5. *What is the name of this place?*

a. Ask the participant where they are. Any appropriate answer is okay. On home visits, the examiner can ask, *What is the address of this place?*

Fu340 6. *What floor of the building are we on?*

Fu341 7. *I am going to name 3 objects. After I have said them I want you to repeat them back to me. Remember what they are because I will ask you to name them again in a few minutes: Apple, Table, Penny.*

a. Make sure participant is attentive when beginning the question.
b. Read the list of objects slowly. DO NOT REPEAT ITEMS UNTIL AFTER THE FIRST TRIAL.
c. If participant asks you to repeat the 3 items, respond, *Can you tell me the items I just mentioned?* or *Just do the best you can.*
d. Read *Apple, Table, Penny.*
e. Script: *Could you repeat the three items for me?*
f. Record the score for the first trial.
g. If, after scoring the first attempt, the participant has not learned the 3 objects, repeat the list of objects up to 6 times until he/she has learned them.
h. If, 3 items are repeated regardless of order, score 3 points. Occasionally hearing impairments prevent subjects from correctly hearing test questions (for example, when asked to repeat three items, *apple, table, penny,* they may repeat *April, tablet, pencil* -- these alternate responses should be accepted both under the repetition and recall conditions).

Fu342 8. *Now I am going to spell a word forward and I want you to spell it backwards. The word is WORLD. W-O-R-L-D. Please spell it in reverse order.* Write in letters _____ (letters are entered and computer scored later. For tabulating a total MMSE score for screening purposes, please determine a total score between 0-5 for this item).

a. Read the question slowly. Where *world* has hyphens between the letters, spell out the word.
b. Repeat the spelling if necessary.
c. Record the participant's response. Write in the letter as the participant has spelled the word.

Fu343 9. *What are the 3 objects I asked you to remember a few moments ago?*

a. Items may be repeated in any order.

Fu344 10. *What is this called?* (Watch)

Show the wristwatch to the participant
Correct responses include: watch, wristwatch, timepiece
Code 1 = correct answer

Fu345 11. *What is this called?* (Pencil)

a. Show the pencil to the participant. NOTE: the pencil should be a standard sharpened wooden pencil with eraser.
b. Correct responses include: Pencil, number 2 pencil
c. Code **1** = correct for correct answer.

FW346 12. *Please repeat the following: No ifs, ands or buts.*

a. Enunciate clearly -- include the "**S**" at the end of *ifs, ands, or buts*, (if you think the participant heard you but repeated it incorrectly, make a note of what was missed and score **0**).
b. Allow only **one** attempt.
c. Code **1** = correct when the participant correctly repeated the phrase.
d. Code **0** = incorrect when the participant did not repeat the phrase exactly.

Occasionally hearing impairments prevent participants from correctly hearing test questions. In the case of repeating *no ifs, ands, or buts,* some judgment must be made on the part of the examiner as to whether the participant could hear the "***s***" or not.

FW347 13. *Please read the following and do what it says.*

a. Hand participant the "Please Close Your Eyes" card.
b. The participant may read the sentence out loud. The task to be coded is the participant's ability to follow instructions by closing his/her eyes. It is not necessary for the sentence to be read out loud if the participant performs the function properly.
c. Code **1** = correct when the participant closes his/her eyes.
d. Code **0** = incorrect when the participant did not close his/her eyes.

FW348 14. *Please write a sentence.*

a. Script: *Write any complete sentence on this piece of paper for me.*
b. Repeat the instructions to participant if necessary.
c. Code **1** = correct if the participant wrote a complete sentence as directed.
d. Written commands, such as *sit down*, where the subject is implied, are considered correct responses.
e. Spelling and/or punctuation errors are not counted as errors.
f. Code **0** = incorrect when the participant did not write a complete sentence as directed.
g. Code **1** = if the participant is cognitively able to dictate a sentence but is physically unable to write it. In this case the examiner should write the dictated sentence and make a note that it was dictated.
Code **6** = Low vision

FW349 15. *Please copy this drawing.*

a. Script: *Here is a drawing. Please copy the drawing on the same piece of paper.*
b. If the participant asks if the figures should be drawn separately or together the examiner should respond, *Draw the figures as you see them.*

c. To be correct, each pentagon must have 5 sides, 5 sides that point outward. The two figures must be overlapping.
d. The overlap figures must have 4 sides.
e. Code "**0**" = incorrect when the participant's figure did not match.

Fu350 16. *Take this piece of paper in your right hand, fold it in half with both hands, and put it in your lap.*

(If participant is unable to use right hand because of physical disability, you can alter instructions to read "Take this piece of paper in your left hand, fold it in half with your left hand, and put it in your lap". The goal is to see whether the subject is able to follow a 3-step command, so this variation to the directions to accommodate subject's physical limitations is allowable.)

a. Read the full statement **BEFORE** handing the paper to the participant.
b. **DO NOT** direct the paper to participant's right side. Hold the paper in front and have the participant reach out to take it. Observe which hand is used.
c. **DO NOT** repeat instructions or coach participant. Only repeat if the examiner felt it was not heard or if instructions were not given clearly (just repeat the directions in full as they were the first time).
d. Score: **1** for <u>each</u> correctly performed act (code **6** if low vision).

F. <u>Factors Potentially Affecting Mental Status Testing</u>
The examiner's impression for Cohort Cycle 28 will include the following:

NO	YES	MAYBE	UNKNOWN	
0	1	2	9	Illiteracy or low education Fu351
0	1	2	9	Not fluent in English Fu352
0	1	2	9	Poor eyesight Fu353
0	1	2	9	Poor hearing Fu354
0	1	2	9	Paralysis
0	1	2	9	Depression/Possible Depression Fu355
0	1	2	9	Aphasia Fu356
0	1	2	9	Coma Fu357
0	1	2	9	Parkinsonism or neurological impairment Fu358
0	1	2	9	Other Fu359

FU347

PLEASE CLOSE YOUR EYES

Fu382 → Fu393

Socio-demographics and Subjective Health: Self-Reported Performance Part 1

This is a self-reported form. If not self reported the Proxy Section of the exam must be completed.

A. Socio-demographics

Fu382 1. *Where do you live?*

Coding
0 = Private residence
1 = Nursing home
2 = Other institution, such as an assisted living facility or retirement community
9 = Unknown

Fu383 2. *Does anyone live with you?* (NOTE: Code nursing home resident as NO to these questions.)

Coding
0 = No
1 = Yes
9 = Unknown

NOTE: If the answer to the above question was **0** or **9** you may skip the following section. If the answer was yes, the examiner needs to determine who lives in the same household. It is important to ask whether others lives in the same household for < 3 months per year or > 3 months per year. The list is:

Fu384 Spouse
Fu385 Significant other
Fu386 Children
Fu387 Friends
Fu388 Relatives
Fu389 Pets

Coding
0 = No
1 = Yes, less than 3 months per year
2 = Yes, more than 3 months per year
9 = Unknown

FU390 3. *Are you Currently working at a paying job or doing unpaid volunteer or community work?*

Coding
0=No
1=Yes, full time(>=32hrs/week)
2=Yes, part time (<32 hrs/week)
9=Unknown

FU391 4. *During the past 6 months (180 days) how many days were you so sick that you were unable to carry out your usual activities?*

Coding
999 = Unknown

B. Subjective Health

The following two questions MAY NOT be answered by a proxy.

FU392 1. *In general, how is your health now?*

Coding
1 = Excellent
2 = Good
3 = Fair
4 = Poor
9 = Unknown

FU393 2. *Compare your health to most people your own age:*

Coding
1 = Better
2 = About the same
3 = Worse than most people your own age
9 = Unknown

FU395 → FU405

Activities of Daily Living: Self Reported Performance Part 2

A. Background and Rationale:

This section is designed to assess the following spectrum of physical functioning. This section assesses:

a. General level of physical functioning and mobility
b. Ability to carry out instrumental activities of daily living
c. Ability to carry out activities of daily living
d. Framingham Disability Index

B. Activities of Daily Living (Title on top of form):

Part 1:

Ask the participant, *During the course of a normal day, can you do the following activities independently or do you need human assistance or the use of a device?*

The answers will be coded by the examiner as:

0 = No help needed, independent
1 = Uses device, independent
2 = Human assistance needed, minimally dependent
3 = Dependent
4 = Does not do during a normal day
5 = Special Products used for continence
8 = Takes no medications regularly
9 = Unknown

NOTE: With a nursing home visit, the participant's chart may be used to verify or to obtain accurate information on ADL's. If information is obtained from the nursing home chart or staff then proxy information on screen must be completed.

The activities include:

Fu395 1. Dressing
- Undressing and redressing
- Picking out clothes, dress oneself including buttoning, fastening, etc.
- Devices such as: velcro, elastic laces.

Fu396 2. Bathing
- Including getting in and out of tub or shower
- Getting water, soap, towel and other necessary items and wash oneself
- Devices such as: bath chair, long handled sponge, hand held shower, safety bars.

Fu397 3. Eating
- Able to eat from a dish and drink from a cup
- Devices such as: rocking knife, spork, long straw, plate guard.

Fu398 4. Transferring
- Getting in and out of a chair
- Arising from a sitting position to a standing position and back
- Devices such as: sliding board, grab bars, special seat.

Fu399 5. Toileting activities
- Using the bathroom facilities and handling clothing
- Devices such as: special toilet seat, commode.

Fu400 6. Bladder continence
- Ask if person has "accidents" (code =5 if use special product)
- Devices such as: external catheter, drainage bags, ileal appliance, protective device.

Fu401 7. Bowel continence
- Ask if person has "accidents" (code=5 if use special products)
- Devices such as: suppositories, bedpan, regular enemas.

Fu402 8. Walking on a level surface about 50 yards
- Devices such as: cane, crutches, or walker.

Fu403 9. Walking up and down one flight of stairs
- Devices such as: handrail, cane.

Fu404 10. Using a telephone
- Able to dial a phone number: ex. 935-3400. (The participant does not need to be observed doing this task).
- Devices such as: large numbers, voice activation, amplication.

Fu405 11. Preparing and taking own medications
- Is able to measure out and take medications without being dependent on another person.
- Medications include prescriptions and aspirin taken on a regular basis.
- Specify Date_____

Part B Activities Questions (Title on top of form)

Fu437 1. *Are you in bed or a chair for most or all of the day (on the average)?*

Coding
0 = No
1 = Yes
9 = Unknown

Fu438 2. *Do you need a special aid (wheelchair, cane, or walker) to get around?*

Coding
0 = No
1 = Yes
9 = Unknown

If yes, which of the following equipment do you use?

Fu439 Cane or Walking Stick
Fu440 Wheelchair
Fu441 Walker
Fu442 Other (write in)

Coding
0 = No
1 = Yes, always
2 = Yes, sometimes
9 = Unknown

Fu407 → Fu435

Use of Nursing and Community Services

Coding for the following questions is:

0 = No
1 = Yes
9 = Unknown

Fu407 1. Ask the participant, *Have you been admitted to a nursing home (or skilled facility) since your last exam or medical history update?*

Fu408 2. *Since your last exam, have you been visited by a nursing service, or used home, community or outpatient programs?*

Ask which services were used and how often.

Fu409 → Fu411 1. Home health aides
Fu412 → Fu414 2. Homemaker visits
Fu415 → Fu417 3. Visiting nurses
Fu418 → Fu420 4. (PCA) Personal Care Attendant
Fu421 → Fu423 5. Rehabilitation services (such as physical therapy, occupational therapy, speech therapy)
Fu424 → Fu426 6. Cardiac rehabilitation
Fu427 → Fu429 7. Meals on wheels (including assisted living prepared meals)
Fu430 → Fu432 8. Community day programs (including assisted living activities)
Fu433 → Fu435 9. Other

Coding

Currently	Since Last Exam	# Months Used Since Last Exam
	0=No At least once per… 1=Day 2=Week 3=Month 4=Other (write in) 9=Unknown	0=None 1=One month or less 2-98= Put in actual number of months service used 99=Unknown

NOTE: If a participant moved into a nursing home prior to the two year interim, then the first question is 0 = No. If the first question is No because the participant has been living in a nursing home for more than 2 years, the rest of Nursing and Community Services should be coded as 0. This section is to gather information on use of community services in the interim.

FU443 → FU449

Rosow-Breslau Questions

A. Rationale & Background

Respondents' self-assessments of health may raise questions about the validity of such judgments. However, we are not interested in the literal details of people's medical condition as much as in the behavioral consequences, their physical capacity for role fulfillment and social participation. We are primarily concerned with the *functional* health which old people report, i.e., the degree to which they claim they can manage adequately or are restricted in their activities because of their physical condition or capacity. *Breslau, M, Rosow, I: A Guttman Health Scale for the Aged. 556-559*

B. Methods

The method of assessing physical functioning is **self-report**. The questions assess the degree of difficulty that a person has performing a specific activity. This form has several important purposes:

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

C. Procedures

Questions:

Coding
0 = No, unable to do
1 = Yes, independent
2 = Does not do
9 = Unknown

FU443 1. *Are you able to do heavy work around the house, like shovel snow or wash windows, walls, or floors without help?* (Scrub floors, wash windows, rake leaves, mow lawn). *(Note:* Code **2** if person **does not** do this activity).

FU444 2. *Are you able to walk half a mile without help?* (Walk one half mile or 4-6 blocks without stopping for more than 5 minutes). *(Note:* Code **2** if person does not do this activity).

FU445 3. *If you had to, could you do all the housekeeping yourself (like washing clothes and cleaning)?*

FU446 4. *If you had to, could you do all the cooking yourself?*

FU447 5. *If you had to, could you do all the grocery shopping yourself?*

Note: this does not include driving to the store; it's only the actual act of shopping.

FU448 6. *Do you drive?*

Coding
0 = No
1 = Yes, currently
2 = Yes, not now
9 = Unknown

FU449 *Reason for not driving now:*

Coding for not driving:
1 = Health
2 = Other non-health reason
3 = Never licensed
8 = N/A, current driver
9 = Unknown

With the information above use the answer key accordingly. For example if a person says that can do something, but do not do it-code with #2. It doesn't matter that they can do it, we are just looking to see if they can or can't do it, or if they don't do it at all.

ADL I J

FU443-FU449

A Guttman Health Scale for the Aged[1]

Irving Rosow, Ph.D., and Naomi Breslau, M.A.[2]

This paper reports a Guttman scale of the functional health of older people developed in a study of 1200 persons in Cleveland over the age of 62. This was a theoretical study of the social integration of the aged which effectively tested age-homogeneity or heterogeneity as alternative principles for anchoring group membership and participation of this age group (Rosow, in press).

In any sociological study of the elderly, health must be taken into account in the consideration of virtually any problem, if only as a control variable in the analysis. Authoritative medical data on respondents are, of course, seldom available in such research. Consequently, surveys and other non-medical field studies of this age group must necessarily rely on interview data to assess relative health in old age.

Respondents' self-assessments of health may raise questions about the validity of such judgments. However, we are not interested in the literal details of people's medical condition as much as in the behavioral consequences, their physical capacity for role fulfillment and social participation. We are primarily concerned with the *functional* health which old people report, i.e., the degree to which they claim they can manage adequately or are restricted in their activities because of their physical condition or capacity. Their claims in this respect may possibly be biased, but in terms of the specific capacities involved, this should be considerably less problematic than the issue of bias routinely involved in attitudinal data. For example, when a respondent says that he can (or cannot) walk up and down stairs to the second floor, this is much less problematic than when we probe for ideal-real or attitudinal-behavioral discrepancies in his views on race. Furthermore, various studies show that, on balance, there is a high correlation between subjective and objective assessments of older people's health, i.e., what respondents report and what their doctors report, how they rate themselves and how physicians rate them (Friedsam & Martin, 1963; Heyman & Jeffers, 1963; Lindhardt, 1957; Maddox, 1962; Suchman, Streib, & Phillips, 1958).

Levels of agreement between patients and physicians vary around 75% for health ratings and for actual diagnoses. When proper allowance is made for unshared knowledge which is not communicated from patient to doctor or vice versa, the agreement is even higher. But the sheer fact of such validation between subjective and objective judgments in various populations is a separate issue. For our purposes, on purely conceptual grounds, old people's self-assessments of functional health are valid and they raise no special validity problems different from those in social surveys of any population. We are interested in how a respondent's perception of his health limits or constrains his social functioning. Certainly, people's functional capacity in this sense is sociologically more significant than their technical medical condition. Thus, our perspective is not medical, but sociological.

Materials and Methods

Subjects.—The respondents of two social classes were drawn by purposive sampling of apartments with different proportions of older tenants, and we estimated that we had screened up to 85% of all the apartment buildings in the Cleveland area which met a series of specific sampling criteria. Within the eligible apartments, all the solitary aged were qualified respondents and random tables designated the potential person in households which had more

[1] The study from which the present materials are drawn was supported principally by funds from the Ford Foundation.

[2] Western Reserve University, Cleveland, Ohio.

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FU443-FU449

than one old member. Two-thirds of the sample was under 75 years of age and one-third over. Because of the sex composition of apartment tenants of this age group, women outnumbered men by approximately three to one. Middle-class persons and those who had never married were over represented for the age group as a whole.

Self-assessment interview.—Our interview contained a section of 25 diversified questions on respondents' health. The referents of the questions were objective, i.e., specific items of activity and judgment which the respondent related to himself. Some were multiple response questions of the type: "Which of the following can you do . . . ?" Three questions produced six response categories from which we were able to construct an excellent Guttman scale of reported functional health (Stouffer, Guttman, Suchman, Lazarsfeld, Star, & Clausen, 1950). The three questions in their complete original form and order in the interview are as follows, with the responses used in the scale indicated by the symbol +:

H-4. Is there any physical condition, illness, or health problem that bothers you now?
+ A. No
B. Yes

H-6. Which of these things are you still healthy enough to do without help?
+ A. *Heavy* work around the house, like shoveling snow or washing walls?
B. (Men) Work at a full-time job.
(Women) Do the ordinary work around the house yourself.
+ C. Walk half a mile (about eight ordinary blocks).
+ D. Go out to a movie, to church or a meeting, or to visit friends.
+ E. Walk up and down stairs to the second floor.

H-10. Which of these statements fits you best?
A. I cannot work (keep house) at all now because of my health.
B. I have to limit some of the work or other things that I do.
+ C. I am not limited in any of my activities.

Results

On analysis, the six scale response categories were arrayed as they appear in Table 1, which includes relevant information on the over-all scale and specific items. The responses ordered the individual items according to their relative "difficulty," from the easiest to the hardest or from the activity which most people were able to do (H-6D) to that which fewest could do (H-6A). Accordingly, the majority of respondents were still healthy enough to go to a movie, church, meeting, or visit without any help (86%) but only a minority could still do heavy work around the house, like shoveling snow or washing walls (21%). The positive frequencies on the other scale items were ranged between these two extremes with, incidentally, only about one-half the sample free of any current illness or bothersome physical condition (46%) or not limited in any of their activities (53%).

The combined response patterns produced a refined Guttman scale which met all the formal criteria for these instruments. Item error for the six individual scale responses varied between 4 and 12%, as the right-hand column of Table 1 indicates. For the total scale, the Coefficient of Reproducibility = .91, and a 9% level of error is extremely low for a Guttman scale based on six items. These six response categories yielded seven groups whose scores ranged from zero to six "healthy" replies. In actual practice, we collapsed the two worst health ratings into a single score. This provided a reasonably flat distribution of respondents, as appears in Table 2, and the six categories made for high flexibility in the data analysis. For various problems, we could simply dichotomize the sample according to better or worse health

Table 1. Health Scale Items.

	Question Items	Healthy Response Category	% Healthy Response	% Item Error
H-6.	Still healthy enough to do without help:			
D	Go out to movie, church, meeting, visit	Yes	86	12
E	Walk up and down to second floor	Yes	79	12
C	Walk half a mile	Yes	69	4
H-10.	Which statement fits you best:			
C	Not limited in any activities	Yes	53	9
H-4.	Physical condition or illness now?			
A	No	No	46	12
H-6.	Still healthy enough to do without help:			
A	Heavy work around the house	Yes	21	5

Coefficient of Reproducibility = .91

Table 2. Distribution of Scale Scores.

Health Scale Score		N	%
Best:	Six	148	12
	Five	241	20
	Four	192	16
	Three	181	15
	Two	236	20
Worst:	One-Zero	202	17
	Total	1200	100

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(48% and 52%) or into roughly equal thirds of relatively good-moderate-poor health groups (32% - 31% - 37%). By the same token, we could identify those in the finest health and people in the very poorest health who could give no more than one healthy reply to the six-scale items. The latter group, incidentally, represented 17% of the total sample and this approximates the proportion of the national population over 65 with a major limitation of activity because of chronic illness (U.S. Dept. of Health, Education, & Welfare, 1959).

Discussion

A question might be raised about the extent to which the particular sequence of questions in the interview may have reduced over-all error and thereby artificially contributed to the scale's reproducibility. We could not experimentally exclude this possibility by printing various sets of questionnaires which systematically varied item order and thereby took this prospect into account. However, this source of bias seems unlikely because the questionnaire avoided the two main sources of such error. Hayes (1964) reported experimental studies on Guttman scales in which he manipulated responses through varying the sequence of questions, thereby altering the distribution of scale types and over-all scale reproducibility. The effect on his distributions was substantial on one of his two scales, but over-all reproducibility was never altered by as much as .04. The major errors which affected the results were: (1) to present the scale questions in a solid array rather than interspersing them with others; and (2) to present either of the two extreme scale items as the first question in the series. Both procedures had the effect of creating a cumulative halo effect and thereby artifactually contributed to the ordering of positive response frequencies.

The interview from which the present Guttman scale was drawn avoided both these pitfalls. Our scale questions were separated by non-scale questions, and the order of presentation did not initiate a rising or declining response-set by the use of either extreme polar item as the first question. Indeed, there is no relation between the sequence of asking the questions and the frequency of healthy replies. Therefore, we do not regard the percentage of individual item error or over-all reproducibility in our health scale as spurious because of question order.

Actually, on substantive and formal grounds, the health scale seems sound, particularly in view of the number of items that sustain it. We strongly suspect that, as with the studies cited earlier on subjective-objective health estimates, there would probably be a fairly high correlation between our measure of functional health and objective ratings on which examining physicians could agree. For surveys and sociological studies of the aged which must effectively depend on self-assessments of health in interviews, this scale provides a simple, economical means of differentiating functional health within a sample. It certainly orders respondents on a continuum that enables the analysis of other problems to take health differences into account. It is quickly administered and can easily be incorporated into various studies that require a relative health measure.

Summary

This paper presented a Guttman scale of functional health of the aged suitable for social research that is restricted to interview data. Although based on respondents' judgments, the six-scale items rely essentially on objective referents of people's activity and specific functional capacity. While there is other evidence of reasonably high correlation between patients' subjective and physicians' objective health assessments, from a sociological perspective people's perceived functional health is valid on conceptual grounds. The specific scale components ordered respondents in a fairly flat distribution on this health continuum and met the formal criteria of a satisfactory Guttman scale. There is no indication that original question sequence in the interview artificially reduced error and raised scale reproducibility.

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FU451 → FU401

Nagi Scale

1. Show and explain the answer key *before* administering the questionnaire. The participant is to choose one of the following answers for each activity:

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

2. Start with, *For each activity, tell me whether you have No Difficulty, A little Difficulty, Some Difficulty, A Lot of Difficulty, if you are Unable to do it, if you Do not do it on MD Orders or Institutional Orders, or if you are Unable to Assess Difficulty Because the activity is not done as part of your daily activities.*

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

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

FU451-FU461

No Difficulty

A Little Difficulty

Some Difficulty

A Lot of Difficulty

Unable to Do

Don't Do on MD Orders or Institutional Orders

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

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FU361 → FU380

CES-D

A. Rationale and Background:

The Center for Epidemiologic Studies Depression Scale (CES-D) was developed for use in epidemiologic research of depressive symptomatology in the general population. It was designed as a screening instrument to elicit symptoms associated with depression. It is intended to document the presence and severity of depressive symptoms but is not intended to make clinical diagnosis. It assesses the current state of the subject by focusing on symptomatology in the past week.

Note: The depression questions used in the NHANES 1 survey were the 20-item set of the CES-D developed and validated by the Center for Epidemiologic Studies, National Institute of Mental Health (NIMH).

The scale is given at each exam. The scale is not given if the patient is: sedated, aphasic, non-English speaking, or uncooperative.

B. Procedure:

1. Each question is read to the participant who responds with one of four answers.

2. Response alternatives should be printed on paper which is placed in front of the participant for reference.

3. Each category of response should be explained to the participant prior to administering the scale.

4. If the participant is unable to read the response sheets, the interviewer should read each response as well as the question referring to their feelings in the past week.

5. Be sure the participant understands that the questions refer to his/her feelings only during the past week.

FU361-FU380

C. CES-D Scoring:

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

Code	*Response Option*
0	Rarely or none of the time (less than 1 day)
1	Some or a little of the time (1-2 days)
2	Occasionally or a moderate amount of the time (3-4 days)
3	Most or all of the time (5-7 days)

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 fours 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 final score is calculated by the computer.

D. Methods:

The CES-D Questionnaire consists of 20 questions. Since it is a scale for depression, it must be completed using responses by the participant, not a proxy.

SCRIPT: *The questions below ask about your feelings. For each of the following statements, please say if you felt that way during the past week.*

1. Hand the response sheet to the participant and explain the response options. The following definitions should be given:

   Code
   Rarely or none of the time (< one full day)
   Some or a little of the time (1 to 2 days in the past week)
   Occasionally or moderate amount of time (3 to 4 days in the past week, or about 1/2 the time)
   Most of the time (5 to 7 days in the past week)

   If participant answers *YES* to a given statement, repeat the above responses to get a correct answer.

FU361-FU380

2. Read each item as it is written on the form, prefacing each question with the statement *During the past week*, then continuing with the response categories. For example:

   SCRIPT: *During the past week I was bothered by things that usually don't bother me. Did you feel that way rarely or none of the time, some or a little of the time, occasionally or moderate amount of time, or most or all of the time?*

3. Discontinue reading the responses when the participant provides a response before you are finished. On the next item, however, again begin to read the entire set of responses.

4. Code **9** = *Refused* or *Do not know* is used when:

   a. The question was asked, but the participant chooses not to answer. For example, response was *I would rather not say,* or *Go on to the next question.*
   b. The question was asked, but the participant does not know, does not remember, or does not understand the statement.

** If "unknown" is used more than 4 times on the questionnaire it is no longer considered valid for research. Do your best to have the participant give you an answer listed on the response key.**

5. Circle the response on the form.

6. When the participant asks about the meaning of any item or tries to qualify a statement, simply repeat the statement. For example:

   Participant: *What do you mean by bothered?*

   Interviewer: *I was bothered by things that usually don't bother me. Did you feel that way rarely or none of the time, some or a little of the time, occasionally or moderate amount of time, or most or all of the time during the past week?*

7. When the participant still asks about the meaning or says he/she does not understand, check **9** = refused or do not know. Do not try to interpret the statement for the participant.

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)

FU361-FU380

8

Fu486 → Fu497

Berkman Social Network Questionnaire

A. Background & Rationale

The intent of the Berkman Social Network Questionnaire (BSNQ) is to determine the participant's social support systems, both from friends and relatives. Response sheets, using large print should be given to the participant to help them better understand and answer the questions.

B. Procedures

Before administering the BSNQ, read the following statement, *The next questions ask about your social support. Please tell me the response that most closely describes your current situation.*

The first four (4) questions should be answered with the following responses:

None	*6 to 9*
1 or 2	*10 or more*
3 to 5	*Unknown**

* ***Unknown*** can be used only when participant is unable to answer, refuses, or if the question was not asked. The participant is not told this is an option for an answer.

Fu486 1. *How many **close friends** do you have; people that you feel at ease with and can talk to about private matters?*

The response should be based on whom the participant can **talk** to, in person and telephone contact.

Fu487 2. *How many of these **close friends** do you see at least once a month?*

This question refers only to friends the participant has been in physical contact with, or spoken to in person. **Talking on the phone should not be included in the scoring.** This separates how often the participant talks to people versus physically meeting with them.

Fu488 3. *How many **relatives** do you have; people that you feel at ease with and can talk to about private matters?*

The response should be based on relatives whom the participant can **talk** to, in person and telephone contact

Fu489 4. *How many of these **relatives** do you see at least once a month?*

This question refers only to relatives the participant has been in physical contact with, or spoken to in person. **Talking on the phone should not be included in the scoring.** This separates how often the participant talks to people versus physically meeting with them.

Fu490 5. *Do you participate in any groups such as a senior center, social or work group, religious connected group, self-help group, or charity, public service or community group?*

This can include volunteer work or groups where the participant physically works or joins others. Again, it does not include telephone contact.

Coding
0 = No
1 = Yes
9 = Unknown

Fu491 6. *About how often do you go to religious meetings or services?*

The answer should reflect how often the participant **goes** to meetings or services. Watching services on television should not be scored as having gone to meetings or services. The intent of this question is how often the person **joins** others in this particular activity.

Coding
1 – 9
See Exam Form

Question 7 asks about insurance coverage.

Fu492 7. *Do you have health insurance other than Medicare or Medicaid?*

The intent of questions 8-12 is for friends and family, not mental health specialists. They should be answered with the following responses:

None of the time	*Most of the time*
A little of the time	*All of the time*
Some of the time	

* ***Unknown*** can be used only when participant is unable to answer, refuses, or if the question was not asked. The participant is not told this is an option for an answer.

Hand participant answer key.

Fu493 8. *Is there someone available to you whom you can count on to listen to you when you need to talk?*

Fu494 9. *Is there someone available to give you good advice about a problem?*

Fu495 10. *Is there someone available to you who shows you love and affection?*

Fu496 11. *Can you count on anyone to provide you with emotional support (talking over problems or helping you make a difficult decision)?*

Fu497 12. *Do you have as much contact as you would like with someone you feel close to, someone in whom you can trust and confide?*

None

1 or 2

3 to 5

6 to 9

10 or more

FU486-FU489

48

None of the time

A little of the time

Some of the time

Most of the time

All of the time

FU493-FU497

FU499 -> FU574

Leisure Time Cognitive and Physical Activities

I. Background and Rationale

The intent of the Leisure Time Cognitive and Physical Activities questionnaire is to determine whether increased participation in leisure activities lowers the risk of dementia or participation in leisure activities declines during the preclinical phase of dementia. Response sheets, using large print should be given to the participant to help them better understand and answer the questions.

II. Procedures

1. Show and explain the answer key *before* administering the questionnaire. The participant is to choose one of the following answers for each activity:

Never
Daily (7 days/week)
Several Days Per Week (2-6 days/week)
Once Weekly (1 day/week)
Monthly (once a month)
Occasionally (less than once a month)

2. Ask each question individually. Start with, *During the past year, how often have you participated in the following leisure time activities?*

3. These questions can be answered by the participants' proxy. For nursing home visits this information can also be taken from the up-to-date Minimum Data Sheets.

4. This questionnaire can be asked of all participants regardless of their cognitive status.

Note:
"Climbing 2 flights of stairs"-this is only counted as a leisure activity if the participant does this as exercise.

"Group exercises" is considered done as a group, not exercise done by themselves.

"Bicycling" Include the stationary bike

"Crossword Puzzles" Include word searches

"Reading books/Newspapers" If the participant is legally blind but listens to books on tape, this is considered as a book on tape reader. It involves the same process once it migrates to the brain: attention, memory, and sequence.

FU499-FU514

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Leisure Activities and the Risk of Dementia in the Elderly

Joe Verghese, M.D., Richard B. Lipton, M.D., Mindy J. Katz, M.P.H., Charles B. Hall, Ph.D., Carol A. Derby, Ph.D., Gail Kuslansky, Ph.D., Anne F. Ambrose, M.D., Martin Sliwinski, Ph.D., and Herman Buschke, M.D.

ABSTRACT

BACKGROUND

Participation in leisure activities has been associated with a lower risk of dementia. It is unclear whether increased participation in leisure activities lowers the risk of dementia or participation in leisure activities declines during the preclinical phase of dementia.

METHODS

We examined the relation between leisure activities and the risk of dementia in a prospective cohort of 469 subjects older than 75 years of age who resided in the community and did not have dementia at base line. We examined the frequency of participation in leisure activities at enrollment and derived cognitive-activity and physical-activity scales in which the units of measure were activity-days per week. Cox proportional-hazards analysis was used to evaluate the risk of dementia according to the base-line level of participation in leisure activities, with adjustment for age, sex, educational level, presence or absence of chronic medical illnesses, and base-line cognitive status.

RESULTS

Over a median follow-up period of 5.1 years, dementia developed in 124 subjects (Alzheimer's disease in 61 subjects, vascular dementia in 30, mixed dementia in 25, and other types of dementia in 8). Among leisure activities, reading, playing board games, playing musical instruments, and dancing were associated with a reduced risk of dementia. A one-point increment in the cognitive-activity score was significantly associated with a reduced risk of dementia (hazard ratio, 0.93 [95 percent confidence interval, 0.90 to 0.97]), but a one-point increment in the physical-activity score was not (hazard ratio, 1.00). The association with the cognitive-activity score persisted after the exclusion of the subjects with possible preclinical dementia at base line. Results were similar for Alzheimer's disease and vascular dementia. In linear mixed models, increased participation in cognitive activities at base line was associated with reduced rates of decline in memory.

CONCLUSIONS

Participation in leisure activities is associated with a reduced risk of dementia, even after adjustment for base-line cognitive status and after the exclusion of subjects with possible preclinical dementia. Controlled trials are needed to assess the protective effect of cognitive leisure activities on the risk of dementia.

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THE INCIDENCE OF DEMENTIA increases with increasing age.[1,2] Although the prevention of dementia has emerged as a major public health priority, there is a paucity of potential preventive strategies.[3-5] Identifying protective factors is essential to the formulation of effective interventions for dementia. Cross-sectional studies report associations between dementia and reduced participation in leisure activities in midlife, as well as between cognitive status and participation in leisure activities in old age.[6,7] Katzman proposed that persons with higher educational levels are more resistant to the effects of dementia as a result of having greater cognitive reserve and increased complexity of neuronal synapses.[8] Like education, participation in leisure activities may lower the risk of dementia by improving cognitive reserve.[9-15]

In observational studies, elderly persons who had participated to a greater extent in leisure activities had a lower risk of dementia than those who had participated to a lesser extent.[10-15] Although these results suggest that leisure activities have a protective role, an alternative explanation is possible. In most types of dementia, there is a long period of cognitive decline preceding diagnosis.[16-18] Reduced participation in activities during this preclinical phase of dementia may be the consequence and not the cause of cognitive decline. Resolution of this issue requires a long period of observation before diagnosis to enable researchers to disentangle the potential effects of preclinical dementia. Base-line cognitive status, educational level, and level of depression may confound the relation between leisure activities and dementia.[10-15] Moreover, most studies have not assessed the associations between leisure activities and particular types of dementia.[10-14]

The Bronx Aging Study provided us with the opportunity to study the influence of leisure activities on the risk of dementia over a long period[19,20] while accounting for previously identified confounders. This community-based study has followed a cohort of persons who did not have dementia at base line, with the use of detailed clinical and neuropsychological evaluations performed at intervals for up to 21 years.[19,20] We examined the influence of individual and composite measures of cognitive and physical leisure activities on the risk of the development of dementia.

METHODS

STUDY POPULATION

The study design and recruitment methods of the Bronx Aging Study have been described previously.[19,20] Briefly, the study enrolled English-speaking subjects between 75 and 85 years of age who resided in the community. Criteria for exclusion included severe visual or hearing impairment and a previous diagnosis of idiopathic Parkinson's disease, liver disease, alcoholism, or known terminal illness. Subjects were screened to rule out the presence of dementia at base line and were included if they made eight or fewer errors on the Blessed Information–Memory–Concentration test.[19-21] This test has a high test–retest reliability (0.86), and its results correlate well with the stages of Alzheimer's disease.[22,23] At the inception of the study, the cohort was middle-class, most subjects were white (91 percent), and the majority were female (64 percent). Written informed consent was obtained at enrollment. The local institutional review board approved the study protocol.

The study enrolled 488 subjects between 1980 and 1983. Subjects underwent detailed clinical and neuropsychological evaluations at enrollment and at follow-up visits every 12 to 18 months. The potential study period consisted of the 21-year period from 1980 to 2001. We excluded 2 subjects without documented leisure activities and 17 subjects who moved or declined to return for follow-up. After these subjects had been excluded, 469 subjects (96.1 percent) were eligible. In 1992, 73 surviving subjects were still having study visits in our current project, the Einstein Aging Study.

CLINICAL EVALUATION

During the study, subjects were interviewed with the use of a structured medical-history questionnaire and were examined by study clinicians.[19,20] Functional limitations on 10 basic and instrumental activities of daily living were rated on a 3-point scale for each activity (range of total scores, 10 to 30 points), with 1 point indicating "no limitation," 2 points indicating "does activity with difficulty," and 3 points indicating "unable."[19,20] A spouse or family member accompanied most subjects or was contacted for confirmation of the history.

NEUROPSYCHOLOGICAL EVALUATION

An extensive battery of neuropsychological tests was administered at study visits.[18-20] We examined

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performance on the Blessed Information–Memory–Concentration test (range of scores, 0 to 33),[21] the verbal and performance IQ according to the Wechsler Adult Intelligence Scale,[24] the Fuld Object-Memory Evaluation (range of scores, 0 to 10),[25] and the Zung depression scale (range of scores, 0 to 100).[26] These tests were used to inform the diagnosis of dementia at case conferences.

LEISURE ACTIVITIES

At base line, subjects were interviewed regarding participation in 6 cognitive activities (reading books or newspapers, writing for pleasure, doing crossword puzzles, playing board games or cards, participating in organized group discussions, and playing musical instruments) and 11 physical activities (playing tennis or golf, swimming, bicycling, dancing, participating in group exercises, playing team games such as bowling, walking for exercise, climbing more than two flights of stairs, doing housework, and babysitting). Subjects reported the frequency of participation as "daily," "several days per week," "once weekly," "monthly," "occasionally," or "never." We recoded these responses to generate a scale with one point corresponding to participation in one activity for one day per week. The units of the scales are thus activity-days per week; the scales were designed to be intuitively meaningful to clinicians and elderly persons and to be useful in the design of intervention studies or public health recommendations. For each activity, subjects received seven points for daily participation; four points for participating several days per week; one point for participating once weekly; and zero points for participating monthly, occasionally, or never. We summed the activity-days for each activity to generate a cognitive-activity score, ranging from 0 to 42, and a physical-activity score, ranging from 0 to 77.

The estimates of the overall level of participation were consistent with good test–retest reliability for scores obtained on entry and at the next visit a year later on the cognitive-activity scale (Spearman r=0.518, P=0.001) and the physical-activity scales (Spearman r=0.410, P=0.001). There was no direct measurement of the time spent in activities, although participation was verified by family members or friends. The scores were not correlated with age. Scores on the cognitive-activity scale correlated with scores on the Blessed test[21] (Spearman r=−0.286, P=0.001), but not functional status (Spearman r=−0.042, P=0.77). Scores on the physical-activity scale correlated with functional status (Spearman r=−0.293, P=0.001) but not with scores on the Blessed test (Spearman r=−0.021, P=0.65).[21]

DIAGNOSIS OF DEMENTIA

At study visits, subjects in whom dementia was suspected on the basis of the observations of members of the study staff, results of neuropsychological tests, or a worsening of the scores on the Blessed test[21] by four points or a total of more than seven errors underwent a workup including computed tomographic scanning and blood tests.[19,20] A diagnosis of dementia was assigned at case conferences attended by study neurologists, a neuropsychologist, and a geriatric nurse clinician, according to the criteria of the *Diagnostic and Statistical Manual of Mental Disorders*, third edition (DSM-III) or, after 1986, the revised third edition (DSM-III-R).[27-29] Updated criteria for the diagnosis of dementia and particular types of dementia were introduced after the study had begun.

To ensure uniformity of diagnosis, all cases were discussed again at new diagnostic conferences held in 2001 and involving a neurologist and a neuropsychologist who had not participated in diagnostic conferences between 1980 and 1998.[29] Dementia was diagnosed according to the DSM-III-R criteria.[28] Reduced participation in leisure activities was used to assess functional decline, but the leisure-activity scales were not available to the raters assessing such decline. Disagreements between raters were resolved by consensus after the case was presented to a second neurologist, with blinding maintained. Cases of dementia were classified according to the criteria for probable or possible Alzheimer's disease published by the National Institutes of Neurological Disorders and Stroke and the Alzheimer's Disease and Related Disorders Association[30] and the criteria for probable, possible, or mixed vascular dementia published by the Alzheimer's Disease Research Centers of California.[31]

STATISTICAL ANALYSIS

Continuous variables were compared with use of either an independent-samples t-test or the Mann–Whitney U test, and categorical variables were compared with use of the Pearson chi-square test.[32] In primary analyses, we studied the association between cognitive and physical activities and the risk of dementia and specific types of dementia using Cox proportional-hazards regression analysis to es-

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timate hazard ratios, with 95 percent confidence intervals.[33] The time to an event was defined as the time from enrollment to the date of a diagnosis of dementia or to the final contact or visit for subjects without dementia. All multivariate models reported include the following covariates unless otherwise specified: age at enrollment, sex, educational level (high school or less vs. college-level education), presence or absence of chronic medical illnesses, and base-line scores on the Blessed test. Presence of the following self-reported chronic medical illnesses was individually entered in the models: cardiac disease (angina, previous myocardial infarction, or cardiac failure), hypertension, diabetes mellitus, stroke, depression, and hypothyroidism. We also divided the study cohort into thirds on the basis of their scores on the two activity scales and determined the risk of dementia according to these groups. We examined the role of individual leisure activities by comparing subjects who participated in an activity several days or more per week (frequent participation) with subjects who participated weekly or less frequently (rare participation) and, in the full models, adjusted for participation in other leisure activities.

In secondary analyses, we examined the influence of base-line cognitive status and possible preclinical dementia. First, we sequentially excluded from the full models subjects in whom dementia developed during the first two, four, seven, and nine years of follow-up in order to avoid confounding by a possible influence of preclinical dementia on participation in leisure activities. Second, we used linear mixed models controlled for age, sex, and educational level to assess the relation between cognitive activities and base-line cognitive status and the annual rate of change in cognitive status.[34] We analyzed verbal IQ as well as specific cognitive domains, including episodic memory (with the Buschke Selective Reminding test [range of scores, 0 to 72, with lower scores indicating worse memory][35] and the Fuld Object-Memory Evaluation[25]) and executive function (with the Digit–Symbol Substitution subtest of the Wechsler Adult Intelligence Scale [range of scores, 0 to 90, with lower scores indicating worse cognition]).[24] Each model included terms for the cognitive-activity score, time, and the interaction between the two. The assumptions of the models were examined analytically and graphically and were adequately met.

RESULTS

DEMOGRAPHIC CHARACTERISTICS

During 2702 person-years of follow-up (median follow-up, 5.1 years), dementia developed in 124 subjects (Alzheimer's disease in 61, vascular dementia in 30, mixed dementia in 25, and other types of dementia in 8). By the end of the study period, 361 subjects had died, 88 subjects had dropped out (mean [±SD] follow-up, 6.6±4.9 years), and 20 subjects were still active. When the cohort was divided into thirds according to the cognitive-activity score or the physical-activity score, no significant differences in the length of follow-up were found among these subgroups.

On average, subjects in whom dementia developed were older, had lower levels of education, and had significantly lower scores on the cognitive-activity scale, but not on the physical-activity scale, than subjects in whom dementia did not develop (Table 1). Although their scores on neuropsychological tests were in the normal range (Table 1), subjects in whom dementia later developed had poorer cognition on the Blessed test ($P=0.001$)[21] and a lower base-line performance IQ ($P=0.07$).[24] The frequency of chronic medical illnesses did not differ significantly between subjects in whom dementia developed and those in whom it did not. Nineteen subjects were receiving antidepressants at enrollment. Cognitive-activity scores were inversely correlated with the Zung depression scale[26] (Spearman $r=-0.215$, $P<0.001$), as were physical-activity scores (Spearman $r=-0.254$, $P<0.001$), indicating that lower levels of participation were associated with increasing levels of depression.

A smaller proportion of the 361 subjects with a high-school education or less than of the 108 subjects who had attended college participated in reading (90 percent vs. 96 percent, $P=0.05$), writing (67 percent vs. 80 percent, $P=0.01$), doing crossword puzzles (21 percent vs. 36 percent, $P=0.001$), and playing musical instruments (7 percent vs. 15 percent, $P=0.02$). There was no difference according to educational level in the proportion of subjects who played board games or participated in group discussions.

LEISURE ACTIVITIES

Among cognitive activities, reading, playing board games, and playing musical instruments were as-

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Table 1. Base-Line Characteristics of Subjects in Whom Dementia Developed and Subjects in Whom It Did Not.*

Variable	Subjects in Whom Dementia Did Not Develop (N=345)	Subjects in Whom Dementia Developed (N=124)	P Value
Age (yr)	78.9±3.1	79.7±3.1	0.01
Female sex (%)	63	67	0.51
White race (%)	92	91	0.60
Duration of follow-up (yr)	5.6±4.1	5.9±4.1	0.52
High-school education or less (%)	74	84	0.02
Functional rating	10.9±1.9	11.5±2.1	0.01
Physical-activity score	13.6±7.6	12.8±8.2	0.31
Cognitive-activity score	10.6±5.8	7.5±5.5	<0.001
Neuropsychological tests			
Blessed Information–Memory–Concentration test	2.1±1.9	3.5±2.4	0.001
Performance IQ	105.8±12.4	97.5±13.8	0.07
Verbal IQ	111.0±15.5	103.9±15.6	0.35
Fuld Object-Memory Evaluation	7.5±1.2	6.7±1.5	0.001
Zung depression scale	46.4±10.4	48.4±10.9	0.32
Medical illnesses (%)			
Hypertension	52	45	0.12
Cardiac disease	29	23	0.72
Stroke	7	3	0.99
Diabetes	11	12	0.87
Thyroid illness	14	9	0.12
Depression	17	19	0.10

* Plus–minus values are means ±SD. P values for scales and tests were calculated by the Mann–Whitney U test. The functional rating ranges from 10 to 30, with higher scores indicating better function; scores on the physical-activity scale range from 0 to 77, with higher scores indicating greater participation; scores on the cognitive-activity scale range from 0 to 42, with higher scores indicating greater participation; the range of scores on the Blessed Information–Memory–Concentration test is 0 to 33, with higher scores indicating worse general cognitive status; the normal ranges of performance IQ and verbal IQ are 85 to 115; the range of scores on the Fuld Object-Memory Evaluation is 0 to 10, with higher scores indicating better memory; and the range of scores on the Zung depression scale is 0 to 100, with higher scores indicating a greater level of depression.

sociated with a lower risk of dementia (Table 2). Dancing was the only physical activity associated with a lower risk of dementia. Fewer than 10 subjects played golf or tennis, so the relation between these activities and dementia was not assessed.

COGNITIVE ACTIVITIES

When the cognitive-activity score was modeled as a continuous variable (Table 3), the hazard ratio for dementia for a one-point increment in this score was 0.93 (95 percent confidence interval, 0.89 to 0.96). Adjustment for the base-line score on the Blessed test in a second model (Table 3) did not attenuate the association. Participation in cognitive activities was associated with a reduced risk of Alzheimer's disease (hazard ratio, 0.93 [95 percent confidence interval, 0.88 to 0.98]), vascular dementia (hazard ratio, 0.92 [95 percent confidence interval, 0.86 to 0.99]), and mixed dementia (hazard ratio, 0.87 [95 percent confidence interval, 0.78 to 0.93]). The frequency of participation in cognitive activities was related to the risk of dementia. According to the model in which we adjusted for the base-line score on the Blessed test, the hazard ratio for subjects with scores in the highest third on the cognitive-activity scale, as compared with those with scores in the lowest third, was 0.37 (95 percent confidence interval, 0.23 to 0.61) (Table 3).

In additional analyses, adjustment for intellec-

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tual status with the use of the verbal IQ[24] did not alter the association between participation in cognitive activities and the risk of dementia (hazard ratio, 0.92 [95 percent confidence interval, 0.87 to 0.97]). Participation in cognitive activities was also associated with a reduced risk of dementia among the 361 subjects with a high-school education or less (hazard ratio, 0.94 [95 percent confidence interval, 0.91 to 0.98]). The association of cognitive activities with dementia was not affected by adjustment for functional status, the restriction of the analyses to subjects with scores of less than 5 on the Blessed test,[21] or the exclusion of subjects who died during the first year after enrollment.

PHYSICAL ACTIVITIES

The physical-activity score was not significantly associated with dementia, either when analyzed as a continuous variable or when the study cohort was divided into thirds according to this score (Table 3).

INFLUENCE OF PRECLINICAL DEMENTIA

The presence of preclinical dementia might reduce participation in leisure activities,[6,7] leading to the overestimation of its protective influence. The association between the base-line cognitive-activity score and dementia was significant even after the exclusion of 94 subjects in whom dementia was diagnosed during the first seven years after enrollment (hazard ratio, 0.94 [95 percent confidence interval, 0.88 to 0.99]) (Table 4). The association was no longer significant after the exclusion of the 105 subjects in whom dementia was diagnosed during the first nine years after enrollment. However, only 19 subjects were given a diagnosis of dementia after this point.

We used linear mixed models to examine the influence of participation in cognitive activities on the annual rate of change in cognitive function.[34] In these models (Table 5), the term for the cognitive-activity score represents the cross-sectional association between the cognitive activities and the scores on the selected tests administered at enrollment. These results indicate that subjects with increased participation in cognitive activities at entry had better overall cognitive status. Analysis with use of the term for time indicates that cognitive performance declines linearly as a function of follow-up time. The term for the interaction between the cognitive-activity score and time represents the longitudinal effect of the base-line measure of participation in cognitive activities on the annual rate of decline in

Table 2. Risk of Development of Dementia According to the Frequency of Participation in Individual Leisure Activities at Base Line.*

Leisure Activity and Frequency	Subjects with Dementia	All Subjects	Hazard Ratio for Dementia (95% CI)
	no.		
Cognitive activities			
Playing board games			
Rare	108	366	1.00
Frequent	16	103	0.26 (0.17–0.57)
Reading			
Rare	40	87	1.00
Frequent	84	382	0.65 (0.43–0.97)
Playing a musical instrument			
Rare	120	452	1.00
Frequent	4	17	0.31 (0.11–0.90)
Doing crossword puzzles			
Rare	117	407	1.00
Frequent	7	62	0.59 (0.34–1.01)
Writing			
Rare	104	382	1.00
Frequent	20	87	1.00 (0.61–1.67)
Participating in group discussions			
Rare	117	437	1.00
Frequent	7	32	1.06 (0.48–2.33)
Physical activities			
Dancing			
Rare	99	339	1.00
Frequent	25	130	0.24 (0.06–0.99)
Doing housework			
Rare	39	106	1.00
Frequent	85	363	0.88 (0.60–1.20)
Walking			
Rare	19	65	1.00
Frequent	105	404	0.67 (0.45–1.05)
Climbing stairs			
Rare	44	153	1.00
Frequent	80	316	1.55 (0.96–2.38)
Bicycling			
Rare	116	443	1.00
Frequent	8	26	2.09 (0.97–4.49)
Swimming			
Rare	108	386	1.00
Frequent	16	83	0.71 (0.22–2.29)
Playing team games			
Rare	120	450	1.00
Frequent	4	19	1.00 (0.14–7.79)
Participating in group exercise			
Rare	88	330	1.00
Frequent	36	139	1.18 (0.72–1.94)
Babysitting			
Rare	114	429	1.00
Frequent	10	40	0.81 (0.11–6.01)

* The frequency of participation in leisure activities was categorized as frequent if the subject participated at least several times per week and as rare if the subject participated once per week or less frequently. Hazard ratios were adjusted for age, sex, educational level, presence or absence of medical illnesses, score on the Blessed Information–Memory–Concentration test, and participation or nonparticipation in other leisure activities. For each activity, rare participation was used as the reference category. CI denotes confidence interval.

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Table 3. Risk of Dementia According to the Base-Line Scores on the Cognitive-Activity Scale and the Physical-Activity Scale.*

Leisure Activity	No. of Subjects	Hazard Ratio for Dementia (95% CI)	
		Model 1	Model 2
Cognitive-activity score			
1-Point increment		0.93 (0.89–0.96)	0.93 (0.90–0.97)
<8 Points	182	1.00	1.00
8–11 Points	137	0.50 (0.31–0.75)	0.48 (0.29–0.74)
>11 Points	150	0.33 (0.21–0.51)	0.37 (0.23–0.61)
Physical-activity score			
1-Point increment		0.99 (0.91–1.01)	1.00 (0.98–1.03)
<9 Points	162	1.00	1.00
9–16 Points	157	1.06 (0.67–1.65)	1.44 (0.91–2.28)
>16 Points	150	0.92 (0.58–1.45)	1.27 (0.78–2.06)

* Model 1 was adjusted for age, sex, educational level, and the presence or absence of chronic medical illnesses; model 2 includes the variables in model 1 and the base-line score on the Blessed Information–Memory–Concentration test. For each scale, scores in the lowest third were used as the reference category. CI denotes confidence interval.

Table 4. Risk of Dementia per 1-Point Increment in the Base-Line Cognitive-Activity Score, with the Sequential Exclusion of Subjects in Whom Dementia Developed during the First Nine Years of Follow-up.*

Analysis	Excluded Subjects with Dementia	Subjects in Whom Dementia Developed	Hazard Ratio (95% CI)
	no.		
Overall	0	124	0.93 (0.90–0.97)
With exclusion of subjects with a diagnosis of dementia			
Diagnosis during first 2 yr	36	88	0.94 (0.90–0.97)
Diagnosis during first 4 yr	63	61	0.94 (0.89–0.98)
Diagnosis during first 7 yr	94	30	0.94 (0.88–0.99)
Diagnosis during first 9 yr	105	19	0.96 (0.89–1.04)

* Hazard ratios are adjusted for age, sex, educational level, presence or absence of chronic medical illnesses, and score on the Blessed Information–Memory–Concentration test. CI denotes confidence interval.

performance on the selected tests; this effect was significant only for the tests of episodic memory. The estimates show that for a one-point increment in the cognitive-activity score, the annual rate of decline in scores on the Buschke Selective Reminding test is reduced by 0.043 point (P=0.02), and the annual rate of decline on the Fuld Object-Memory Evaluation is reduced by 0.006 point (P=0.04).

DISCUSSION

This prospective, 21-year study demonstrates a significant association between a higher level of participation in leisure activities at base line and a decreased risk of dementia — both for Alzheimer's disease and for vascular dementia. A one-point increment in the cognitive-activity score, which corresponds to participation in an activity for one day per week, was associated with a reduction of 7 percent in the risk of dementia. The association between cognitive activities and the risk of dementia remained robust even after adjustment for potential confounding variables such as age, sex, educational level, presence or absence of chronic medical illnesses, and base-line cognitive status. Increased participation in leisure activities was associated with a lower risk of dementia. Subjects with scores in the highest third on the cognitive-activity scale (more than 11 activity-days) had a risk of dementia that was 63 percent lower than that among subjects with scores in the lowest third.

We identified three possible explanations for the association between greater participation in leisure activities and a decreased risk of dementia. First, the presence of preclinical dementia may decrease participation in leisure activities. Second, unmeasured confounding may influence the results. Third, there may be a true causal effect of cognitive activities. We used several strategies to test the hypothesis that reduced participation in leisure activities appears to be a risk factor for, but is in fact a consequence of, preclinical dementia. Adjustment for base-line scores on cognitive tests, which predict dementia, did not alter the association between participation in cognitive activities and dementia. We have reported that an accelerated decline in memory begins seven years before dementia is diagnosed.[18] The exclusion of subjects in whom dementia was diagnosed during the first seven years after enrollment should eliminate most subjects who had preclinical dementia at enrollment. However, participation in cognitive activities predicted dementia even among those in whom it developed more than seven years after enrollment. Results from the linear mixed models that analyzed cognitive function over time corroborate the findings of previous studies[13,36] and show that increased participation in cognitive activities is associated with slower rates of cognitive decline, especially in terms of episodic memory.

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Because of the observational nature of our study, there is a possibility of residual or unmeasured confounding. The observed association appears to be independent of educational level and intellectual level, which may influence the choice of leisure activities. Perhaps reduced participation in leisure activities is an early marker of dementia that precedes the declines on cognitive tests.[13] Alternatively, participation in leisure activities may be a marker of behavior that promotes health. But the specificity of our findings for cognitive activities and not physical activities argues against this hypothesis. We did not study the effect of apolipoprotein E genotype, which may influence the rates of cognitive decline.[15,36] Hence, despite the magnitude and consistency of the associations, our findings do not establish a causal relation between participation in leisure activities and dementia, and controlled trials are therefore needed.

If there is a causal role, participation in leisure activities may increase cognitive reserve, delaying the clinical or pathological onset of dementia.[8,37,38] Alternatively, participation in cognitive activities might slow the pathological processes of disease during the preclinical phase of dementia. Our findings do not imply that subjects who were less active cognitively increased their risk of dementia.

The role of individual leisure activities is not well known, since most studies have used composite measures. In a French cohort, knitting, doing odd jobs, gardening, and traveling reduced the risk of dementia.[10] In the Nun Study, low density of ideas and low levels of grammatical complexity in autobiographies written in early life were associated with low cognitive test scores in later life.[39] Reading, playing board games, playing musical instruments, and dancing were associated with a lower risk of dementia in our cohort. There was no association between physical activity and the risk of dementia. Exercise is said to have beneficial effects on the brain by promoting plasticity, increasing the levels of neurotrophic factors in the brain, and enhancing resistance to insults.[40] Cognitive and physical activities overlap, and therefore it is not surprising that previous studies have disagreed on the role of physical activities.[10-15] Although physical activities are clearly important in promoting overall health,[41] their protective effect against dementia remains uncertain.

Our study has several limitations. Ours was a cohort of volunteers who resided in the community; whites and subjects older than 75 years of age were overrepresented, as compared with the general population of those over 65 years of age, thus potentially limiting the generalizability of our results. Although standard criteria and well-established procedures were used to make diagnoses, some misclassification is inevitable. Time spent in each activity was not directly measured, although the history was verified by family members or other informants. Duration and cognitive demand are both important in the assessment of an activity. It is difficult to assign weights to the cognitive demands of leisure activities, since such demands vary among activities and among the persons who engage in each activity. Leisure activities were arbitrarily classified as cognitive or physical. For instance, doing housework requires not only a certain functional status but also the ability to plan, prepare, and adapt to changes in circumstances and the environment. The leisure activities we studied reflect the interests of our cohort, and it is quite likely that activities other than the ones we studied are also protective.[10-15]

Participation in leisure activities is associated with a reduced risk of development of dementia, both Alzheimer's disease and vascular dementia. The reduction in risk is related to the frequency of participation. According to our models, for example, elderly persons who did crossword puzzles four days a week (four activity-days) had a risk of dementia that was 47 percent lower than that among subjects who did puzzles once a week (one activity-day).

Table 5. Association of Participation in Cognitive Leisure Activities with Base-Line Cognitive Function and Rate of Change in Cognitive Function.*

Cognitive Test	Estimated Change in Test Score (±SE)	P Value
Buschke Selective Reminding test		
Cognitive-activity score (per 1-point increment)	0.383±0.092	<0.001
Time (per 1-year increment)	−1.578±0.211	<0.001
Interaction	0.043±0.018	0.02
Fuld Object-Memory Evaluation		
Cognitive-activity score (per 1-point increment)	0.028±0.011	0.007
Time (per 1-year increment)	0.961±0.466	0.04
Interaction	0.006±0.003	0.04
Digit-Symbol Substitution test		
Cognitive-activity score (per 1-point increment)	0.569±0.097	<0.001
Time (per 1-year increment)	−0.998±0.172	<0.001
Interaction	−0.001±0.014	>0.05
Verbal IQ		
Cognitive-activity score (per 1-point increment)	0.789±0.131	<0.001
Time (per 1-year increment)	4.472±1.980	0.02
Interaction	0.020±0.012	>0.05

* Associations were assessed by linear mixed models, controlled for age, sex, and educational level. The term for the interaction between the cognitive-activity score and time represents the longitudinal effect of the base-line measure of participation in cognitive activities on the annual rate of decline in performance on the given test.

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Clinical trials are needed to define the causal role of participation in leisure activities. A recent study reported reduced cognitive declines after cognitive training in elderly persons without dementia.[36] If confirmed, our results may support recommendations for participation in cognitive activities to lower the risk of dementia that parallel current recommendations for participation in physical activities to reduce the risk of cardiovascular diseases.[42,43]

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95

Never

Daily

Several Days Per Week

Once Weekly

Monthly

Occasionally

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FU297-FU333

End of Life Preference Questionnaire

A. Rationale and Background:

Americans today enjoy a longer lifespan, many living well into their 80s and 90s. For many, however, an unfortunate consequence of living well into old age is a life accompanied by chronic and debilitating illnesses. Advances in medical technology have left many frail elderly patients vulnerable to a prolonged death commonly characterized by extended hospitalizations and costly invasive medical procedures. A key element to improving care at the end of life is the principle of patient autonomy including patients' rights to participate in decisions about the medical care. However, many patients near the end of life are not cognizant and are unable to participate in these important decisions. Therefore, advance care planning is a necessary component to achieve quality of care at the end of life.

The questionnaire should be introduced to the participant by using the following text:

People have many ideas about health and health care. Understanding these ideas is crucial to improving care. We are interested in learning what you believe to be the most important considerations at this point in your life. There are no right or wrong answers. We are simply interested in your opinions. We understand that this is a sensitive topic. Your participation is voluntary and you may choose to stop answering questions at any time.

Would you like to proceed? (0=No, 1=Yes, 9=Not done due to cognitive status)

This question will be used to assess the feasibility of collecting information about advance care planning in community-dwelling elders and the acceptability of this questionnaire to original cohort participants.

B. Definition of Terms:

Health Care Proxy - is a legal document that designates a trusted relative or friend to make health care decisions for you if, because of an illness or accident, you're incapable of making or communicating them yourself.

Living Will - A living will is a document in which you specify in advance medical treatment that you would or would not want in the event that you became unable to express your wishes. Massachusetts is one of only three states that recognizes health care proxies but does not recognize living wills. Living wills are still potentially useful because they guide Agents (for example your health care proxy, family members) and physicians about the types of choices a person would make.

Health Care Preferences - Are a statement of what an individual values in their life and their preferences concerning future health states such as being permanently comatose, ventilated or

FU297-FU333

tube fed. Some patients want to "fight to the end" while others believe if they decline treatment they are "giving up"; yet others want to focus on their "quality of life" or "live life until they die". Depending on an individual's preferences their medical care can be focused on extending life as much or on minimizing suffering and promoting comfort until death.

Power of Attorney – is a legal document that designates a trusted relative or friend to make legal and financial decisions for you if, because of an illness or accident, you're incapable of making or communicating them yourself. Sometimes, a Power of Attorney also gives the designee the right to make health care decisions.

If the participant requests further information encourage the participant to contact their physician or other health care provider.

C. Procedure:

1. Read the introduction to the participant including the statement that this is a sensitive topic, their participation is voluntary, and they may choose to stop answering questions at any time.

2. Ask if they want to proceed.

3. Always read the introduction to each set of questions.

4. Remember that we are asking a participant about their beliefs and preferences. There are no right or wrong answers. We want to know their thoughts.

5. These questions must be answered by the participant, not a proxy.

D. Methods:

There are 13 items included in the Health Care Preferences Questionnaire.

1. Read the introduction to each set of questions.

2. Read each question as it is written on the form and then read the available responses.

3. Code 9 = Refused or Do not know is used when:

a. The question was asked, but the participant chooses not to answer. For example, response was I would rather not say or Go on to the next question.

b. The question was asked, but the participant does not know, does not remember or does not understand the statement.

4. Circle the response on the form.

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5. When the participant asks about the meaning of any item or tries to qualify a statement, simply repeat the statement. If the participant still asks about the meaning or says he/she does not understand, check 9 = refused or don't know. Do not try to interpret the statement for the participant.

6. If a participant becomes visibly upset by the questions do not continue and document which question they found upsetting and inform [redacted]

7. If a participant wants further information refer them to their physician.

E. Interviewer Feedback:

At the end of each questionnaire, the interviewer will be asked to answer the following questions for each participant:

1. Did the participant choose to stop before completing all 13 questions. If so, why did they stop and at what question.

2. Did the participant seem upset or bothered by any of the questions that were asked. If yes, which question.

3. Where there any questions that the participant had particular difficulty understanding? If yes, which one(s).

Important Differences Between Health Care Proxies and Living Wills
Committees and MINS - Advance Directives 08/01/2000

Advance Directives, such as Health Care Proxies and Living Wills, allow people to retain control over medical decisions. Massachusetts law allows people to make their own Health Care Proxies, but does not officially recognize Living Wills. A Health Care Proxy designates another person to make medical decisions should you be unable to do so, and a Living Will allows you to list medical treatments that you would or would not want if you became terminally ill and unable to make your own decisions.

Massachusetts is one of only three states that recognizes Health Care Proxies but does not recognize Living Wills. Living Wills are still potentially useful because they guide Agents and physicians about the types of choices a person would make. More information about advance directives can be found at:

What is a Living Will?

A living will is a document in which you specify in advance medical treatment that you would or would not want in the event that you become unable to express your wishes. Massachusetts is one of only three states that recognizes health care proxies but does not recognize living wills. Living Wills are still potentially useful because they guide Agents and physicians about the types of choices a person would make.

MASSACHUSETTS HEALTH CARE PROXY

What does the Health Care Proxy Law allow?

The Health Care Proxy is a simple legal document that allows you to name someone you know and trust to make health care decisions for you if, for any reason and at any time, you become unable to make or communicate those decisions. It is an important document, however, because it concerns not only the choices you make about your health care, but also the relationships you have with your physician, family, and others who
may be involved with your care. Read this and follow the instructions to ensure that your wishes are honored.

Under the Health Care Proxy Law (Massachusetts General Laws, Chapter 201D), any competent adult 18 years of age or over may...appoint a Health Care Agent. You (known as the "Principal") can appoint any adult EXCEPT the administrator, operator, or employee of a health care facility such as a hospital or nursing home where you are a patient or resident UNLESS that person is also related to you by blood, marriage, or adoption.

What can my Agent do?

Your Agent will make decisions about your health care only when you are, for some reason, unable to do that yourself. This means that your Agent can act for you if you are temporarily unconscious, in a coma, or have some other condition in which you cannot make or communicate health care decisions. Acting with your authority, your Agent can make any health care decision that you could, if you were able.

Your Agent will make health care decisions for you according to your wishes or according to his/her assessment of your wishes, including your religious or moral beliefs. It is very important that you talk with your Agent so that he or she knows what is important to you. If your Agent does not know what your wishes would be in a particular situation, your Agent will decide based on what he or she thinks would be in your best interests...if you still object to any decision made by your Agent, your own decisions will be honored unless a Court determines that you lack capacity to make health care decisions.

Your Agent's decisions will have the same authority as yours would, if you were able, and will be honored over those of any other person, except for any limitation you yourself made, or except for a Court Order specifically overriding the Proxy.

Who should have the original and copies?

After you have filled in the form, remove this information page and make at least four photocopies of the form. Keep the original yourself where it can be found easily (not in your safe deposit box). Give copies to your doctor and/or health plan to put into your medical record. Give copies to your Agent. You can give additional copies to family members, your clergy and/or

lawyer, and other people who
may be involved in your health care decision making.

How can I revoke or cancel the document?

Your Health Care Proxy is revoked when any of the following four things happens:
1. You sign another Health Care Proxy later on.
2. You legally separate from or divorce your spouse who is named in the Proxy as your Agent.
3. You notify your Agent, your doctor, or other health care provider, orally or in writing, that you want to revoke your Health Care Proxy.
4. You do anything else that clearly shows you want to revoke the Proxy, for example, tearing up or destroying the Proxy, crossing it out, telling other people, etc.

For More Information on Choice in Death and Dying:

http://www.abcd-caring.org Americans for Better Care of Dying

http://www.careguide.net Everything families need to understand, plan, and manage care for their elderly loved ones

http://www.choices.org (Choice In Dying web site, which has general information as well as information about Massachusetts)

http://www.partnershipforcaring.org Partnership for caring: *America's voices for the dying.*

The following information on Advance Directives was printed from the Partnership for Caring website.

http://www.partnershipforcaring.org Partnership for caring: *America's voices for the dying.*

Never

Daily

Several Days Per Week

Once Weekly

Monthly

Occasionally

FU315-FU316

90% or better

About 75%

About 50-50

About 25%

10% or less

Visit our W[illegible]e at: www.bidmc.caregroup.org

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Planning for Your Care: Information About the Health Care Proxy

The Massachusetts alternative to a living will

About this brochure

This brochure offers information on the Health Care Proxy — the Massachusetts alternative to a living will. Situations sometimes arise — such as accidents or severe illnesses — that can prevent you from participating in decisions about your care. Therefore, it is important to state your health care wishes regarding issues such as life support while you are healthy and able to think through what you would want if you were too sick to make your own decisions.

Beth Israel Deaconess Medical Center encourages all patients to establish an advance medical directive such as the Health Care Proxy. Massachusetts law requires that all patients be given the opportunity to complete a Health Care Proxy.

Please read through this brochure carefully. We encourage you to discuss this information with your physician, nurse, or social worker, and those who are closest to you.

What is a Health Care Proxy?

A Health Care Proxy is a legal document, recognized under Massachusetts law, that enables you to choose a health care agent — a person to speak for you if you ever become incapable of making decisions about your medical care. In most cases, this person is a family member or close friend. Your doctor would consult with your agent in making decisions for you. The agent you designate has full legal authority to speak on your behalf, so you can feel confident that your wishes will be respected.

Do I need a proxy if I already have a living will?

Yes. Only a Health Care Proxy is formally recognized by Massachusetts law. Generally speaking, a living will is a document that details a person's preferences about life-sustaining medical treatments if he or she becomes terminally ill. When writing a living will, it is difficult to anticipate all of the circumstances under which complicated medical decisions may have to be made. Living wills do not identify an individual with whom your doctor can discuss important medical decisions on your behalf.

In contrast, a proxy is not limited to situations of terminal illness, and it designates individuals you think can best help your doctor understand your values, preferences, and the carrying out of your wishes — assuming, of course, you have discussed your wishes with those close to you.

Is the Health Care Proxy only for people who are sick?

No. Although the proxy would take effect only if you ever become too sick to make your own health care decisions, many people who are perfectly healthy decide to prepare a Health Care Proxy.

How do I obtain a Health Care Proxy?

Ask your physician, nurse, or social worker for a Health Care Proxy form. The form must be signed by you and witnessed by two others.

How long is the proxy valid?

The proxy remains in effect unless you decide to change it. If you are admitted to the hospital again, you will be asked about your Health Care Proxy, and you can, if you desire, change it at any time.

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- What are your feelings regarding issues such as prolonged life support?

What should I do once I have completed the Health Care Proxy?

Discuss your wishes with your family. Let them know that you have identified an agent and what that means.

Once you have completed the proxy, keep the original and give copies to your agent and your physician for inclusion in your medical record.

Talk to your doctor. Ask any questions that you may have regarding certain treatment issues. He or she should also know the substance of the discussions you have had with your agent, and how to reach this individual.

To be treated at Beth Israel Deaconess Medical Center, do I have to choose an agent?

No. You do not have to fill out a Health Care Proxy to receive care at Beth Israel Deaconess Medical Center.

How do I revoke a proxy?

A proxy is automatically revoked if you fill out another proxy at a later date, or if you legally separate from or divorce your spouse (and your spouse has been named as your agent). You also may revoke your proxy by notifying your agent, doctor, or other health care provider, orally or in writing, that you want to revoke the proxy, or by any other act that indicates a clear intention to revoke.

If you have questions, please talk with your physician, nurse, or social worker. If you need any additional information, call the department of social work on the East Campus at [redacted] or the division of Case Management on the West Campus at [redacted]

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Massachusetts Health Care Proxy:
Expressing your wishes regarding your care and treatment

information

Your voice in health care decisions

When health care decisions are made, the patient's voice and opinion are of utmost importance. In fact, expressing your personal health care wishes and taking part in decisions related to your health care are part of your basic rights as a patient. However, situations – such as accidents or severe illnesses – sometimes arise that can prevent you from participating in decisions about your care. Therefore, while you are able, it is important for you to decide what is important to you about your care in case you ever become too sick to speak for yourself. It is equally important that you communicate your wishes to your family and friends and your health care providers.

Beth Israel Deaconess Medical Center encourages all patients to prepare a document called a Health Care Proxy form. This document will identify the person you have chosen to express your wishes regarding your health care in the event that you become unable to speak for yourself.

Some of the common questions about the Health Care Proxy appear below. Please read through this information and discuss it with your family and those who are closest to you, as well as with your physician, nurse, social worker, or chaplain. Please ask one of our staff if there is anything you do not understand.

For your convenience, a Health Care Proxy form is included with this brochure.

What is a Health Care Proxy?

A Health Care Proxy is a legal document that names the person you have chosen to express your health care wishes. This "proxy" – also called your health care "agent" – is recognized under Massachusetts law as the person who can speak for you regarding health care decisions. If your doctor makes a determination that you are no longer able to communicate your wishes about your care, your health care providers will ask your health care agent to be your voice. Often, this person is a family member or close friend. Ideally, it is someone who knows your personal wishes, values, and beliefs well. It is someone you can trust to make the same health care decisions *you* would make if you could. Choosing this person before he or she is needed can help you feel confident that you will always be treated according to your own wishes and values.

Do I need a proxy if I already have a living will?

Yes. Only a Health Care Proxy is formally recognized by Massachusetts law. Generally, a living will is a document that details a person's preferences about the use of life-sustaining medical treatments in the event of terminal illness. Yet, when writing a living will, it is very difficult to anticipate all of the circumstances under which complex medical decisions may need to be made. When serious illness occurs, questions about your wishes may still arise. A living will does not identify an individual with whom a doctor can discuss these important issues of care.

In contrast, a Health Care Proxy is not limited to situations of terminal illness. It enables you

to designate someone who can communicate your values and preferences, and who will make sure that your wishes about health care are carried out.

Should the Health Care Proxy only be completed by people who are sick?

No. All adults– people who are perfectly healthy as well as people who are sick – are encouraged to prepare a Health Care Proxy.

How do I obtain a Health Care Proxy?

A Health Care Proxy form is included with this brochure. If you need another copy, your physician, nurse, social worker, or chaplain can get you one. The form becomes valid after it is signed by you and witnessed by two adults. The person you are naming as your agent **cannot** be one of the witnesses.

When does my Health Care Proxy take effect?

Your proxy takes effect only after your doctor determines that you are unable to make or communicate your wishes about your health care. Your doctor will make this decision according to accepted standards of medical practice. This decision will be recorded in your medical record. It will include your doctor's opinion as to why you cannot speak for yourself and whether or not you are expected to recover. At this point, your agent begins to speak for you.

If your doctor determines that your ability to speak for yourself has returned, your health care agent no longer speaks for you.

What happens if a member of my family disagrees with my agent's decisions?

In general, your doctor will follow the direction of your agent. If a family member either disagrees with the care plans that are being made, or believes that your agent is not carrying out your wishes, the family member may bring action in court to challenge your agent's decisions.

Will my health care agent have any legal authority beyond medical decisions, such as those concerning my financial affairs?

No. The Health Care Proxy applies only to medical decisions.

Do I need another form if I go to another hospital?

If you go to another hospital, you will probably be asked if you have a completed Health Care Proxy. If you have a copy of your current Health Care Proxy with you, you may use it at another hospital. If you don't have a copy available, or if you wish to make changes in your Health Care Proxy, you may choose to fill out a new form.

Whom should I choose as my agent?

Your agent should be a person who is close to you and who is willing and able to respect your values and wishes. In selecting your agent, you may wish to consider the following questions:

- Do you think the agent would be able to make the same decisions you would make

regarding your health care?

- Is your agent comfortable with the idea of speaking for you?
- Are you able to discuss serious issues with your agent?

Your agent will have the right to receive medical information about you that he or she needs to make informed decisions about your care. This includes confidential medical information. He or she must make decisions that follow your wishes, including your religious and moral beliefs. If these are unknown, your agent must make decisions that he or she believes are in your best interest.

May I name more than one person as my agent?

You may name one individual as your primary agent and a second individual as your alternate. The alternate will serve as your agent if your primary agent is unable or unwilling to serve. You may identify more individuals in the order they might serve, recognizing that they will become your agent only if the person named before is unable or unwilling to do so.

May I name my physician as my agent?

It is not recommended that you choose one of your health care providers as your agent. This is because it may place the provider in a difficult position as he/she tries to act as both your health care provider and your agent. Physicians often feel they must decline this request when patients ask them to serve as health care agents.

Your physician is legally permitted to serve as your agent **only if** you name him/her as such before being admitted to a hospital (or other health care facility) where your physician is employed, and providing he/she agrees to be your agent. This rule applies also for other health care providers or hospital/nursing home employees, such as nurses or facility administrators. Once you are admitted to a health care facility, you cannot name one of its employees as your agent (unless the employee is a relative). If your physician is your agent, he/she cannot be the one to determine that you are unable to make your own health care decisions.

What should I discuss with my agent?

Once you have told someone that you would like to designate him or her to be your health care agent, you should have thorough conversations about your values and preferences. These conversations are important so that your proxy can speak with knowledge on your behalf. They will help to make sure your proxy will be comfortable making decisions consistent with your values. Some questions to help guide your discussions include:

- What are the things that make your life most worth living?
  - Interacting with other people?
  - Living independently?
  - Being physically active?
  - Being mentally alert?
  - Being at home? Other things?Are there any conditions under which you would not want your doctor to prolong your life?
- Are there specific religious or ethical perspectives that should be considered in planning your care?
- What are your thoughts and feelings regarding organ donation?
- If your agent is called upon to speak for you, what family members or friends do you want the agent to be in touch with? Is there anyone you do **not** want the agent to communicate with about your care?

information

What should I do once I have completed the Health Care Proxy?

It is always advisable to discuss your wishes and preferences with your family and those closest to you – including those who have **not** been named as your agent. Let them know that you have identified a health care agent(s) and what this means.

Once you have completed the Health Care Proxy form, keep the original and give copies to your agent(s) and to your physician for inclusion in your medical record. If possible, bring a copy with you each time you are admitted to the hospital.

Also, talk to your doctor. Continue to ask questions that you may have regarding certain treatment issues and concerns. Your doctor should also know about the discussions you have had with your agent(s) and how these individuals may be reached.

Do I have to choose a health care agent in order to be treated at Beth Israel Deaconess Medical Center?

No. You do not have to complete a Health Care Proxy to receive care at Beth Israel Deaconess Medical Center.

May I revoke a Health Care Proxy?

You may revoke your proxy at any time. A proxy is automatically revoked in any of the following circumstances:

- You fill out another Health Care Proxy at a later date
- You legally separate from or divorce your spouse (and your spouse was named as your agent)
- You notify your agent, doctor, or other health care provider, verbally or in writing, that you want to revoke the proxy
- You clearly indicate in another way that you want to revoke your proxy

Whom can I talk with if I have questions?

If you have any questions please talk with your physician, nurse, social worker, or chaplain. If you need additional information, call the Department of Social Work [redacted] Pastoral Care [redacted] or the Ethics Support Service [redacted]

*This material was prepared by clinicians from the departments of social work, pastoral care, medicine, and nursing Beth Israel Deaconess Medical Center. ©2002 Beth Israel Deaconess Medical Center. **MC0874** 7/02*

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MASSACHUSETTS HEALTH CARE PROXY

Information, Instructions, and Form

What does the Health Care Proxy Law allow?

The **Health Care Proxy** is a simple legal document that allows you to name someone you know and trust to make health care decisions for you if, for any reason and at any time, you become unable to make or communicate those decisions. It is an important document, however, because it concerns not only the choices you make about your health care, but also the relationships you have with your physician, family, and others who may be involved with your care. Read this and follow the instructions to ensure that your wishes are honored.

Under the Health Care Proxy Law (Massachusetts General Laws, Chapter 201D), any competent adult 18 years of age or over may use this form to appoint a Health Care Agent. You (known as the "Principal") can appoint any adult EXCEPT the administrator, operator, or employee of a health care facility such as a hospital or nursing home where you are a patient or resident UNLESS that person is also related to you by blood, marriage, or adoption. Whether or not you live in Massachusetts, you can use this form if you receive your health care in Massachusetts.

What can my Agent do?

Your Agent will make decisions about your health care *only* when you are, for some reason, unable to do that yourself. This means that your Agent can act for you if you are temporarily unconscious, in a coma, or have some other condition in which you cannot make or communicate health care decisions. Your Agent cannot act for you until your doctor determines, in writing, that you lack the ability to make health care decisions. Your doctor will tell you of this if there is any sign that you would understand it.

Acting with your authority, your Agent can make any health care decision that you could, if you were able. If you give your Agent full authority to act for you, he or she can consent to or refuse any medical treatment, including treatment that could keep you alive.

Your Agent will make decisions for you only after talking with your doctor or health care provider, and after fully considering all the options regarding diagnosis, prognosis, and treatment of your illness or condition. Your Agent has the legal right to get any information, including confidential medical information, necessary to make informed decisions for you.

Your Agent will make health care decisions for you according to your wishes or according to his/her assessment of your wishes, including your religious or moral beliefs. You may wish to talk first with your doctor, religious advisor, or other people before giving instructions to your Agent. It is very important that you talk with your Agent so that he or she knows what is important to you. If your Agent does not know what your wishes would be in a particular situation, your Agent will decide based on what he or she thinks would be in your best interests. After your doctor has determined that you lack the ability to make health care decisions, if you still object to any decision made by your Agent, your own decisions will be honored unless a Court determines that you lack capacity to make health care decisions.

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Your Agent's decisions will have the same authority as yours would, if you were able, and will be honored over those of any other person, except for any limitation you yourself made, or except for a Court Order specifically overriding the Proxy.

How do I fill out the form?

1 At the top of the form, print your full name and address. Print the name, address, and phone number of the person you choose as your Health Care Agent. (**Optional:** If you think your Agent might not be available at any future time, you may name a second person as an Alternate Agent. Your Alternate Agent will be called if your Agent is unwilling or unable to serve.)

2 Setting limits on your Agent's authority might make it difficult for your Agent to act for you in an unexpected situation. If you want your Agent to have full authority to act for you, leave the limitations space blank. However, if you want to limit the kinds of decisions you would want your Agent or Alternate Agent to make for you, include them in the blank.

3 **BEFORE** you sign, be sure you have two adults present who will be witnesses and watch you sign the document. The only people who cannot serve as witnesses are your Agent and Alternate Agent. Then sign the document yourself. (Or, if you are physically unable, have someone other than either witness sign your name at your direction. The person who signs your name for you should put his/her own name and address in the spaces provided.)

4 Have your witnesses fill in the date, sign their names and print their names and addresses.

5 **OPTIONAL:** On the back of the form are statements to be signed by your Agent and any Alternate Agent. This is not required by law, but is recommended to ensure that you have talked with the person or persons who may have to make important decisions about your care and that each of them realizes the importance of the task they may have to do.

Who should have the original and copies?

After you have filled in the form, remove this information page and make at least four photocopies of the form. Keep the original yourself where it can be found easily (*not* in your safe deposit box). Give copies to your doctor and/or health plan to put into your medical record. Give copies to your Agent and any Alternate Agent. You can give additional copies to family members, your clergy and/or lawyer, and other people who may be involved in your health care decisionmaking.

How can I revoke or cancel the document?

Your Health Care Proxy is revoked when any of the following four things happens:

1. You sign another Health Care Proxy later on.
2. You legally separate from or divorce your spouse who is named in the Proxy as your Agent.
3. You notify your Agent, your doctor, or other health care provider, orally or in writing, that you want to revoke your Health Care Proxy.
4. You do anything else that clearly shows you want to revoke the Proxy, for example, tearing up or destroying the Proxy, crossing it out, telling other people, etc.

AFTER FILLING IN THE FORM, REMOVE THIS INSTRUCTION PAGE. BE SURE TO TALK WITH YOUR AGENT.

YOUR BIRTH DATE (m/d/y)
____/____/____

MASSACHUSETTS HEALTH CARE PROXY

1 I, _____, residing at
(Principal: PRINT your name)

_____
(Street) (City/town) (State)

appoint as my **Health Care Agent**: _____
(Name of person you choose as Agent)

of _____
(Street) (City/town) (State)

Agent's tel (h) _____ (w) _____ E-mail _____

(**OPTIONAL**: If my agent is unwilling or unable to serve, then I appoint as my **Alternate Agent**:

_____
(Name of person you choose as Agent)

of _____
(Street) (City/town) (State) (Phone)

2 My Agent shall have the authority to make all health care decisions for me, including decisions about life-sustaining treatment, subject to any limitations I state below, if I am unable to make health care decisions myself. My Agent's authority becomes effective if my attending physician determines in writing that I lack the capacity to make or to communicate health care decisions. My Agent is then to have the same authority to make health care decisions as I would if I had the capacity to make them **EXCEPT** (here list the limitations, *if any*, you wish to place on your Agent's authority):

I direct my Agent to make health care decisions based on my Agent's assessment of my personal wishes. If my personal wishes are unknown, my Agent is to make health care decisions based on my Agent's assessment of my best interests. Photocopies of this Health Care Proxy shall have the same force and effect as the original and may be given to other health care providers.

3 **Signed**: _____

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

_____ _____
(Name) (Street)

_____
(City/town) (State)

4 **WITNESS STATEMENT:** We, the undersigned, each witnessed the signing of this Health Care Proxy by the Principal or at the direction of the Principal and state that the Principal appears to be at least 18 years of age, of sound mind and under no constraint or undue influence. Neither of us is named as the Health Care Agent or Alternate Agent in this document.
In our presence, on this day ____/____/____ (mo / day / yr).

Witness #1 _____ Witness #2 _____
(Signature) (Signature)

Name (print) _____ Name (print) _____

Address _____ Address _____

_____ _____

5

Statements of Health Care Agent and Alternate Agent (OPTIONAL)

Health Care Agent: I have been named by the Principal as the Principal's **Health Care Agent** by this Health Care Proxy. I have read this document carefully, and have personally discussed with the Principal his/her health care wishes at a time of possible incapacity. I know the Principal and accept this appointment freely. I am not an operator, administrator or employee of a hospital, clinic, nursing home, rest home, Soldiers Home or other health facility where the Principal is presently a patient or resident or has applied for admission. But if I am a person so described, I am also related to the Principal by blood, marriage, or adoption. If called upon and to the best of my ability, I will try to carry out the Principal's wishes.

(Signature of **Health Care Agent**)_____

Alternate Agent: I have been named by the Principal as the Principal's **Alternate Agent** by this Health Care Proxy. I have read this document carefully, and have personally discussed with the Principal his/her health care wishes at a time of possible incapacity. I know the Principal and accept this appointment freely. I am not an operator, administrator or employee of a hospital, clinic, nursing home, rest home, Soldiers Home or other health facility where the Principal is presently a patient or resident or has applied for admission. But if I am a person so described, I am also related to the Principal by blood, marriage, or adoption. If called upon and to the best of my ability, I will try to carry out the Principal's wishes.

(Signature of **Alternate Agent**)_____

* * * * *

Model Health Care Proxy form developed by a Task Force of the following organizations:

Boston University Schools of Medicine and Public Health:
Law, Medicine, and Ethics Program
Deaconess ElderCare Program
Hospice Federation of Massachusetts
Massachusetts Bar Association
Massachusetts Department of Public Health
Massachusetts Executive Office of Elder Affairs
Massachusetts Federation of Nursing Homes
Massachusetts Health Decisions
Massachusetts Hospital Association
Massachusetts Medical Society
Massachusetts Nurses Association
Medical Center of Central Massachusetts
Suffolk University Law School:
Elder Law Clinic
University of Massachusetts at Boston:
The Gerontology Institute
Visiting Nurse Associations of Massachusetts

Providers: For prices and information on quantity orders or for non-English language licensing, please contact
Massachusetts Health Decisions, PO Box 417, Sharon, MA 02067

rev. 6/02

NOT for Distribution

INTRODUCTION TO YOUR MASSACHUSETTS ADVANCE DIRECTIVE

This packet contains two legal documents that protect your right to refuse medical treatment you do not want, or to request treatment you do want, in the event you lose the ability to make decisions yourself:

1. The **Massachusetts Health Care Proxy** lets you name someone to make decisions about your medical care—including decisions about life support—if you can no longer speak for yourself. The Health Care Proxy is especially useful because it appoints someone to speak for you any time you are unable to make your own medical decisions, not only at the end of life. Your Health Care Proxy becomes effective when your doctor determines in writing that you are unable to make or communicate health care decisions. Your doctor must also record the cause and nature of your incapacity as well as its extent and probable duration.

If you lack decision-making capacity because of mental illness or developmental disability, your doctor must have, or consult with a health care professional who has, specialized training or experience in diagnosing or treating mental illness or developmental disabilities.

2. Massachusetts does not have a statute governing the use of living wills. However, you have a constitutional right to state your wishes about medical care in the event that you develop an irreversible condition that prevents you from making your own medical decisions. The **Partnership for Caring Living Will** has been created to protect this right. The Living Will becomes effective if you become terminally ill, permanently unconscious or minimally conscious due to brain damage and will never regain the ability to make decisions.

Partnership for Caring recommends that you complete both of these documents to best ensure that you receive the medical care you want when you can no longer speak for yourself.

Note: These documents will be legally binding only if the person completing them is a competent adult (at least 18 years old).

Whom should I appoint as my health care agent?

Your agent is the person you appoint to make decisions about your medical care if you become unable to make those decisions yourself. Your agent may be a family member or a close friend whom you trust to make serious decisions. The person you name as your agent should clearly understand your wishes and be willing to accept the responsibility of making medical decisions for you. (An agent may also be called an "attorney-in-fact" or "proxy.") The person you appoint as your agent cannot be an operator, administrator or employee of a treating health care facility, unless he or she is related to you by blood, marriage or adoption.

You can appoint a second person as your alternate agent. The alternate will step in if the first person you name as agent is unable, unwilling or unavailable to act for you.

How do I make my Massachusetts Health Care Proxy legal?

The law requires that you sign your document, or direct another to sign it, in the presence of two adult witnesses, who must also sign the document to show that they believe you to be at least 18 years of age, of sound mind and under no constraint or undue influence. *The person you appoint as your agent cannot serve as a witness.*

Note: You do not need to notarize your Massachusetts Health Care Proxy

Should I add personal instructions to my Massachusetts Health Care Proxy?

Partnership for Caring advises you not to add instructions to this document. One of the strongest reasons for naming an agent is to have someone who can respond flexibly as your medical situation changes and deal with situations that you did not foresee. If you add instructions to this document, you might unintentionally restrict your agent's power to act in your best interest.

Instead, we urge you to talk with your agent about your future medical care and describe what you consider to be an acceptable "quality of life." If you want to record your wishes about spe-

COMPLETING YOUR MASSACHUSETTS HEALTH CARE PROXY (CONTINUED)

cific treatments or conditions, you should use your Partnership for Caring Living Will.

What if I change my mind?

You may revoke your Health Care Proxy at any time by:

- notifying your agent or doctor orally or in writing,
- taking any action, such as tearing up or destroying the document, which indicates your intent to revoke your Proxy, or
- executing another Health Care Proxy.

If you have appointed your spouse as your agent, and your marriage ends, your agent's power is automatically revoked.

Do I need to have my Living Will witnessed?

Because Massachusetts does not have a statute governing the use of living wills, there are no specific requirements to make your Living Will legally binding. However, Partnership for Caring recommends that you sign your Living Will in the presence of two adult witnesses.

Your witnesses should **not** be:

- related to you by blood or marriage,
- beneficiaries of your estate,
- your health care provider or an employee of your health care provider, **or**
- your health care agent or alternate.

Note: You do not need to notarize your Living Will.

Can I add personal instructions to my Living Will?

Yes. You can add personal instructions in the part of the document called "Other directions." For example, if there are any specific forms of treatment that you wish to refuse that are not already listed on the document, you may list them here. Also, you can add instructions such as, "I do not want to be placed in a nursing home," or "I want to die at home."

If you have appointed a health care agent, it is a good idea to write a statement such as, "Any questions about how to interpret or when to apply my Living Will are to be decided by my agent."

It is important to learn about the kinds of life-sustaining treatment you might receive. Consult your doctor or order the Partnership for Caring booklet, "Advance Directives and End-of-Life Decisions."

What if I change my mind?

You may revoke your Living Will at any time by:

- executing a new Living Will,
- tearing, burning, or otherwise destroying your document, or
- notifying your doctor orally or in writing of your intent to revoke your document.

AFTER YOU HAVE COMPLETED YOUR DOCUMENTS

1. Your Massachusetts Health Care Proxy and Partnership for Caring Living Will are important legal documents. Keep the original signed documents in a secure but accessible place. Do not put the original documents in a safe deposit box or any other security box that would keep others from having access to them.

2. Give photocopies of the signed originals to your agent and alternate agent, doctor(s), family, close friends, clergy and anyone else who might become involved in your health care. If you enter a nursing home or hospital, have photocopies of your documents placed in your medical records.

3. Be sure to talk to your agent and alternate, doctor(s), clergy, and family and friends about your wishes concerning medical treatment. Discuss your wishes with them often, particularly if your medical condition changes.

4. If you want to make changes to your documents after they have been signed and witnessed, you must complete new documents.

5. Remember, you can always revoke your Massachusetts Health Care Proxy and Partnership for Caring Living Will.

6. Be aware that your Massachusetts documents will not be effective in the event of a medical emergency. Ambulance personnel are required to provide cardiopulmonary resuscitation (CPR) unless they are given a separate order that states otherwise. These orders, commonly called "nonhospital do-not-resuscitate orders," are designed for people whose poor health gives them little chance of benefiting from CPR. These orders must be signed by your physician and instruct ambulance personnel not to attempt CPR if your heart or breathing should stop. Currently not all states have laws authorizing nonhospital do-not-resuscitate orders. Partnership for Caring does not distribute these forms. We suggest you speak to your physician.

If you would like more information about this topic contac.t Partnership for Caring or consult the Partnership for Caring book - let "Cardiopulmonary Resuscitation, Do-Not-Resuscitate Orders and End-Of-Life Decisions."

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INSTRUCTIONS

PRINT YOUR NAME

PRINT THE NAME, HOME ADDRESS AND TELEPHONE NUMBER OF YOUR AGENT

(OPTIONAL)

PRINT THE NAME, HOME ADDRESS AND TELEPHONE NUMBER OF YOUR ALTERNATE AGENT

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MASSACHUSETTS HEALTH CARE PROXY

(1) I, _____, hereby appoint
(name)

_____

_____
(name, home address and telephone number of agent)

as my health care agent to make any and all health care decisions for me, except to the extent that I state otherwise below.

This Health Care Proxy shall take effect in the event I become unable to make or communicate my own health care decisions.

(2) Name of alternate agent if the person I appoint above is unable, unwilling or unavailable to act as my health care agent (optional):

_____

_____

_____
(name, home address and telephone number of alternate agent)

(3) I direct my agent to make health care decisions in accord with my wishes and limitations as as may be stated below, or as he or she otherwise knows. If my wishes are unknown, I direct my agent to make health care decisions in accord with what he or she determines to be my best interests.

ADD PERSONAL INSTRUCTIONS (IF ANY)

(4) Other directions (optional):

SIGN AND DATE THE DOCUMENT AND PRINT YOUR ADDRESS

(5) Signature: _____ Date: _____

Address: _____

WITNESSING PROCEDURE

YOUR WITNESSES MUST SIGN AND PRINT THEIR ADDRESSES

Statement by Witnesses

I declare that the person who signed this document appears to be at least 18 years of age, of sound mind, and under no constraint or undue influence. He or she signed (or asked another to sign for him or her) this document in my presence. I am not the person appointed as agent or alternate agent by this document.

Witness 1: _____

Address: _____

_____

Date: _____

Witness 2: _____

Address: _____

_____

Date: _____

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1620 Eye Street, NW Suite 202 Washington, DC 20006 800-989-9455

INSTRUCTIONS

PRINT YOUR NAME

CROSS OUT ANY STATEMENTS THAT DO NOT REFLECT YOUR WISHES

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PARTNERSHIP FOR CARING
LIVING WILL

I, _____,

being of sound mind, make this statement as a directive to be followed if I become permanently unable to participate in decisions regarding my medical care. These instructions reflect my firm and settled commitment to decline medical treatment under the circumstances indicated below:

I direct my attending physician to withhold or withdraw treatment that merely prolongs my dying, if I should be in an **incurable or irreversible mental or physical condition with no reasonable expectation of recovery**, including but not limited to: (a) **a terminal condition**; (b) **a permanently unconscious condition**; or (c) **a minimally conscious condition in which I am permanently unable to make decisions or express my wishes**.

I direct that treatment be limited to measures to keep me comfortable and to relieve pain, including any pain that might occur by withholding or withdrawing treatment.

While I understand that I am not legally required to be specific about future treatments, **if I am in the condition(s) described above I feel especially strongly about the following forms of treatment**:

I do not want cardiac resuscitation.
I do not want mechanical respiration.
I do not want tube feeding.
I do not want antibiotics.

However, I **do want** maximum pain relief, even if it may hasten my death.

ADD PERSONAL INSTRUCTIONS (IF ANY)

Other directions (insert personal instructions):

These directions express my legal right to refuse treatment under federal and state law. I intend my instructions to be carried out, unless I have revoked them in a new writing or by clearly indicating that I have changed my mind.

SIGN AND DATE THE DOCUMENT AND PRINT YOUR ADDRESS

Signed: _____ Date: _____

Address: _____

_____

WITNESSING PROCEDURE

TWO WITNESSES MUST SIGN AND PRINT THEIR ADDRESSES

I declare that the person who signed this document appeared to execute the living will willingly and free from duress. He or she signed (or asked another to sign for him or her) this document in my presence.

Witness: _____

Address: _____

_____

Witness: _____

Address: _____

_____

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ADVANCE DIRECTIVES

Advance Directive is a general term that applies to two types of legal documents. The two basic types of advance directives, which may be called by different names, are:

Living Wills
Medical Powers of Attorney

These documents let you give instructions about the medical care you want to receive in the event that you become unable to speak for yourself due to serious illness or incapacity. (See Talking About Your Choices.) A living will provides specific instructions. A medical power of attorney names a person that you trust to make decisions on your behalf. (See Appointing A Health Care Agent and Being a Health Care Agent.) Each state treats these documents somewhat differently. (For more information see Frequently Asked Questions.)

You can obtain state specific documents at this web site by clicking on Download State Specific Documents.

You can obtain a printed set of documents for $10.00
(plus tax where applicable: $.83 for New York State residents and $.58 for Washington, DC residents).

Call 1-800-989-9455 to order by credit card, or send a check or money order to:
Partnership for Caring Publications
1620 Eye Street, NW, Suite 202
Washington, DC 20006

Be Sure To Specify Your State

You can also use the order form on this site.

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Questions or comments regarding this web site may be directed to pfc@partnershipforcaring.org

FREQUENTLY ASKED QUESTIONS

Click on one of the 12 questions below for answers

1. WHAT ARE ADVANCE DIRECTIVES?

"Advance Directives" is a general term that refers to your oral and written instructions about your future medical care, in the event you become unable to speak for yourself. Each state regulates the use of advance directives differently. There are two types of advance directives: a living will and a medical power of attorney.

2. WHAT IS A LIVING WILL?

A living will is a type of advance directive in which you put in writing your wishes about medical treatment should you be unable to communicate at the end of life. Your state law may define when the living will goes into effect, and may limit the treatments to which the living will applies. States name this document differently: for example it might be called a directive to physician, declaration or medical directive. Your right to accept or refuse treatment is protected by constitutional and common law as well as state law.

3. WHAT IS A MEDICAL POWER OF ATTORNEY?

A medical power of attorney is a document that lets you appoint someone you trust to make decisions about your medical care if you cannot make those decisions yourself. This type of advance directive also may be called a health care proxy, appointment of health care agent or a

durable power of attorney for health care. The person you appoint through a medical power of attorney normally is authorized to speak for you any time you are unable to make your own medical decisions, not only at the end of life.

4. WHY DO I NEED ADVANCE DIRECTIVES?

Advance directives give you a voice in decisions about your medical care when you are unconscious or too ill to communicate. As long as you are able to express your own decisions your advance directives will not be used and you can accept or refuse any medical treatment. But if you become seriously ill, you may lose the ability to participate in decisions about your own treatment.

5. WHO SHOULD PREPARE AN ADVANCE DIRECTIVE?

These are not just for the elderly. A serious accident could happen to anyone so every adult over the age of 18 should prepare an advance directive. Several landmark legal cases dealing with the rights of individuals to refuse unwanted medical treatments have involved young people under the age of 30 including those dealing with [redacted] and [redacted] The case involving [redacted] was heard by the United States Supreme Court.

6. DO I NEED BOTH A LIVING WILL AND A MEDICAL POWER OF ATTORNEY?

Yes, you can best protect your treatment wishes by having a living will and appointing a health care agent. Each offers something the other does not. The appointment of an agent ensures a more flexible form of decision making, since the agent can respond to unanticipated changes and base decisions not only on written or verbal expressions of treatment wishes, but also on general knowledge of the patient. None-the-less, the living will can be very useful for several reasons. If the agent becomes unavailable or unwilling to serve, the living will can serve to guide medical decision making. The living will can reassure the agent that he or she is following the wishes of the principal and ease the burden of decision making. If the agent's decisions are challenged, the living will can provide evidence that the agent is acting in good faith. Finally, not everyone has someone to serve as a health care agent.

7. WHERE DO I GET THESE DOCUMENTS?

Your local hospital or long-term care facility may distribute them. Some physicians make them available to their patients. You can also get them for a nominal charge through Partnership for Caring by calling [redacted] You can download them at no charge from this site.

8. WHAT DO I DO WITH MY DIRECTIVES AFTER THEY ARE SIGNED?

Make several photocopies of the completed documents. Keep the original in a safe but accessible place (not a safe deposit box). Give the copies to your agent, alternate agent, your doctor and anyone else who might be involved with your health care.

9. WILL MY ADVANCE DIRECTIVES BE HONORED IN ANOTHER STATE?

Many states' laws explicitly honor out of state directives as long as they do not conflict with that state's own law and other state statutes don't address the issue. In fact, a state would probably have to honor an advance directive that clearly expressed your treatment wishes, because your constitutional and common-law rights to accept or refuse treatment may be even broader than your rights under a specific state law. However, if you spend significant time in more than one state, we recommend that you complete the advance directives for all of the states involved. It will be easier to have your advance directives honored if they are the ones with which the medical facility is familiar.

10. WILL MY ADVANCE DIRECTIVES BE HONORED IN AN EMERGENCY?
No.Generally, advance directives such as living wills and medical powers of attorney are not effective in a medical emergency. There is no time in an emergency either to consult the directions in an advance directive or determine a person's underlying medical condition. Once the person comes under the care of a physician, the contents of a living will can be evaluated and the instructions of a health care agent determined in light of that person's overall prognosis.

11. WHAT HAPPENS IF MY DOCTOR (OR FAMILY) WON'T HONOR MY WISHES?
There is no simple answer to this question. For this reason it is essential that you have honest and open discussions with your agent, family members and physician about their willingness to support and if necessary advocate to see that your wishes are carried out. If you find they are not willing to support your choices, you may wish to consider appointing a non-family member who will honor your wishes or change your physician before a conflict arises. If you wish to talk about this further call Partnership for Caring at [redacted]

12. IF I SIGN ADVANCE DIRECTIVES, WILL DOCTORS STILL TAKE CARE OF ME IF I'M SICK?
Yes, a doctor or hospital cannot condition treatment on whether or not you have an advance directive. Even if you decline certain kinds of treatment, you may need care to ensure that you are kept comfortable and free of pain. For additional information you can order Partnership for Caring's Question and Answer booklet Advance Directives and End-of-Life Decisions

Back to the top

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Questions or comments regarding this web site may be directed to [redacted]

FU463 → FU484

Falls and Fractures

1. Falls

FU463 Ask the question, *Since your last exam have you accidentally fallen and hit the floor or ground?*

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

FU464 If yes, ask *How many times did you fall in the past year?*

NOTE: Falls during sports activities are not coded.

2. Fractures

FU465

Ask the participant, *Since your last exam or medical history update have you broken any bones?*

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

a. List the year the participant broke a bone in the space corresponding to fracture site.
b. All fractures not listed are to be handwritten next to *other*.
c. If there were no broken bones, skip the rest of the section.
d. If a broken bone was noted in one area, all the other boxes must be completed (**0** = No).

Note: If a participant has had a fracture since the last encounter, email [redacted] at [redacted] (Bone Study).

FU516 → FU548

Observed Physical Performance Measures

A. Overview

An objective performance measure of physical functioning is an assessment instrument in which an individual is asked to perform a specific task and is evaluated in an objective, standardized manner using predetermined criteria, which may include counting of repetitions or timing of the activity as appropriate. Two theoretical models of the pathway from disease to disability have been developed. The first comes from the World Health Organization and goes from disease to impairment to disability, to handicapped. The second, which is being used more now by geriatricians and aging researchers, progresses from disease, to impairment, to functional limitations, to disability.

Definitions

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

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

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

B. Methods

During all tests, participant safety is paramount. Participants who do not feel safe or who are unable to perform a test should not be pressed. All procedures should be clearly demonstrated to the participant prior to performing any test and the participant should be queried to ensure that they understand the instructions. If it is obvious that the participant has not understood the directions, reread the standard instructions. You will be demonstrating each maneuver. Someone who may not completely understand the verbal instructions may still be able to perform the test following the demonstration.

C. Equipment:

1. Data sheets
2. Pen
3. Stopwatch
4. 1 Armless straight back chair measuring approximately 18" high from floor to top of seat.
5. 5 Meter Chain
6. 1" Masking tape
7. JAMAR Dynamometer
8. Straight back chair with arm rests

FU516-FU548

D. A note on encouragement:

If a participant expresses doubt as to whether he or she can perform the task, ask the participant whether they would like to try. If they say yes, proceed with the task but if they say no, honor the participant's choice to decline the testing.

E. Introductory script:

We are going to try to do different physical activities together. I will ask you to stand in different positions for me. I will ask you to walk for me and then I will ask you to stand up from a chair.

I will first explain what I would like you to do, then I will demonstrate it for you, and then I will ask you to try it for me.

F. Performance Measures:

1. Hand Grip Strength Test
2. Stands
3. Repeated Chair Stands
4. Measured Walks

FU516 → FU523

JAMAR Hand Grip Strength Test:

1. Introductory script: ***This instrument will measure your grip strength. The instrument is a little heavy, so be careful. When I tell you, I want you to squeeze the instrument as hard as you can. Do not expect the handle to move very much.***

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

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

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

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

6. Take back JAMAR, hold at eye level at about a foot from your eyes and record reading on the kilogram scale. If directly in the middle of the scale then the reading is the odd number between the two even hash marks; otherwise record as the closest hash mark.

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

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

Fu524 → Fu532

Stands:

The tests of balance provide an assessment of the participant's ability to hold three basic standing positions with the eyes open. These positions are side-by-side, semi-tandem, and full tandem stand (or heel-to-toe) and are performed in this order. Participants taking this test must be able to stand unassisted without using a cane or a walker. Don't assume that a participant who arrives for testing using a cane or walker can't stand unassisted. Ask them if they can stand without the device and are willing to try the test. If they say yes, you can assist them to assume the correct position for the testing.

The participant will hold each standing position for ten seconds.

Side by Side: Feet together
Semi-Tandem: Heel of one foot lines up with the big toe of the other foot
Tandem: Heel of one foot touching the toes of the other foot

While performing stands, the participant should be wearing comfortable shoes, with low heels. No bare feet or slippers. The participant must be able to stand unaided. You may assist participant with getting up from a chair.

1. Side by Side stand:

Fu524→Fu526 *First, I would like you to stand with your feet together, side by side, for ten seconds. Please watch first while I demonstrate. You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I say "stop".*

Are you ready? Begin.

You may help the participant into the position. Allow them to hold onto your arms to obtain their balance. If they are holding on, say, *When you are ready, let go of my arms.* Begin timing the ten seconds when he or she lets go.

When the subject steps out of position, grasps your arm, or when the ten seconds have elapsed, stop timing and say, *stop*. If the participant steps out of position, the stopwatch is stopped when their foot is replanted on the floor. Record results on data sheet.

If the participant is unable to hold the side by side position for ten seconds, skip the next two stands.

2. Semi-tandem stand:

Fu527→Fu529 *Next, I would like you to stand with the heel of one foot touching the big toe of the other foot for ten seconds. You may put either foot in front, whichever is more comfortable for you. Please watch while I demonstrate. You may use your arms, bend your knees or*

move your body to maintain your balance, but try not to move your feet. Try to hold this position until I say "stop".

Are you ready? Begin.

<u>If the participant is unable to hold the semi-tandem stand for ten seconds, skip the tandem stand.</u>

3. <u>Tandem</u>:

Fu530 → Fu532

Next, I want you to try to stand with the heel of one foot in front of and touching the toes of the other foot for ten seconds. You may put either foot in front, whichever is more comfortable for you. Please watch while I demonstrate. You may use your arms, bend your knees or move your body to maintain your balance but try not to move your feet. Try to hold this position until I say "stop".

Are you ready? Begin.

The following questions should be answered for each stand:

Was this test completed? (Held for 10 seconds)

<u>Coding</u>
0 = No
1 = Yes
8 = N/A
9 = Unknown

If test was not attempted or completed, why not?

<u>Coding</u>
1 = Physical limitation
2 = Refused
3 = Other (write in)
9 = Unknown

Number of seconds held if less than 10 seconds.

FU534 -> FU538a

Repeated Chair Stands:

The participant will attempt to stand up once from his chair without using his or her arms. This is not timed. If he or she is able to do this, then proceed to the timed five consecutive chair stands.

If participant feels it is unsafe, skip the chair stands

Do you think it is safe to try to stand up from a chair without using your arms?

The next tests measure the strength in your legs. First, I will ask you to fold your arms across your chest and sit so that your feet are flat on the floor. Then I will ask you to stand up without using your arms.

Please watch while I demonstrate.

Please fold your arms across your chest and begin when I say, "Ready, stand."

Stand in front of the participant before he or she begins. Be prepared to supply physical support if the participant's safety requires it, but do not stand so close as to impede the task.

If he or she cannot get up from his chair the first time without using their arms, ask him to try standing up using his arms. Score this and skip the repeated stands.

Do you think it is safe to try and stand up from a chair five times without using your arms?

If participant does not feel that it would be safe, abort the five chair stands and record on data sheet.

I will ask you to stand up straight, as quickly as you can, five times without stopping in between. After you stand up each time, sit down and then stand up again. Keep your arms folded across your chest. I will be timing you.

When you have finished the last stand, please sit down and hold out your left arm, with the palm facing up, so that I can take your pulse.

Please watch while I demonstrate.

Please fold your arms across your chest and begin when I say, "Ready, stand".

Start timing on the word "Stand".

Count aloud after the participant reaches the top of each stand.

If the participant appears to be fatigued before completing all five stands, ask if they can continue. Only if they say "no" should the examiner stop timing and stop the procedure.

If the participant did not use his or her hands during the initial chair stand, but begins to use them during the repeated stands, then stop.

If, after one minute has elapsed, the participant has not completed all five stands, then stop.

Stop timing when the participant has straightened up completely for the fifth time.

Have the subject sit down immediately after the fifth stand so that you can take the thirty second pulse on the left wrist.

Answer the following questions:

Was this test completed?
Coding
0= No
1= Yes
8= Not attempted
9= Unknown

If not attempted or completed, why not?
Coding
1 = Physical limitations
2 = Test not completed
3 = Refused
4 = Other_____
5 = Test stopped in 60 seconds
9 = Unknown

If it is an offsite visit, the height of the chair used is measured and recorded.

The time to complete five stands in seconds is recorded.

If less than five stands are completed, enter the number of stands completed.

Fu 539 → Fu 548

Measured Walks:

The participant will first observe while the examiner demonstrates how to walk the measured course at a normal pace. The participant will then be asked to walk the measured 4 meter course at a normal walking pace while being observed and timed. Next, he or she will repeat this usual pace while being timed. The examiner will then demonstrate the rapid pace walk and the participant will be asked to walk the course at a rapid pace while being timed.

A cane or walker may be used during the walk, but if people with such devices can walk short distances without them, they should be encourage to do so. Many people with assistive devices use them only when they walk outdoors or for long distances indoors. Doing the test without the device provides a much more accurate assessment of the functional limitation of the participant. Ask the participant if she ever walks at home without the device. Then ask the participant if s/he thinks he/she can walk a short distance for the test. Participants who normally use assistive devices should be watched particularly closely during the test to prevent falling.

The walking course should be unobstructed and include at least an extra one-half meter on each end. You will need a measuring tape to measure the distance of the walking course and masking tape to mark the starting and finish lines.

1. Walk #1:

   Now I am going to observe how you normally walk, if you use a cane or other walking aid and would be more comfortable with it, you may use it.

   This is our walking course. I want you to walk to the other end of the course at your usual speed, just as if you were walking down the street. Walk all the way past the other end of the tape before you stop. Do you think this would be safe?

   If participant says that it would not be safe indicate this on the data sheet and abort walks.

   Please watch while I demonstrate. When I want you to start, I will say "Ready, begin."

   Have the participant line up his or her toes behind the line on the floor. Start timing when you say, "begin" and stop timing when the participant breaks the plane of the line at the end of the course. Record the time on data sheet.

2. Walk #2:

   Now I want you to repeat the walk. Remember to walk at your usual pace, and all the way past the other end of the course.

   Ready? Begin.

3. Walk #3:

Now I want you to repeat the walk again, but this time, I would like you to walk at a rapid pace, as fast as you can. Make sure you go all the way past the other end of the course.

Please watch while I demonstrate.

Ready? Begin.

Fu539 If a walking aid is used, this will be recorded.

Coding

0 = No aid	**2** = Walker	**4** = Other
1 = Cane	**3** = Wheelchair	**9** = Unknown

For each walk, the following questions will be answered:

Fu540 *Was this test completed?*

Coding
0 = No
1 = Yes
8 = Not attempted
9 = Unknown

Fu541 *If the test was not attempted or completed, why not?*

Coding
1 = Physical limitation
2 = Refused
3 = Other (write in)
9 = Unknown

Fu542 Walk time for each walk is recorded.

Information on Observed Physical Performance found in this section was obtained through:

Guralnik MD, PhD, Jack. Assessing Physical Performance in the Older Patient: *An overview of the Short Physical Performance Battery (SPPB).* CD-ROM. 2003

See vascular data sets

Noninvasive Vascular Testing

The **ultrasound FMD brachial reactivity test** is widely used in research to non-invasively assess endothelial function, and has resulted in over 1000 publications to date. Endothelial function by brachial reactivity has been related to cardiovascular disease [CVD] risk factors, sub-clinical CVD, prevalent CVD, and prognosis in CVD. However, brachial ultrasound dilation to reactive hyperemia is technically very difficult to perform reproducibly, so it's utility in a clinical sphere remains unknown.

The **PAT** device involves using a noninvasive device by ***Itamar*** which records changes in arterial pulsatile blood volume, called PAT – peripheral arterial tone. The device is applied to the 2nd digit on the same arm undergoing the brachial ultrasound test, and to the contralateral arm's 2nd digit. Using the device would significantly increase the amount of data collected during FMD, because as well as assessing FMD in a large conduit artery [brachial artery] we will assess the changes in pulse amplitude in the small distal vessels of the finger. The data of all beats is output into an excel spread sheet and automatically analyzed by Itamar software. The reproducibility is comparable or superior to brachial FMD. November 25, 2003, the FDA approved the Endo_PAT for the detection of Endothelial Dysfunction, making it the first non-invasive system ever cleared by the FDA for that intended use. The PAT device is painless [inflation pressure is 50 mm Hg] and poses no risk to the subject, except those with latex allergies, which we routinely inquire about. If a history of latex allergy exists we forgo the test. Cuff inflation for 5 minutes may be uncomfortable, but most participants tolerate it well, and the sonographers verbally remind the participants to ask to stop the test if it is too uncomfortable. About 2% of the time older participants develop painless petechiae, which resolve spontaneously over 1-2 days.

Participants will be asked to participate in two experimental tests of vascular function, which will take about 15 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.

There are few risks and discomforts associated with this testing station:
The Brachial Ultrasound Test: The main risks are tingling or mild pain, and painless red spots (petechiae). About 2% of older participants who have the brachial ultrasound test develop painless red spots or bruising 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.

see vascular data sets

The Framingham Heart Study

Non-Invasive Cardiovascular Testing Station Description

The following is a description of the two tests at this station that will non-invasively examine your blood vessels' structure and function:

1. **Brachial ultrasound**
   The sonographer will hold an ultrasound transducer over your right arm artery (brachial) and measure the size and the flow in the artery at baseline. Then the sonographer will inflate a blood pressure cuff over your lower arm for 5 minutes. After the cuff is released the sonographer will take a picture of the size and blood flow in the artery for 2 minutes. ***It is very important that your arm remain still while the ultrasound pictures are being taken.***
2. **Fingertip Pulse Test**
   While the technician is performing the ultrasound test, s/he will also measure your pulse at one fingertip on each hand. If you have a known latex allergy, s/he will not apply the fingertip device.

The Brachial Artery Vascular Reactivity Ultrasound Test Q & A

What is the purpose of the brachial artery vascular reactivity ultrasound test?
The test determines how healthy the blood vessel lining is by measuring the ability of the brachial artery to get bigger (dilate) when exposed to increased blood flow.

What will the cuff feel like on my arm?
There may be temporary numbness or tingling when the cuff is on your arm. While it is being inflated, your arm may feel like it is going to sleep or numb. After the cuff is released your arm may feel pins & needles, warm, or cold.

Will any side effects occur after the brachial artery vascular reactivity ultrasound test?
This test has been performed on thousands of research participants safely, but in approximately 2% of participants red, painless spots appear on their arm. The spots disappear after a few days. If you notice red spots on your arm after the test, please call the sonographer at [redacted] as we would like to know if it happens to you.

Will you be able to tell me the results now?
Since the changes in the artery are very small, we will not be able to tell you the results while we are doing the study. At a later date we will make computer measurements of the amount that your artery expands after the cuff was released.

Will you send the results to my physician?
No, the results from the brachial ultrasound are used solely for research purposes. The test is not used for making medical decisions.

If, at any point during the testing, you are uncomfortable and would like to stop the tests, please tell the technicians.

If you have any additional questions, please contact [redacted] at [redacted] or [redacted] at [redacted].

IRB# 1910
VALID THRU: 6-22-04
PER IRB: NJB
Valid Form 2-2-04 UTH. INIT.

FU549-FU557, FU561-FU572

Referral Tracking

1. Was further medical evaluation recommended for this participant?

This question is to be answered by the physician completing the chart.

In addition to the physician writing in their physician ID number on the form, he/she will code this question using the following codes:

Coding
0= No
1= Yes
9= Unknown

If No, go to the next section.
If Yes, the MD is to code the reason for further evaluation:

a. Blood Pressure result ___/___
Phone call > 200/110
Expedite ≥180/100
Elevated > 140/90

Write in abnormality

b. ECG abnormality _____
c. Clinical Physician _____
identified medical problem
d. Other_____
_____

2. Was there an adverse event in clinic/offsite exam that does not require further medical evaluation?

This questions is to be completed by a staff member completing the exit interview.

In addition to the staff member writing in their technician ID number on the form, he/she will code this question using the following codes:

Coding
0= No
1= Yes
9= Unknown

If Yes, write in any comments and photocopy this form and give to [redacted]

FU549-FU557, FU561-FU572

3. Was a FHS physician contacted during the examination due to adverse exam findings?

This questions is to be completed at offsite exams only by the staff member completing interview.

In addition to the staff member writing in their technician ID number on the form, he/she will code this question using the following codes:

Coding
0= No
1= Yes
9= Unknown

If Yes, write in any comments regarding the telephone encounter.

4. Method used to inform participants of need for further medical evaluation

This information is to be coded by the physician completed the chart.

Circle ALL that apply

1= Face-to-face in clinic
2= Phone call
3= Result letter
4= Other

5. Method used to inform participant's personal physician of need for further medical evaluation.

This information is to be coded by the physician completed the chart.

Circle ALL that apply

1= Phone call
2= Results letter mailed
3= Results letter FAX'd
4= Other

Date referral made: ___--___--__ __ __ __ Use 4 digits for year

ID number of person completing this referral:_____

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

Protocol for Scheduling Offsite Visits

Before making a call, check the roster.

- On the main screen, check the comment line and Consent Status and C.S. Date.
- Check the Referral screen (F14 or shift F4) for additional comments.
- Check the Booking screen (F12 or shift F2) for scheduled exams, exam history, and the participant's age.

If an appointment is already scheduled for the near future or the participant was seen within the past two months, wait a reasonable amount of time to try to schedule the offsite visit: we do not want to call our participants or their contacts too frequently, and the original members can get confused if they get several calls from the Framingham Heart Study.

There is a minimum of one year required between exams when starting a new cycle for the Original Cohort. A signed consent is good for two years or until the next cycle begins. Each exam cycle the participants must sign a new consent form. This exam cycle (28) we will no longer be using consent by substituted judgment, some of these participants will now fall under the Waiver of Informed Consent.

When an appointment has been scheduled, the schedule is e-mailed to the offsite email list and a hard copy is given to [redacted] with the appropriate letter (with the nursing home or home visit form letters attached). [redacted] will send the appointment letter with the medical information form attached for Home Visits.

A. Home Visits

You may call the participant directly to schedule an offsite appointment if:

(1) there is no notation of cognitive impairment (*COG IMP* on the comment line or the F4/F14 screen),

(2) the Consent Status is less than 3,

(3) if the participant has not had the regular exam within the past year; and

4) there are no comments regarding severe hearing loss or speech difficulties.

If the participants' consent status is 3 or greater or if you have ANY question of their cognitive status, call the participants "FHS Proxy" first following the Waiver of Informed Consent protocol, if they have not designated a proxy, call a family member, preferably a Heart Study member. If you called the participant directly and any "red flags" were raised, call their proxy (if there is not a proxy call a family member) before scheduling. Given the ages of the Original Cohort, it is better to call someone in the next generation, preferably one of the children in the Offspring study. All Heart Study members are listed in the Family screen (**F18 or shift F8**), but check the F14 or F4 screen to see if they have a FHS proxy, if they don't check the comments and contact names to determine the best person to call. Whenever possible, call someone who lives near the participant.

If you cannot reach any contacts, (telephones disconnected, etc.), check the participant's chart (the Salmon Sheet) and/or any recent medical records in the chart to see who was listed as the responsible party or next of kin. If the contact person denies any problems (which often happens) and says the participant can sign any necessary form ask the contact if they would be willing to answer any unanswered questions after the exam.

When doing Home Visits where the Waiver of Informed Consent is used and you're not certain whether the participant can accurately answer questions, request that a family member or caretaker very familiar with the participant be present at the exam.

B. Nursing Home Visits

If there is no cognitive impairment noted in the roster, first call the nursing home to schedule the appointment. Identify yourself by name as a staff member of the Framingham Heart Study and ask to speak to the person in charge of the care of the participant. Once you have the nurse in charge of the participant on the line, identify yourself again as noted above, let them know why you are calling, and ask the nurse what the best time to visit the participant would be (some participants have other commitments during the day) and once the best time is determined, schedule an appointment. As a courtesy, call their proxy, if one is not listed contact a relative we have listed, starting with the spouse (unless there are instructions to the contrary on the roster) to inform her/him that we will be going to the nursing home; sometimes a relative wants to be present at the exam.

If the participant has a cognitive impairment follow the procedure for the Waiver of Informed Consent.

If the nursing home staff member tells you the participant has died since our last visit or health update, complete a Death Information Form which goes to [redacted] If the nursing home can't or won't provide the information we need and the death occurred several months ago, call the proxy (if available) or a family member for information.

If you're told the participant is too ill for a visit and/or has had serious medical events since our last update, you may call a family member and ask them about the participants' condition and whether they feel we can visit, if they also say no, ask if you can complete a health update with them (using the Medical History Update form).

Preparation For An Off-site Examination

Supplies

The following supplies should be brought with you on an offsite visit.

1 Portable EKG machine
1 Portable EKG acquisition module
1-2 Packs of EKG electrodes
1 Heart square
Alcohol wipes
Gauze
Adhesive remover pads
3 Blood pressure cuffs; large adult, adult and pediatric
1 Pocket Aneroid Sphygmomanometer
1 Litman Classic II Stethoscope
1 Pencil
1 Wristwatch
1 Portable scale
4 Response sheets for participant
1 JAMAR dynamometer
1 Stopwatch
1 Tape measure
5 Meter Chain
1 Pocket Talker (very helpful for hearing impaired participants)
Masking tape or tape of equal visibility
Participant's chart containing last exam, including the MMSE and paperwork for Exam 28

Preparation

On the day of the scheduled Heart Study visit it is best to call the participant or nursing home to confirm the appointment. Instruct the participant that he/she should wear a top that easily opens in the front to facilitate the ECG and remind them to have any available medications they take. With their confirmation letter, a form is included that helps to summarize their medical history since their last exam. Ask them to have this form ready.

When calling a nursing home inform the nurse that access to their patient's chart is necessary. Most nursing homes are accommodating and have the chart set aside for the visit.

Proposed Sequence Of Exam (clinic/offsite)

Clinic Exam

Intake Staff completes:

1. Informed Consent
2. Sociodemographic and family history (Salmon Sheet)
3. HIPPA Medical Release Form
4. Healthcare proxy form
5. Photocopy all forms the participant signed and give them one copy of each

Clinic Staff completes (Part 1):

1. Numerical Data: Height, Weight, Marital Status

Lab Staff completes

1. Blood Draw

Clinic Staff completes (Part 2):

1. ECG
2. MMSE
3. End of Life Preference Questions
4. Questionnaires: ADL's, Nagi, CES-D, R-B, etc.
5. Tech Blood Pressure
6. Observed Physical Performance

MD completes:

1. Medical History Update
2. 2 Blood Pressures
3. Referral Tracking Form

Foot Study Staff completes (some participant only):

1. Questionnaire
2. Foot Exam

Vascular Testing Staff completes:

1. Brachial Ultrasound
2. PAT

Clinic Staff completes (Part 3):

1. Referral Tracking Sheet
2. Procedure Sheet & Exit Interview
3. Chart Order

Offsite Exam

Offsite Technician completes:

1. Informed Consent (Use of Waiver if applicable)
2. Sociodemographic and family history (Salmon Sheet)
3. HIPPA Medical Release Form
4. Healthcare proxy form
5. Medical History Update
6. 2 Blood Pressures
7. MMSE
8. Numerical Data: Weight, Marital Status
9. ECG
10. End of Life Preference Questions & Questionnaire's (CES-D, ADL's, Nagi, R-B, etc)
11. Observed Performance
12. Foot Study (some participants only)
13. Vascular Testing (clinic only)
14. Nursing Home Chart Review-Update any incomplete information (offsite NH exam only)
15. Proxy Interview (if needed)
16. Chart Completion

MD Completes:

1. Medical History
2. MD Letter
3. Referral Tracking
4. Patient Letter

Visiting The Cognitively Impaired

The physical component of the exam requires the cooperation of the participant. The following are some suggestions to be able to effectively communicate with those with dementia.

Be patient
Do not try to reason
Keep information simple
Use given names
Use eye contact
Give one direction at a time
Give clear instructions instead of asking questions
Keep communication in the present
Use sensitive touch when possible
Give frequent acknowledgment and encouragement
Ignore misinformation and simply acknowledge the communication

Numerical Data Sheet
(clinic & offsite)

Site of Exam

Coding
0 = Heart Study
1 = Nursing Home
2 = Residence
3 = Other (living situations that would not fit into categories **1** or **2**)

Marital Status
Confirm marital status with participant.

Examiner's Number
Fill in interviewer three digit number.

Weight and Height
See the following pages on protocol for obtaining and recording weight and height. If any modifications were made, they must be noted on the form.

Proxy Information
Whenever someone else is providing information about a participant that is collected on the forms, this person is considered a "proxy". When an offsite visit is to a nursing home, frequently a nurse familiar with the participant will be the proxy. Sometimes during offsite exams there will be more than one proxy. For example a Home Health Aid may answer all of the questions relating to ADL's, and the daughter may answer all of the medical questions. In cases like these, record information for both proxies on the numerical data sheet.

Important: The proxy that is designated by the participant as their FHS proxy does not have to be the same person as the one listed on the numerical data sheet.

On the back of the Numerical Data Sheet there is a Procedure Sheet and Exit Interview.

Prior to the exit interview staff should check the participant chart to see what procedures were completed. The staff should then fill in the procedure sheet using the corresponding codes.

Once the procedures are reviewed an exit interview is to be completed with the participant. During the exit interview:
(1) check the referral tracking sheet (complete with your ID number and any adverse events in clinic) and review with the participant any referral recommendations.
(2) Make sure the participant leaves the clinic area with all of their belongings; and
(3) Ask for feedback from the participant on how they felt about their examination..
   a. Enter one of the following codes:
   0=No Feedback 1=Positive Feedback 2=Negative Feedback 3=Other
   b. Write in any comments that are made.

Update Socio-demographic Data And Family History

Personal and family information are found on the Personal and Family History, salmon colored sheets. A copy is made in which to write updated information. The information can be obtained from either the participant, the proxy, or the chart at the long term care facility.

Updated information regarding the participant's current address, physician, and two contacts should be written on the photocopied sheet provided.

The participant's social security number will be written at the bottom lower right corner of the front of the salmon sheet. However, if this number is absent, ask the participant for it and assure them that it will be kept strictly confidential.

On the inside of the form is the family demographic information. This covers the participant's spouse, children, parents, and siblings. Updated information regarding their vital status (living or dead) and health status should be documented.

Nursing Home Chart Review Protocol

When visiting a participant in a Nursing Home, most of the necessary information may be obtained through the review of their Nursing Home chart. When calling to confirm the offsite visit to the Nursing Home, inform the nurse taking care of the participant that you will need to look through his or her chart. Most nurses will ensure that the chart will be available upon your arrival.

1. Updating Socio-demographic Data and Family History

   Upon opening the nursing home chart, one should see a face sheet. This sheet contains all the personal demographic data on their patient, including their next of kin. If these name(s) vary from the most recent ones on the Personal and Family History they should be documented, along with their addresses and phone numbers.

   Check the bottom of the Personal and Family History sheet to note if we have their Social Security Number on record. If not, obtain that number from the sheet also. Do not take the number if "Refused" is written in the Social Security field. This helps in tracking the participant. At the bottom of the face sheet it often lists the admission diagnosis of the patient. This is extremely important, especially if this is their first Nursing Home offsite visit.

2. Medications

   Most charts contain an up-to-date list of the patients medications. Some facilities keep the medications in a separate chart. If the patient's medications are not listed in their chart, ask for the medication book. Many times the medication sheets for months prior may also still be in the chart. It is helpful to flip through these to see if any of the patient's medications had been discontinued recently.

3. Interim Medical History

   The two sections that are most helpful in locating medical history information are "Consults" and "Medical History". Some nursing homes keep copies of all hospitalization records in a clear sleeve. The "Physician's Notes" and "Nurses Notes" sections are also helpful.

4. Activities of Daily Living

   To update a participant's activities of daily living the best reference is the MDI or minimum data sheet. This is a computer sheet, usually at the front of the chart, and it is updated about every 4 to 6 months. This sheet lists activities of daily living, hospitalizations etc. Always refer back to notes and daily documented information to corroborate data, but this gives a nice head start. To truly confirm the current level of functioning of the patient consult with his or her nurse and list nurse as the Proxy.

5. Weight

   If a current weight is not recorded in the participant's chart, ask to see a weight chart.

Since all facilities have their own chart organization system it is best to thoroughly examine the whole chart. Some facilities thin their charts more frequently and if only the last month's information is present, then ask to see the whole interim period. This will ensure that nothing is missed.

Elevated Blood Pressure

If, during a home visit the blood pressure is:

> **200/110** a call is made to a FHS physician who will notify the participant's personal physician. The chart will be marked "expedite" so that the letter to the personal physician is sent out ASAP.

> **180/100** the chart is expedited

-The Referral sheet is completed to note that contact was made to an FHS MD during the exam.

-If a phone contact was made by an FHS MD to the participant's personal physician, the FHS MD is to completed a "Record of Telephone Encounter" form.

If, during a nursing home visit the blood pressure is:

> **140/90** inform the nurse caring for the participant or the charge nurse

> **180/100** inform the nurse caring for the participant or the charge nurse. The chart will be marked "expedite" so that the letter to the personal physician is sent out ASAP.

Healthcare (Screen 1)

FU003 1. Hospitalization in interim
From (date of last FHS exam or medical history update) until today (date of exam 28), have you been hospitalized?

A hospitalization is considered an overnight stay.
If the participant was in the Emergency Room (E.R.) and then admitted, the event would be considered only for Hospitalization and not as E.R. visit.

Coding
0 = No, participant was not hospitalized at all
1 = Yes, participant was hospitalized only once
2 = Yes, participant was hospitalized more than one time
9 = Unknown

FU004 2. E.R. visit in interim
From (date of last FHS exam or medical history update) until today, have you been to the Emergency Room?

An emergency room visit is when the person is both admitted to and discharged from the emergency room.

Coding
0 = No, participant had no visits to the E.R.
1 = Yes, participant had one or more visits to ER.
9 = Unknown

FU005 3. Day surgery in interim
From (date of last FHS exam or medical history update) until today, have you had any day surgery?

Day surgery is a surgical procedure performed on an out-patient basis either in an ambulatory surgery department of a hospital or in a physician's office.
The person is in and out the same day.

Coding
0 = No
1 = Yes
9 = Unknown

FU006 4. Illness with visit to the doctor in interim
From (date of last FHS exam or medical history update) until today, have you had an illness(s) for which you saw your physician?

Illness with visit to physician is defined as a visit outside of a regular check-up. It can be further clarified by defining it as a visit to the doctor for a specific reason. It is imperative that the reason for the visit be documented.

Coding
0 = No visits for illness
1 = Yes, participant had only one visit to the doctor due to illness
2 = Yes, participant had more than one visit to the doctor due to illness

FU007 5. Check-up in interim by doctor
From (date of last FHS exam or medical history update) until today, have you been to your physician for a check-up?

A check-up is considered to be a routine visit

Coding
0 = No, participant did not have a check-up
1 = Yes, participant did have a check-up.
9 = Unknown

Details of all hospitalizations, ER visits, day surgery, and physician visits must be provided as follows:

A. Medical encounter section
Write the details about the medical event. If patient cannot give a "medical condition", symptoms leading to the medical encounter should be listed (for example, chest pain, shortness of breath).

B. Month/Year
Record the date of the medical encounter. People often cannot recall the exact month or even the year. Trying to couple the event with a season or holiday sometimes helps.

C. Site of the hospital or office
The hospital and the city and state are most important.

D. Doctor
Record the name of the physician seen. If the participant sees a physician's assistant or a nurse practitioner in the physician's office, obtain both names.

Fu009 → Fu013

Medications (Screens 2-4)

Fu009 1. *Since your last exam have you taken medication for hypertension (high blood pressure)?*

Coding

0 = No
1 = Yes, Now
2 = Yes, Not Now
9 = Unknown

2. List all medications on Screen 3.

Fu010 3. Do you take aspirin regularly?

Coding

0 = No **1** = Yes **9** = Unknown

Be sure to clarify that ASA does not include Tylenol, Advil, Motrin, etc.

If Yes, complete the following:

Fu011 A. Number of aspirins taken regularly. Fill in number or 99 = Unknown
Try to establish the number of aspirin usually taken.

Fu012 B. Aspirin frequency
How often do you take the aspirin?

Coding

0 = Never
1 = Day
2 = Week
3 = Month
4 = Year
9 = Unknown

Fu013 C. Usual Aspirin Dose
How many milligrams do you take?

81mg = baby aspirin
160mg = half dose
325mg = regular adult aspirin
500mg = extra strength adult aspirin or larger
999 = Unknown

The offsite interviewer should only obtain the names, dosage, frequency, and prn of the medications the participant is taking, presently and in the interim, along with the dosage and frequency

Blood Pressure F0019, F0020

The first blood pressure reading is taken after the medication is completed. See the manual section name "Blood Pressure" to ensure proper reading.

FU023 -> FU034

Medical History - Genitourinary and Thyroid Disease (Screen 5)

1. Female Hormone Replacement

FU023 *A. Estrogen use since your last exam?*

Coding

0 = No
1 = Yes, now
2 = Yes, not now
8 = Man
9 = Unknown

FU024 FU025 FU026 If yes, write in the Name of most recent estrogen preparation, the strength, and the number of days taken per month

Coding
Write in number of days per month
88 = Man
99 = Unknown

FU027 B. *Estrogen Cream use since your last exam?*

Coding

0 = No
1 = Yes, Now
2 = Yes, Not Now
8 = Man
9 = Unknown

FU028 C. *Progesterone use since your last exam?*

Coding

0 = No
1 = Yes, Now
2 = Yes, Not Now
8 = Man
9 = Unknown

FU029 FU030 FU031 If Yes, write in the name of the most recent progesterone preparation, the strength, and the number of days per month taken.

2. Prostate Disease

FU032 Prostate Trouble

Have you experienced any trouble with your prostate since your last exam?

Prostate symptoms include difficulty starting the urine flow, decreased strength of the urinary stream, frequent urination especially at night, difficulty emptying the bladder, and dribbling of urine. Prostate disorders also include infection and cancer.

FU033 *Have you had prostate surgery since your last FHS exam?*

Coding
0 = No
1 = Yes
2 = Maybe
8 = Woman
9 = Unknown

3. Thyroid History

FU034 *Since your last exam have you had a diagnosis of a thyroid condition?*

Coding
0 = No
1 = Yes
9 = Unknown

Comments_____
(write in)

Fu035 → Fu049

Alcohol Consumption and Smoking (Screen 6)

1. Alcohol Consumption

Do you drink any of the following beverages at least once a month?

Fu035 Beer
Fu036 White wine
Fu037 Red Wine
Fu038 Liquor/spirits
Fu039 Other

Coding
0 = No
1 = Yes
9 = Unknown

What is your average number of servings in a typical week or month since your last exam?

Fu040 → Fu041 Beer (12 oz. bottle, can, glass)
Fu042 → Fu043 White wine (4 oz. glass)
Fu044 → Fu045 Red wine (4 oz. glass)
Fu046 → Fu047 Liquor/spirits (1 oz.) (cocktail, highball)
Fu048 → Fu049 Other

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

2. Smoking

Fu050 *Have you smoked cigarettes regularly since your last exam?*

Coding
0 = No
1 = Yes, now
2 = Yes, not now
9 = Unknown

Fu051 Ask the participant "*How many cigarettes do or did you smoke a day,*" and record the number in the area provided.

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Fu052 → Fu063

Respiratory Symptoms Part I (Screen 7)

Cough:

Fu052 *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)

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

Fu053 *During the past 12 months, have you had a cough upon getting up or first thing in the morning?*

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

If yes to either question above answer the following:

Fu054 *Do you cough on most days (4 or more days/week) for three months or more during the past 12 months?*

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

Fu055 *How many years have you had this cough? (99=Unknown) enter the # of years*

Phlegm:

Fu056 *During the past 12 months, have you brought up phlegm from your chest apart from colds? (Exclude phlegm from the nose)*

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

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FU057 *During the past 12 months, have you brought up phlegm from your chest upon getting up or first thing in the morning?*

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

If yes to either question ask following:

FU058 *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?*

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

FU059 *How many years have you brought phlegm up from your chest on most days?*
(99=Unknown) Enter # of Years

Wheeze:

FU060 *In the last 12 months, have you had wheezing or whistling in your chest at any time?*

Code

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

If yes, ask the following questions:

FU061 *In the last 12 months, how often have you had this wheezing or whistling?*

Code:
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

FU062 *In the past 12 months, have you had this wheezing or whistling in the chest when you did NOT HAVE A COLD?*

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

FU063 *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?*

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

FU064 → FU079

Respiratory Symptoms Part II (Screen 8)

Sleep Related Symptoms (days/nights)

FU064 *In the past 12 months, on average how many nights a week did you snore?*

Code
0= Never
1= Rarely (1-2 nights/week)
2= Occasionally (3-4 nights/week)
3= Frequently (5/more nights/week)
9= Unknown
Use coding for nights OR days

FU065 *In the past 12 months, on average how many nights a week do you snort, gasp, or stop breathing while you are asleep?*

Code
0= Never
1= Rarely (1-2 nights/week)
2= Occasionally (3-4 nights/week)
3= Frequently (5/more nights/week)
9= Unknown
Use coding for nights OR days

FU066 *In the past 12 months, on average how many days a week have you had excessive (too much) daytime sleepiness?*

Code
0= Never
1= Rarely (1-2 nights/week)
2= Occasionally (3-4 nights/week)
3= Frequently (5/more nights/week)
9= Unknown
Use coding for nights OR days

Nocturnal chest symptoms:

FU067 *In the last 12 months, have you been awakened by shortness of breath?*

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

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FU068 *In the last 12 months, have you been awakened by a wheezing/whistling in your chest?*

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

FU069 *In the last 12 months, have you been awakened by coughing?*

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

If yes is answered, ask:

FU070 *In the last 12 months, how often have you been awakened by coughing?*

Code:
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

Shortness of breath

FU071 *Are you troubled by shortness of breath when hurrying on level ground or walking up a slight hill?*

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

FU072 *Do you have to walk slower than people of your age on level ground because of shortness of breath?*

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

FU073 *Do you ever have to stop for breath when walking at your own pace on level ground?*

Code

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

FU074 *Do you ever have to stop for breath after walking 100 yards (or after a few minutes) on level ground?*

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

FU075 *Do you/have you needed to sleep on two or more pillows to help you breathe?* (orthopnea)

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

FU076 *Have you since your last exam had swelling in both your ankles (ankle edema)?*

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

FU077 *Have you since your last exam been told you had heart failure or congestive heart failure?*

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

FU078 *Have you since your last exam been hospitalized for heart failure?*

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

FU079

NOTE: The area entitled "Examiner's Opinion" at the bottom of the page is not to be completed by the interviewer but by the physician.

NOTE: Use comment section to write a narrative description of the event.

FU080 -> FU099

Chest Discomfort History In Interim (Screen 9)

FU080 1. Any chest discomfort since last exam or medical history update?

This should be asked: *Since (date of last FHS visit or medical history update) until today, have you experienced any chest discomfort?*

Coding
0 = No
1 = Yes (See below)
2 = Maybe (See below)
9 = Unknown

When the participant states that they have not experienced any chest discomfort, ask further *chest pain, tightness, pressure.*

If "No" go to Screen 11.
If "Yes" ask:

FU081 Chest discomfort with exertion or excitement

a. *Have you experienced chest discomfort with exertion or when excited, such as times of emotional upset?*

FU082 Chest discomfort when quiet or resting?

b. *Have you experienced chest discomfort when quiet or resting?*

Coding
0 = No
1 = Yes
2 = Maybe
3 = Unknown

2. Chest Discomfort Characteristics:

FU083-FU084 a. Date of Onset
When did the discomfort first begin?

Code as month and year.
Coding
99/9999 = Unknown

FU085 b. Usual Duration
How long does the chest discomfort usually last?

169

Code in minutes.

Coding

1 = 1 min. or less
900 = 15 hours or more
999 = Unknown

FU086 c. Longest Duration

What is the longest amount of time the chest discomfort lasted?

Code in minutes.

Coding

1 = 1 min. or less
900 = 15 hours or more
999 = Unknown

FU087 d. Location

Where do you feel the discomfort?

Coding

0 = No
1 = Central sternum and upper chest
2 = Left upper quadrant
3 = Left lower ribcage
4 = Right chest
5 = Other
6 = Combination
9 = Unknown

FU088 e. Radiation

Does the pain (or pressure) move around?

Coding

0 = No radiation
1 = Left shoulder or left arm
2 = Neck
3 = Right shoulder or arm
4 = Back
5 = Abdomen
6 = Other
7 = Combination
9 = Unknown

FU089 f. Frequency

How many episodes of chest discomfort have you experienced in the past month?

Code as number of episodes in past month.

Coding

999 = Unknown

FU090 g. Frequency

How many episodes of chest discomfort have you experienced in the past year?

Code as number of episodes in past year.

Coding
999 = Unknown

FU091 h. Type
Can you describe what the discomfort feels like?

Coding
1 = Pressure, heavy, vise
2 = Sharp
3 = Dull
4 = Other
9 = Unknown

FU092 i. Relief by Nitroglycerin in less than 15 minutes
Does taking Nitroglycerin resolve the discomfort in less than 15 minutes?

Be sure to code 8, not 0 for item *i*, if the participant has never used Nitroglycerin.

FU093 j. Relief by rest in less than 15 minutes
Does rest relieve the discomfort in less than 15 minutes?

FU094 k. Relief spontaneously in less than 15 minutes
Does the discomfort relieve itself spontaneously in less than 15 minutes?

FU095 l. Relief by other cause in less than 15 minutes
Is the discomfort relieved in any other way in less than 15 minutes?

Coding (for questions *i, j, k, l*)
0 = No
1 = Yes
8 = Not tried
9 = Unknown

FU096
FU097
FU098
FU099

NOTE: The "CHD First Opinions" section at the bottom of screen 10 is not to be filled out by the interviewer. It is to be filled out by the physician.

NOTE: It is critical to use the comment section to write a narrative description of the chest discomfort. If possible provide some information on participant's activity level (i.e. bed bound, able to perform household/yard chores). This descriptive data provides further information for the physicians on the review committee.

Fu100 → Fu111

Syncope History In Interim (Screen 10)

Fu100 1. *Have you fainted or lost consciousness since your last exam?*
(If due to stroke skip to screen 11)
(If event immediately preceded by head injury or accident code **0** = No)

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

If the participant has experienced no episodes of fainting or loss of consciousness in the interim, code "**NO**" move to screen 12.

If the participant has fainted or lost consciousness or is unsure, record the descriptive data regarding the events.

Fu101 a. Number of episodes in past two years
How many times in the past two years have you fainted or lost consciousness?

Code as number of events.
Coding
999 = Unknown

Fu102-Fu103 b. Date of first episode
Do you recall the first time you fainted or lost consciousness (in past 2 years)?

Code as date: month and year.
Coding
99/9999 = Unknown

Fu104 c. Usual duration of loss of consciousness
How long were you unconscious for?

Code in number of minutes.
Coding
999 = Unknown

FU105 d. Injury caused by the event
Did you have any injury caused by the event?

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

FU106 e. ER/Hospitalized or saw M.D.
Have you seen your physician, gone to the ER or been admitted to the hospital for the event?

Coding
0 = No
1 = Hospital/ER
2 = Saw M.D.
9 = Unknown

If the participant was coded as either **1** or **2**, fill in the allotted spaces the name of the M.D. and the medical facility where he/she was seen.

FU107
FU108
FU109
FU110
FU111

NOTE: The area entitled "Syncope First Opinions" at the bottom of the page is not to be completed by the interviewer but by the physician.

NOTE: Use comment section to write a narrative description of the event.

Fu112 → Fu133

Cerebrovascular Episodes In Interim (Screen 11)

It is important to stress that these CVA symptoms are **sudden**, not a slow progression that might lead to muscle weakness or a visual defect.

Fu112 1. Sudden Muscular Weakness
*Since (date of last FHS exam) until today, have you experienced any **sudden** muscular weakness? Have you noticed your face drooping or loss of strength on one side of your body?*

Fu113 2. Sudden Speech Difficulty
*Since (date of last FHS exam) until today, have you experienced any **sudden** difficulty with your speech?*

Fu114 3. Sudden Visual Defect
*Since (date of last FHS exam) until today, have you experienced any **sudden** visual defect?*

Fu115 4. Double Vision
Since (date of last FHS exam) until today, have you experienced any double vision?

Fu116 5. Sudden Loss of Vision in One Eye
*Since (date of last FHS exam) until today, have you experienced any **sudden** loss of vision in one eye, like a shade coming down and then up over your eye?*

Fu117 6. Unconsciousness
Since (date of last FHS exam) until today, have you experienced any episodes of unconsciousness?

Fu118 7. Numbness, Tingling
Since (date of last FHS exam) until today, have you experienced any numbness or tingling anywhere in your body?

Fu119 If Yes, is numbness and tingling positional?

For questions 1 – 7 use the following code:

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

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FU120 8. CT Scan or MRI (of head) Since Last Exam

Since (date of last FHS exam) until today, have you had either a CT Scan or an MRI done of your head (brain)?

Coding
0 = No
1 = CT
2 = MRI
3 = Both
9 = Unknown

If this is coded 1, 2, or 3, try to obtain the date and place when the CT or MRI was done and put this info in the space provided.

FU121 9. Seen by Neurologist Since Last Exam

Since (date of last FHS exam) until today, have you been seen by a neurologist?

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

If this is coded as either **1** or **2**, document the name of physician and when seen.

10. Details for "Serious" Cerebrovascular Event in Interim

FU122 Using the above criteria, the interviewer must determine at this point whether a "serious" or "significant" cerebrovascular event took place in the interim.

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

If Questions 1 – 3are coded as either **1** or **2** the following data must be recorded:

FU123-FU124 a. Date of event, by month and year.

When did the event occur?

Coding
99-99 = Unknown

FU125-FU126-FU127 b. Duration

Do you recall how long the event lasted?

Code in time using days, hours, and minutes.

Coding
99-99-99 = Unknown

Fu128

c. Hospitalized or saw M.D.

Did you see your physician or go to the hospital?

Coding

0 = No

1 = Hospitalized

2 = Saw M.D.

9 = Unknown

Hospital or M.D. name:

Address:

Fu129
Fu130
Fu131
Fu132
Fu133

"Neurology First Opinions" is not be completed by the interviewer. It is to be filled out by a physician.

NOTE: Use the comment section to provide a narrative description of any symptoms that occurred.

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FU134 → FU150

Peripheral Arterial and Venous Disease (Screen 12)

FU134 1. *Can you walk 50 feet without any help?*

Codes
0 = Able to walk 50 feet without any help
1 = Need of help
2 = Can't walk
9 = Unknown

FU135 *Do you have lower limb (leg) discomfort while walking?*

Codes
0 = No
1 = Yes
2 = Cannot walk
9 = Unknown

FU136 If Yes: *If walking on level ground, how many city blocks until symptoms develop?* (**00** = No, **99** = Unknown) 10 blocks = 1 mile. Code as "**NO**" if more than 98 blocks required to develop symptoms.

FU137 Year symptoms of leg discomfort started?

Code
9999 = Unknown

If Yes continue:

For questions a – f use the following to code:

Codes
0 = No
1 = Yes
9 = Unknown

FU138 - FU139 a. *Discomfort in calf while walking?*

FU140 - FU141 b. *Discomfort in lower extremity (not calf) while walking?*

For questions "a" and "b" code left and right legs separately.

FU142 c. *Occurs with first steps?*

FU143 d. *Occurs after walking a while?*

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Fu144 e. *Related to rapidity of walking or steepness?*

Fu145 f. *Forced to stop walking?*

Fu146 g. *Time for discomfort to be relieved by stopping (minutes)?*

Code as number of minutes it takes for discomfort to subside.

Codes
00 = No relief with stopping.
88 = Non-applicable or participant walks through the discomfort without relief with rest
99 = Unknown

Fu147 h. *Number of days out of a month of lower limb discomfort?*

Code as number of days out of a month that cohort experiences leg discomfort.

Codes
00 = No
88 = Non-applicable.
99 = Unknown.

2. Venous Disease

Fu149 a. *Since your last exam have you had a Deep Vein Thrombosis (blood clot in the veins in your legs or arms)?*

Codes
0 = No
1 = Yes
9 = Unknown

Fu150 b. *Since your last exam have you had a Pulmonary Embolus (blood clot in your lungs)?*

Codes
0 = No
1 = Yes
9 = Unknown

Fu148

NOTE: "PAD First Opinions" (Intermittent Claudication) is to be coded by the reviewing physician. It is not to be coded by interviewer.

NOTE: It is critical to provide a narrative description of the leg discomfort under comment section.

Fu151 → Fu175

Medical History – CVD Procedures (Screen 13)

Cardiovascular Procedure (in the interim only, not lifetime)
- if procedure was repeated, code only first in interim and provide narrative (write four digits for year)

Since your last exam or medical history update, have you had any of the following procedures?

Fu151 – Fu152	a.	*Heart valvular surgery*
Fu153 – Fu154	b.	*Exercise tolerance test*
Fu155 – Fu156	c.	*Coronary arteriogram*
Fu157 – Fu158 – Fu159	d.	*Coronary artery angioplasty*
Fu160 – Fu161	e.	*Coronary bypass surgery*
Fu162 – Fu163	f.	*Permanent pacemaker insertion*
Fu164 – Fu165	g.	*Carotid artery surgery*
Fu166 – Fu167	h.	*Thoracic aorta surgery*
Fu168 – Fu169	i.	*Abdominal aorta surgery*
Fu170 – Fu171	j.	*Femoral or lower extremity surgery*
Fu172 – Fu173	k.	*Lower extremity amputation*
Fu174 – Fu175	l.	*Other cardiovascular procedure (write in below)*

The interviewer should be able to explain what each procedure entails as the participant may know he/she had some invasive procedure performed, but does not know its name.

For each procedure code as follows:

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

Those procedures coded as either **1** or **2**, complete the following:

a. Year procedure was done.
b. Location where procedure was performed.

NOTE: The comment section is provided for interviewer to list all subsequent cardiovascular procedures.

FU176 → FU194

First Examiner-Cancer Site or Type (Screen 14)

FU176 1. *Have you, since your last clinic visit or medical history update have you had a cancer or a tumor?*

The answer will be coded by the examiner as:

0 = No
1 = Yes (fill in table)

If Yes complete table of cancer/tumor site

Below is a list of sites of cancer or tumors and types of cancer.
For each site of cancer or tumor fill in the following:

Coding
1 = Definite cancer
2 = Tumor, nature unknown
3 = Definitely benign
9 = Unknown

For each site of cancer or tumor complete the year of diagnosis, the name of the diagnosing physician and the city or town of that physician.

NOTE: The Comment Section at the bottom of the page there is space to write a narrative regarding the cancer or tumor if participant gives details. If possible, obtain the name of the hospital/outpatient clinic where the biopsy was performed and the name of the physician who performed the biopsy.

Fu 195 → Fu 198

Blood Pressure (Screen 15)

The 2nd blood pressure reading is taken after this section of questioning. Refer to the blood pressure section in the manual for further instructions.

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Electrocardiograph-Part I (Screen16-17) Fu200 → Fu235

This section is to be filled out by the physician reading the ECG and completing the chart

Clinical Diagnostic Impressions-Part III (Screen 18) Fu236 → Fu248

This section is to be filled out by the physician completing the exam and chart.

Offsite Visit Chart Completion

After returning to the Heart Study the following procedure is used to ensure that the chart is processed in an efficient manner.

A. ECG Physician Review

The full size tracing of the ECG, and the ECG from the participant's previous exam should be presented to a FHS physician within 24 hours of the visit or within 24 hours of the tech returning to the FHS. This is done for comparison and reading. Should there be any marked ECG changes, the FHS physician will inform the participant's personal physician immediately.

After a contact is made with the PCP, the physician should complete a phone encounter sheet or the referral tracking form to document his/her actions.

The field visit tech will complete the chart the day of the visit, or the next day if the visit occurred late in the day, or was out of the Metrowest area.

Field visit charts will be processed within 1-2 days of the visit and the tracking sheet will be returned to the off-site tech for confirmation of completion.

C. Chart Review Protocol

1. Review all forms to ensure that all areas are completed. This includes the participant's letter and the physician summary sheet. On the summary sheet, document the medical findings that are new since the last exam and any other significant medical conditions.

2. If the participant had a stroke, suffered a hip fracture, or has shown marked cognitive changes in the interim, a referral is made to the Stroke or Dementia study. After completing the referral forms, attach to the outside of the chart.

3. A Routing Sheet is used to ensure that the doctor, the Study Coordinator, and the Data Technician review the chart. All charts are logged out on a tracking sheet.

Appendix

A. Exam Forms

B. Exam Referral Forms & Medical Encounter Forms

C. Supervisor Observation Forms

D. Scheduling & Refusal Forms

E. Participant Letters

F. Routing Sheets & MD Chart Tracking Forms

G. Massachusetts Counties

admin use only

Neurology Clinic Referral Form

ID#:_____ Name:_____

Date:___/___/___ Person Making Referral:_____

Source of Referral:_____

1= Hospital Admission
2= Biennial Exam
3= Offspring Exam
4= Family
5= Medical Records
6= Other (Please specify)
7= Review

Reason for Referral:_____

_____

Reason for Hospitalization (if applicable):_____

_____

Living Situation (if applicable):_____

1 = Own Home
2 = Elderly House
3 = Hospital
4 = Relative's Home
5 = Nursing Home
6 = Other

DISPOSITION (OFFICE USE)

Date Opened: ___/___/___
Date Closed: ___/___/___

1. To be scheduled for Neuro Clinic
2. Seen in Neuro Clinic: ___/___/___
3. Medical Records to be Obtained
4. Medical Records Complete: ___/___/___
5. Review Status: _____
   - 1 = Reviewed
   - 2 = Awaiting review
   - 3 = No review to be done
6. Enrolled Case in Stroke Study:_____
   - 1 = No
   - 2 = Yes

   Date: ___/___/___
7. Reasons Not Seen:_____
   - 1 = N/A
   - 2 = Refused
   - 3 = Deceased
   - 4 = Out of State
8. Previously Seen:_____
   - 1 = Stroke
   - 2 = Dementia

admin use only

Stroke Tracking Referral Form
The Framingham Study

* Please complete the upper portion of this form if you identify a new neurological event.

ID#:_____ Name:_____

Date Opened: ___/___/___

Date of Event: ___/___/___ Date Type: ___ (0=Exact, 1= Approximate)

Source of Referral:_____

1 = Hospital Admission
2 = Biennial Exam
3 = Offspring Exam
4 = Family
5 = Medical Records
6 = Review
7 = Other (Please specify)

Initials:_____

Reason for Referral:_____

Reason for Hospitalization:_____ (1=Neurology, 2=Other, 3=N/A)

Comments:_____

_____

_____

DISPOSITION (FOR TRACKING PERSONNEL TO COMPLETE)

1. Dictation:_____ (0=Awaiting, 1=In)
2. To be Scheduled in Stroke Clinic:_____ (0=No, 1= Yes, 2=Pending)
3. Date Seen in Stroke Clinic: ___/___/___
4. Reason Not Seen in Clinic:_____(1=N/A, 2=Refused, 3=Deceased, 4=Out of State)
5. Part of PSIP Follow-Up Protocol:_____ (0=No, 1=Yes, 9=Unknown)
6. Previously Seen:_____ (0=No, 1=Stroke, 2=Dementia, 3=Other)
7. Medical Records needed: _____ (0=No, 1=Yes)
8. Date: ___/___/___
9. CT/MRI/MRA to be obtained:_____ (0=No, 1= Yes)
10. Date: ___/___/___
11. Review Status:_____ (1=Awaiting Review, 2=Reviewed, 3=Need Info)
12. Date Reviewed:___/___/___
13. Status of Case:_____ (0=Opened, 1=Closed)
14. Date:___/___/___
15. Diagnosis:_____
    (1=Stroke, 2=TIA, 3=?TIA, 4=Parkinson's, 5=No CVA, 6=Other Neuro, 7=Migraine, 10=?Stroke, 20=Recurrent TIA, 9=Unknown, 11=Multiple Sclerosis)

admin use only

Record of Telephone Encounter

(to be filed in chart)

Participant's ID#: ___-_____ Participant's Name:_____

Date of Incident: ___/___/___

Person Contacted:_____

_____

Regarding:_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Contact Made By:_____

admin use only

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

FRAMINGHAM HEART STUDY

[redacted]

RECORD OF IN-CLINIC MEDICAL ENCOUNTER
(to be filed in chart)

Participant's ID#:_____ Participant's Name:_____

Date of incident:_____

Description of incident:

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Physician:_____

Follow up (if any)

Date of follow-up:_____

_____

_____

_____

Physician/Staff:_____

admin use 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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COGNITIVE FUNTION 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.

The following items apply throughout the exam:		***Comments:***
y	n	The exam is explained to participant.
y	n	Participant seems at ease. If not, tech speaks with the participant to relax him/her.
y	n	Speaks slowly and distinctly, reading at neutral even pace.
y	n	Maintains focus of interview 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/codes answers correctly, following skip patterns as needed.
y	n	Id# filled in throughout exam.
y	n	Answer sheets, props and pictures are transitioned into exam without distraction.
y	n	Blood pressure is taken at the appropriate time.
y	n	Participant thanked for their time and for coming here today.

Overall comments of Supervisor:

Instruction to technician/corrective action:

_____

Signature, Supervisor
3/02

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

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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.	***Comments:***
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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Observed Performance
Supervisor Checklist

Date:_____ Technician:_____

Supervisor:_____ Participant Name & ID#:_____

Instructions: 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.

Repeated Chair Stands:			**Comments**
y	n	Repeated Chair Stands is explained to participant.	
y	n	A demonstration of the Chair Stands is provided to participant.	
y	n	Participant is asked if he would feel safe doing a Chair Stand. (If no, test is over. If yes, continue)	
y	n	Participant is asked to demonstrate the Chair Stand once, without using arms. (arms are folded across chest)	
y	n	The safety and ability of participant is assessed.	
y	n	The Participant is asked if he thinks it would be safe to try and stand up from achair five times without using his arms.	
y	n	It is explained to Participant that they will be timed for the five Chair Stand and they will have one minute to complete the stands.	
y	n	Participant is instructed after the last Chair Stand, while seated, they should hold out their left arm, palm facing up, and a pulse will be obtained.	
y	n	A demonstration is again provided.	
y	n	The command "Ready, Stand" and timing begin simultaneously.	
y	n	The stopwatch is started on the word "Stand".	
y	n	Once participant completes each stand, tester counts out loud.	
y	n	After the fifth chair stand is completed, a 30-second pulse at the wrist is obtained.	
y	n	Data sheet is completely and accurately filled out, questions are answered and pulse rate is recorded.	

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Stands: Side by Side, Semi-Tandem, and Tandem. **Comments**

1. Side by Side

y	n	Instruction for the stand is explained to participant.
y	n	Demonstration of stand is provided to participant.
y	n	Participant is wearing comfortable shoes/no bare feet or slippers.
y	n	The participant is able to stand unaided.
y	n	"Are you ready? Begin."
y	n	Participant is allowed to hold onto something for balance before timing begins.
y	n	Results recorded on data sheet.
y	n	If participant is unable to hold for 10 seconds, then the next two stands are skipped.

2. Semi-Tandem

y	n	Instruction for the stand is explained to participant.
y	n	Demonstration of stand is provided to participant.
y	n	Timing begins once the participant is balanced.
y	n	Participant is allowed to hold onto something for balance before timing begins.
y	n	"Are you ready? Begin."
y	n	Results recorded on data sheet.
y	n	If the participant is unable to complete the semi-tandem stand for 10 seconds, skip the tandem stand.

3. Tandem

y	n	Instruction for the stand is explained to participant.
y	n	Demonstration of stand is provided to participant.
y	n	Timing begins once the participant is balanced.
y	n	Participant is allowed to hold onto something for balance before timing begins.
y	n	"Are you ready? Begin"
y	n	Results recorded on data sheet.

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Measured Walks: First Walk, Second Walk, Quick Walk **Comments**

1. First Walk

y	n	Instruction for the Measured Walk is explained to participant.
y	n	Demonstration of the walk on the measured course is provided to the participant.
y	n	Participant is asked if he/she would feel safe doing the walk(s). If No, test is over. If Yes, continue.
y	n	Participant lines up his/her toes behind the line on the floor.
y	n	Participant was told he/she could use a cane or walker if needed.
y	n	Instructed to walk at a normal or usual pace.
y	n	The command "Ready Begin" and the timer are done simultaneously.
y	n	The timer is stopped when participant breaks the plane at the end of the course.
y	n	Time is recorded.

2. Second Walk

y	n	Instructions are given in repeating the walk at a normal pace and to pass the tape on the floor at the end of the course.
y	n	Participant lines up his/her toes behind the line on the floor.
y	n	The command "Ready Begin" and the timer are done simultaneously.
y	n	The timer is stopped when participant breaks the plane at the end of the course.
y	n	Time is recorded.

3. Quick Walk

y	n	Instructions are given to participant on the walk again, but this time explaining that the pace should be quicker.
y	n	A demonstration of the Quick Walk is provided.
y	n	Instructed to pass the tape on the floor at the end of the course.
y	n	Participant lines up his/her toes behind the line on the floor.
y	n	The command "Ready Begin" and the timer are done simultaneously.
y	n	The timer is stopped when participant breaks the plane at the end of the course.
y	n	Time is recorded.

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JAMAR Hand Grip Strength Test **Comments**

y	n	Technician explains the hand grip to the participant
y	n	Participant is seated in chair with arms, right forearm resting on the arm of the chair, elbow at about a 90 degree angle.
y	n	Participant is instructed to hold JAMAR in upright position, wrist in neutral position, JAMAR facing the technician. The bottom of hand grip should not be pressed against or touching the chair.
y	n	The red peak-hold needle is set to zero.
y	n	The participant is instructed to squeeze as hard as s/he can, hold squeeze for a 3 to 5-1000 second count.
y	n	The JAMAR is held at eye level at about a foot from the tech's eyes and record reading on the kilogram scale. If directly in the middle of the scale then the reading is the odd number between the two even hash marks; otherwise record as the closest hash mark.
y	n	Steps are repeated until three measurements are recorded with the right hand.
y	n	Steps are again repeated for three trials with the left hand.
y	n	Recording is made on data sheet after each maneuver.

Overall Comments of Supervisor:

Instructions to technician/corrective action:

_____ **Signature, Supervisor**

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Cohort Exam 28
Scheduling Form

Pt ID#: ___-_____
Pt Name: _____
Date of Last Encounter: _____

Vital Status Date: _____

Date of Scheduled Exam: _____

Notes:

_____
_____
_____
_____
_____

Change of Address: _____

If yes, new address: _____
_____
_____

Keyer's initials: _____

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Cohort Exam 28
Refusal Form

Pt. ID: ___-_____
Pt. Name:_____
Date of Last Encounter:_____

Vital Status Date:_____
Person making call:_____

Reason for

Refusal:_____

_____

_____

_____

_____

_____

_____

_____

Was a telephone update completed:_____

If no, reason:_____

_____

_____

Can we call back?_____

If yes, date of call back:___/___/___

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Dear _____:

Once again, we thank you for participating in the Framingham Heart Study. Your next clinic appointment is scheduled for _____ at _____P.M.

As you probably know, we are now located at [redacted] in the [redacted] Our clinic is located in the wing on the [redacted] side of the building. The building is handicap accessible and we have reserved parking for you behind the [redacted] wing.

We suggest you wear comfortable clothes that are easy for you to remove. You should bring slippers and, if you wish, your own robe although we provide hospital robes.

Eat your regular meals and take medications as usual. **On the back of this sheet**, please list all medications you take, both prescription and non-prescription. The dosage is especially important. We would also appreciate information regarding hospitalizations and major illnesses since your last visit or health history update with us. **PLEASE BRING THIS LETTER WITH YOU TO THE CLINIC.** If you need help completing it, our staff will be happy to assist you at the time of your appointment.

If you have any questions, please call [redacted], Participant Coordinator, at [redacted] or [redacted] Thank you again for your participation in the Heart Study and your ongoing help in our battle against heart disease

Sincerely yours,

[redacted]
Director
Framingham Heart Study

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Dear _____:

Once again, we thank you for participating in the Framingham Heart Study. Your next clinic appointment is scheduled for _____ at _____P.M. A taxi will pick you up at _____P.M. and will bring you home after your appointment

As you probably know, we are now located at [redacted] in the [redacted] Our clinic is in the wing on the [redacted] side of the building. The building is handicap accessible and we have reserved parking behind the [redacted] wing.

We suggest you wear comfortable clothes that are easy for you to remove. You should bring slippers and, if you wish, your own robe although we provide hospital robes.

Eat your regular meals and take medications as usual. **On the back of this sheet**, please list all medications you take, both prescription and non-prescription. The dosage is especially important. We would also appreciate information regarding hospitalizations and major illnesses since your last visit or health history update with us. **PLEASE BRING THIS LETTER WITH YOU TO THE CLINIC**. If you need help completing it, our staff will be happy to assist you at the time of your appointment.

If you have any questions, please call [redacted] Participant Coordinator, at [redacted] or [redacted] Thank you again for your participation in the Heart Study and your ongoing help in our battle against heart disease

Sincerely yours,

[redacted]
Director
Framingham Heart Study

admin use only

Date

OMB No=0925-0216

<<Participant Name & Address>>

Dear *<<Participant Name>>*:

This letter confirms your appointment for a home visit from the Framingham Heart Study on *<<Date & Time>>*, as part of the Heart Study Exam 28. I, *<<Technician Name>>* will visit you at that time to do the exam.

If you could help us by preparing the following items beforehand, it would be greatly appreciated:

1) Please wear a top that is easily removed for your ECG. Many people prefer to wear their bathrobes.

2) Using the attached form, please list major medical events that have occurred since your last telephone update on *<<date>>*. We would like to know approximate dates, doctors, and where you were seen.

3) Please have all of your medication bottles out, include all of your prescriptions, non-prescriptions, creams, salves, and/or injections.

4) If you have legal healthcare proxy, or Power of Attorney please have a photocopy of this authorization for the Heart Study to put in their records.

This will help the exam run smoothly, but if you are unable to prepare beforehand, we will be happy to help during our visit. If you have any questions, please call me at [redacted] or [redacted] at [redacted] or [redacted]

Sincerely yours,

<<Technician Name>>
Framingham Heart Study Offsite Technician

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Date OMB No=0925-0216

Nursing Home name
Address

Re: *Participant's name*

This letter confirms *<<participant name's>>* appointment for a visit from the Framingham Heart Study on *<<date & time>>*, as part of the Heart Study Exam 28. I, *<<Staff member's name>>* will visit at that time to do the exam.

It would be most helpful if a staff member who knows the patient well and can provide a good history be available to speak with *<<name>>* briefly at the time of her visit. Please let *<<participant's name>>* know we are coming and have *<<her/him>>* wear a top that is easily removed for the ECG. I will also need access to *<<his/her>>* nursing home chart to review medical events since *<<Date last seen>>*.

Thank you in advance for your help. If you have any questions, please call [redacted] at [redacted] or [redacted] at [redacted]

Sincerely yours,

<<Technician name>>
Framingham Heart Study Offsite Technician

Pt Name & FHS ID#

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Primary Care Doctor's Name & Address: _____

_____

_____

Power of Attorney/Legal Healthcare Proxy: _____

Same-Day Emergency Room Visits Since the Last Exam on

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

Overnight Hospitalizations Since the Last Exam on

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

Most Recent Doctors Visits Since the Last Exam on

	Date	Doctor's Name	Findings (if applicable)
Physical:	_____	_____	_____
			_____

Medications:

Name	Strength	Dosage
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Pt Name and ID

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Primary Care Doctor's Name & Address: _____

_____

_____

Power of Attorney/Health Care Proxy: _____
(If you have documentation please have a copy available to give to the FHS for their records)

Same-Day Emergency Room Visits Since Your Last Exam on

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

Overnight Hospitalizations Since Your Last Exam on

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

Most Recent Doctors Visits Since Your Last Exam on

	Date	Doctor's Name	Findings (if applicable)
Physical:	_____	_____	_____
			_____

Other Doctors Visits Since Your Last Exam on

Appt Type	Date	Doctor's Name	Findings (if applicable)
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

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Cohort Exam 28
Home Visit/Nursing Home Visit Routing Sheet

Participant Label: _____

Date of Visit: ___/___/___

Offsite Technician: _____

Chart Flow	Initial & Date Completed
MD Chart/ECG Review in Clinic ↓	
Offsite Technician ↓	
[redacted] ↓	
Neurology Group ↓	
[redacted]	

* Routing Sheet to be returned to [redacted] *

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Month & Year

MD Name	Offsite Chart Completion Date	Total # of charts