Protocol for Scheduling Offsite Visits

Internal Use Only

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) for additional comments.
- Check the Booking screen (F12) 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 us.

There is a minimum of one year required between exams when starting a new cycle for the Original Cohort. A signed consent (regular or substituted judgment) is good for two years or until the next cycle begins. When an appointment has been scheduled, the schedule is e-mailed to the offsite list and a hard copy given to Kathy Dee with the appropriate letter (nursing home and home visit form letters attached). Kathy will send the appointment letter with the medical information form attached for Home Visits.

A. Home Visits

If there is no notation of cognitive impairment (*COG IMP* on the comment line), if the Consent Status is less than 3, if the participant has not had the regular exam within the past year and there are no comments regarding severe hearing loss or speech difficulties, call the participant directly to schedule the appointment.

If you have ANY questions, call a family member first, preferably a Heart Study member. If you called the participant directly and any "red flags" were raised, 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. When checking on an Offspring participant, it is preferable to call a sibling or other relative in the Study, or one of their children (check ages) rather than their parents. All Heart Study members are listed in the Family screen (**F18**), but check comments and contact names to determine the best person to call. Whenever possible, call someone who lives near the participant. If the

participant's only contact is an attorney or someone with Power of Attorney or a Healthcare Proxy, call that person. If the only contact is a friend, call that person. If no contacts are reachable (telephones disconnected, etc.), check the participant's chart (the Salmon Sheet for Cohort or the Green Sheet for Offspring) 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 you can say we prefer to have both the participant and the contact person sign consents.

WHENEVER THERE IS EVEN THE SLIGHTEST QUESTION OF COGNITIVE IMPAIRMENT OR ANOTHER CAUSE WHICH WOULD PROHIBIT THE PARTICIPANT FROM SIGNING HER/HIS OWN CONSENT, OBTAIN A CONSENT BY SUBSTITUTED JUDGMENT BEFORE SCHEDULING AN EXAM.

When doing Home Visits where this consent is required or, when 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. Bring both consent form and consent by substituted judgment forms and have both the participant *and* the family member sign consents.

B. Nursing Home Visits

Call the nursing home before calling a family member. 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. Ask the nurse about the patient's physical and mental condition, and whether she/he feels we can visit and, if so, whether a Consent by Substituted Judgement is required. If there are no cognitive issues, schedule an appointment. As a courtesy, call the contact 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 nurse says the patient "gets confused", "goes in and out", etc., GET THE CONSENT BY SUBSTITUTED JUDGEMENT, even if the staff member says it's not required. If we've previously needed a consent, check with the nurse if the contact we have listed is the same as the nursing home's, and check the telephone number and address if possible. If we haven't needed a

consent before, ask who the nursing home lists as the main contact, and check if this person is one of our listed contacts.

When calling a family member to request permission to visit, explain that we will check records and, if possible, obtain an ECG and blood pressure. We do not take blood or do any invasive tests. If the participant is severely impaired, we will use the consent only to check records and discuss events with the nursing staff. If the family member agrees to the visit, send a cover letter (samples available) with two copies of the consent form (the second copy is for their records) with a return envelope. Highlight the parts that must be completed: the boxes to be checked, signature and witness, and date. When the completed consent form is returned, make sure everything has been properly signed. If so, schedule an appointment with the nursing home and let them know you have a signed 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 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 for a health update (using the Medical History Update form).

For both Home Visits and Nursing Home Visits:

If you had no previous knowledge of cognitive impairment, and the MMSE score is less than 24 or has dropped three or more points since the last exam, we will want a Consent by Substituted Judgment form. If, in your opinion, you feel you should not continue the exam, stop. But if you feel it is appropriate to continue, try to call the next of kin or responsible person and get verbal permission for the exam. When possible, you can fax a Consent by Substituted Judgment form. If you can't reach a family member at the time of the exam but you feel it is appropriate to complete the exam, call a family member/responsible party as soon as possible thereafter, explain that you would be more comfortable having them sign the Consent, and then send the substituted judgment form with a return envelope. The file will be held for data entry and research purposes until we receive the Consent by Substituted Judgment, which is given to [redacted]

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
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 27

Preparation

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 available any 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

Home Visit

1. Obtain Informed Consent or bring signed consent by substituted judgment
2. Update Sociodemograhpics and Family History (Salmon Sheet)
3. Update Medical History
4. Blood Pressures (2)
5. MMSE and Questionnaires
6. Weight
7. ECG
8. Observed Physical Performance
9. Complete Numerical Data Sheet
10. Exam 27 Chart Completion

Nursing Home

Most of the Medical, Personal, and Family History will be obtained from the participant's nursing home chart.

1. Obtain Informed Consent or bring signed consent by substituted judgment
2. Update Medical History
3. Blood Pressures (2)
4. MMSE and Questionnaires
5. Weight
6. ECG
7. Observed Physical Performance
8. Numerical Data Sheet
9. Sociodemographic and family history information obtained from nursing home chart
10. Interview staff nurse
11. Exam 27 Chart Completion

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

ft001-ft024

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
Information is obtained for the participant via a proxy when the subject is cognitively impaired. The proxy does not have to be the person who signed the substituted judgment forms. When an offsite visit is to a nursing home, frequently a nurse familiar with the participant will be the proxy and a family member or whomever holds Power of Attorney will have signed the consent forms. The information regarding the proxy should be obtained and documented in the area.

Was participant able to respond to the interview? (Offsite)

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

Exam 27 Procedure Sheet
ECG Done
Blood Drawn
Observed Performance Measure

Coding
0 = No
1 = Yes
9 = Unknown
88 = Offsite Visit

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Update Sociodemographic Data And Family History

Internal Use only

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

Internal Use Only

When visiting a participant in a Nursing Home, most of the necessary interim 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 Sociodemographic Data and Family History

   Upon opening the nursing home chart, one should see a face sheet. This sheet contains all the personal demographic data on their patient, including their next of kin. If 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. 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 places 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

Internal use only

If, during a home visit the blood pressure is:

> **200/110** a call is made to a FHS physician and the chart is expedited.

> **180/100** the chart is expedited

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 and the chart is expedited.

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Healthcare (Screen 1)

ft237-ft241

1. Hospitalization in interim
From (date of last FHS exam) until today, 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

2. E.R. visit in interim
From (date of last FHS exam) 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

3. Day surgery in interim
From (date of last FHS exam) 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

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ft 237- ft 241

4. Illness with visit to the doctor in interim
From (date of last FHS exam) until today, have you had 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

5. Check-up in interim by doctor
From (date of last FHS exam) 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.

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Medications (Screens 2-6)

ft 243 - ft 318

1. Since your last FHS 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 scratch sheet. FHS physician will complete medication screens.

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, then the following three categories need to be completed.

   A. Number of aspirins taken regularly. Fill in number or 99 = Unknown
   Try to establish the number of aspirin usually taken.

   B. Aspirin frequency
   How often do you take the aspirin?

   Coding

   0 = Never
   1 = Day
   2 = Week
   3 = Month
   4 = Year
   9 = Unknown

   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

NO FURTHER CODING OF MEDICATIONS SHOULD BE PERFORMED BY THE INTERVIEWER.

The interviewer should obtain the names of the medications the participant is taking, presently and in the interim, along with the dosage and frequency, and transcribe them on the "scratch area" of the medication screen. The coding of the medications will be performed by a Heart Study Clinic physician.

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Medical History - Genitourinary and Thyroid Disease (Screen 7)

ft323 - ft333

1. Female Hormone Replacement

A. Have you taken estrogen replacement since your last exam?

Coding

0 = No
1 = Yes, now
2 = Yes, not now
8 = Man
9 = Unknown

If Yes:

Record does of oral estrogen:

Coding

0 = No
1 = 0.3
2 = 0.625
3 = 0.9
4 = 1.25
5 = 2.5
6 = Other_____
8 = Man
9 = Unknown

Record patch does of estrogen

Coding

0 = No
1 = 0. 5 mg/wk
2 = Other_____
8 = Man
9 = Unknown

Record number of days taking estrogen.

Coding

Write in number of days per month
88 = Man
99 = Unknown

B. *Have you ever used estrogen cream in the interim?*

Coding

0 = No
1 = Yes, Now
2 = Yes, Not Now
8 = Man
9 = Unknown

C. *Have you taken progestin (progesterone) replacement since your last exam?*

Coding

0 = No
1 = Yes, Now
2 = Yes, Not Now
8 = Man
9 = Unknown

If Yes:

Record daily dose of oral progestin:

Coding

0 = No
1 = 1.25
2 = 2.5
3 = 5.0
4 = 10.0
5 = Other_____
8 = Man
9 = Unknown

Record number of days taking progestins.

Coding

Write in number of days per month
88 = Man
99 = Unknown

(65)

ft323 - ft333

2. Prostate Disease

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.

Have you had prostate surgery since your last FHS exam?

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

3. Thyroid History

Have you been diagnosed with a thyroid condition since your last FHS exam?

Coding
0 = No
1 = Yes
9 = Unknown

Comments_____
(write in)

(66)

Alcohol Consumption and Smoking (Screen 8)

ft334-ft350

1. Alcohol Consumption

Do you drink any of the following beverages at least once a month?

Beer
White wine
Red Wine
Liquor/spirits
Other

Coding
0 = No
1 = Yes
9 = Unknown

What is your average number of servings in a typical week or month over the past year?

Beer (12 oz. bottle, can, glass)
White wine (4 oz. glass)
Red wine (4 oz. glass)
Liquor/spirits (1 oz.) (cocktail, highball)
Other

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

2. Smoking

Have you smoked cigarettes regularly in the last year?

Coding
0 = No
1 = Yes
9 = Unknown

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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Respiratory Symptoms (Screen 9)

ft351 – ft362

1. *Do you usually cough on most days for 3 consecutive months or more during the year?*

   Coding
   0 = No
   1 = Yes, Cough is new since their last FHS exam
   2 = Yes, Cough is old, had it at time of last FHS exam
   9 = Unknown

   (Alternative Inquiries: *Do you cough on most days of the week for 3 or more months of the year Is this cough new since (date of last FHS exam)?*)

2. *Do you usually bring up phlegm from your chest on most days for 3 consecutive months or more during the year?*

   Coding
   0 = No
   1 = Yes
   9 = Unknown

   (Alternative Inquiry: *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?*)

3. *Have you had asthma in the interim?*

   Coding
   0 = No
   1 = Yes, if asthma was new diagnosis in interim
   2 = Yes, if asthma occurred but was not a new diagnosis in interim
   9 = Unknown

4. *Have you had wheezing or whistling in your chest at anytime in the last twelve months?*

   Coding
   0 = No
   1 = Yes
   9 = Unknown

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ft351- ft362

5. Night cough
Do you experience a night cough?

Coding
0 = No
1 = Yes
9 = Unknown

6. Dyspnea on exertion
Do you experience shortness of breath or difficulty breathing when you exert yourself?

Coding
0 = No dyspnea
1 = Shortness of breath that occurs when climbing stairs or vigorous exertion
2 = Shortness of breath that occurs with rapid walking or moderate exertion
3 = Shortness of breath that occurs with any slight exertion
9 = Unknown

7. Dyspnea has increased over the past two years
Has your shortness of breath or difficulty breathing increased over the past two years?

Coding
0 = No
1 = Yes
9 = Unknown

NOTE: If participant is coded **0** for Dyspnea on exertion, this too should be coded **0** (No). Need to ask both questions.

8. *Do you sleep on two or more pillows to help you breathe?*

Coding
0 = No
1 = Yes
9 = Unknown

(Alternative Inquiry: *How many pillows do you sleep on at night?* If participant sleeps on more than one ask *if it is for comfort or to help with breathing difficulty.*)

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ft351-ft362

9. *Have you awakened suddenly, very short of breath, gasping or choking for air?*
If yes: *How often does this occur?*

Coding
0 = Never
1 = Once or twice a year
2 = A few nights a month (less than one time/week) or under special circumstances
3 = one to two nights/week
4 = 3 to 4 nights a week
5 = 5 to 7 nights a week
9 = Unknown

10. Ankle edema bilaterally
Do both of your ankles swell?

11. Been told you have heart failure or congestive heart failure in the interim
Since (date of last FHS exam) until today, have you been told you have heart failure or congestive heart failure?

12. Been hospitalized for heart failure in interim
Since (date of last FHS exam) until today, have you been hospitalized for heart failure?

Coding (for questions 10, 11, 12)
0 = No
1 = Yes
9 = Unknown

If yes: should be detailed on screen 1.

NOTE: The area containing "Respiratory First Opinions" is not to be filled out by offsite interviewer, but to be filled out by the physician completing the chart.

NOTE: Use the comment section to write a narrative description of the event or symptoms.

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Chest Discomfort History In Interim (Screen 10)

ft 365 - ft 380

1. Any chest discomfort since last exam?

This should be asked: *Since (date of last FHS visit) 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:

Chest discomfort with exertion or excitement

a. *Have you experienced chest discomfort with exertion or when excited, such as times of emotional upset?*

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:

a. Date of Onset
When did the discomfort first begin?

Code as month and year.
Coding
99/9999 = Unknown

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ft365-ft380

b. Usual Duration

How long does the chest discomfort usually last?

Code in minutes.

Coding

1 = 1 min. or less
900 = 15 hours or more
999 = Unknown

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

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

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

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

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ft365-ft380

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

h. Type
Can you describe what the discomfort feels like?

Coding
1 = Pressure, heavy, vise
2 = Sharp
3 = Dull
4 = Other
9 = Unknown

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.

j. Relief by rest in less than 15 minutes
Does rest relieve the discomfort in less than 15 minutes?

k. Relief spontaneously in less than 15 minutes
Does the discomfort relieve itself spontaneously in less than 15 minutes?

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

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.

(13)

Syncope History In Interim (Screen 11)

ft385-ft391

1. *Have you fainted or lost consciousness in the interim?*
(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.

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

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

c. Usual duration of loss of consciousness
How long were you unconscious for?

Code in number of minutes.

Coding
999 = Unknown

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ft 385 - ft 391

d. Injury caused by the event
Did you have any injury caused by the event?

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

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.

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.

Cerebrovascular Episodes In Interim (Screen 12)

ft397 - ft417

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.

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?*

2. Sudden Speech Difficulty
   *Since (date of last FHS exam) until today, have you experienced any **sudden** difficulty with your speech?*

3. Sudden Visual Defect
   *Since (date of last FHS exam) until today, have you experienced any **sudden** visual defect?*

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

5. Sudden Loss of Vision in One Eye
   *Since (date of last FHS exam) until today, have you experienced any **sudden** loss of vision in one eye, like a shade coming down and then up over your eye?*

6. Unconsciousness
   Since (date of last FHS exam) until today, have you experienced any episodes of unconsciousness?

7. Numbness, Tingling
   Since (date of last FHS exam) until today, have you experienced any numbness or tingling anywhere in your body?

   If Yes, is numbness and tingling positional?

   For questions 1 – 7 use the following code:

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

(76)

ft 397 - ft 417

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.

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

Using the above criteria, a FHS physician must determine at this point whether a "serious" or "significant" cerebrovascular event took place in the interim.

Coding

0 = None took place

1 = An event did take place

2 = Perhaps an event took place

9 = Unknown

If Questions 1 – 7 are coded as either **1** or **2** the following data must be recorded:

a. Date of event, by month and year.

When did the event occur?

Coding

99-99 = Unknown

Was it observed by anyone?

Document who witnessed event.

b. Onset time

(77)

ft397-ft417

What were you doing when the event took place?

Coding

1 = Active

2 = During sleep

3 = While rising

9 = Unknown

c. Exact/approximate time

Do you recall at what time the event occurred?

Code time by using 24-hour military time.

Coding

99-99 = Unknown

d. Duration

Do you recall how long the event lasted?

Code in time using days, hours, and minutes.

Coding

99-99-99 = Unknown

e. 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:

f. Number of days stayed at.....

If the cohort was hospitalized, document how many days he/she was an inpatient.

Code as number of days.

Coding

00 = No overnight stays

99 = Unknown

"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.

(78)

Peripheral Arterial and Venous Disease (Screen 13)

ft 423-437

1. *Can you walk 50 feet without any help?*

Coding
0 = Able to walk 50 feet without any help
1 = Need of help
2 = Cannot walk
9 = Unknown

Do you have lower limb (leg) discomfort while walking?

Coding
0 = No
1 = Yes
2 = Cannot walk
9 = Unknown

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.

Year symptoms of leg discomfort started?

Coding
9999 = Unknown

If Yes continue:

For questions a – f use the following to code:

Coding
0 = No
1 = Yes
9 = Unknown

a. *Discomfort in calf while walking?*

b. *Discomfort in lower extremity (not calf) while walking?*

For questions "a" and "b" code left and right legs separately.

c. *Occurs with first steps?*

d. *Occurs after walking a while?*

e. *Related to rapidity of walking or steepness?*

f. *Forced to stop walking?*

(19)

ft423-ft437

g. *Time for discomfort to be relieved by stopping (minutes)?*

Code as number of minutes it takes for discomfort to subside.

Coding
00 = No relief with stopping.
88 = Non-applicable or participant walks through the discomfort without relief with rest
99 = Unknown

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.

Coding
00 = No
88 = Non-applicable.
99 = Unknown.

2. Venous Disease

Have you had a blood clot in the veins in your legs or arms since we saw you last? (Deep Vein Thrombosis or DVT)

Coding
0 = No
1 = Yes
9 = Unknown

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.

(40)

Medical History – CVD Procedures (Screen 14)

ft439 - ft463

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 (date of last FHS visit) until today, have you had any of the following procedures?

The procedures are all cardiovascular in nature:

a. *Heart valvular surgery*
b. *Exercise tolerance test*
c. *Coronary arteriogram*
d. *Coronary artery angioplasty*
e. *Coronary bypass surgery*
f. *Permanent pacemaker insertion*
g. *Carotid artery surgery*
h. *Thoracic aorta surgery*
i. *Abdominal aorta surgery*
j. *Femoral or lower extremity surgery*
k. *Lower extremity amputation*
l. *Other cardiovascular procedure (write in below)*

The interviewer should be able to explain what each procedure entails as a cohort 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.

61

First Examiner-Cancer Site or Type (Screen 15)

ft464-ft482

1. *Have you, since your last FHS clinic visit, 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.

Offsite Visit Chart Completion

Internal use only

After returning to the Heart Study the following procedure is used to ensure that the chart is processed in an efficient manner.

Portable ECG Transmission Protocol

A. Transmitting and Printing an ECG from Portable MAC PC to MUSE

1. Plug cable into front port on **MUSE** and into the side port on MAC PC marked 'Accessory'.
2. Go into **MUSE** by using the following passwords:
   Boot-up password: **MUSE73w**
   User ID: **8**
   Password: **123sue**
   Site #: **1**
   This brings up the "**Edit List by Test Time**" screen, which shows a log of previous ECG participant names. Just leave this screen here.
3. Turn the MAC PC on. (MAC-PC Operator's Manual, section 5-24, "Transmitting Locally")
4. If the ***Main Menu*** (Task, PtInfo, V1+II+V5, Rhythm, 25mm/s, 10mm/mv, More) is not displayed, then press the STOP key.
5. Once the ***Main Menu*** appears, hold down the shift key (key with 2 triangles-one on top of the other) and press the **2** key,
   Systems Functions Menu will appear
   Under ***Storage*** press **1** or **2**
6. Press either the **7** or **8** under the ***Transmit*** display
7. Press either the **3** or **4** under the word ***Local***
8. The following will be displayed—***Select by Patient ID***?
   Press **1** or **2** (under ***Yes***) if selecting those ECG's filed under one ID number.
   If **Yes,** put the ID # of the ECG wanted and press **Enter**
   Press **3** or **4** (under ***No***) if selecting from EVERY ECG in storage.
9. Either choice will bring you to the next display, which is:
   123456789 Allen, Bradley
   Yes No No... Yes... Expand
   Press key **1** or **2** under the first 'Yes' if you want to select this ECG
   Press key **3** or **4** under the first 'No' to bypass this ECG
   Press key **5** or **6** under the second 'No' to bypass this ECG and all subsequent ECG's.
   Press key **7** or **8** under the second 'Yes' to select this ECG and all subsequent ECG's.
   Pressing the **9** or the **10** key under **Expand** allows you to display additional information
10. The display reads ***Waiting for Receiver*** followed by the participant's name.
11. The ECG will now transmit and the message ***1 of 1 Transmitted*** will appear.
    Press any key to continue or press the STOP key to get back to the ***Main Menu*** and to turn off.
12. Participant's name will appear last on the **Edit List By Test Time** screen.
13. To Print: Highlight the participant's name.
    Click on **Print**
    1 System Writer will appear on screen. Click on **OK**. The ECG will now print.
16. ***Disconnect cable and leave it next to the MUSE machine***.

For the **MAC 5000** there is no need to take any further action. The ECG will print out to full size.

(13)

Internal Use Only

B. 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 clinic doctor will inform the participant's personal physician immediately.

After a contact is made with the PCP, the physician should complete a phone encounter sheet 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.

The clinic staff or field tech will distribute the charts to the doctors working in clinic in the morning. The doctor will be required to complete the field visit chart before leaving the clinic that day. The charts are not to leave the clinic area.

Once the doctor completes the chart they will return it to the appropriate off-site tech. The tech will put the chart in correct order, review the MD notes, and bring the chart to the Study Coordinator. The Study Coordinator will then forward the chart to the Data Statistician.

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 Statistician review the chart. All charts are logged out on a tracking sheet. A date completed is logged in when the routing sheet is returned to the offsite tech.

Record Of Telephone Encounter

(to be filed in chart)

Internal Use Only

Participant's ID#: _____ Participant's Name: _____

Date of Incident: ____/____/____

Person Contacted: _____

_____

Regarding: _____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Contact Made By: _____

_____

_____

Stroke Tracking Referral Form
The Framingham Study

Internal use only

* Please complete the upper portion of this form if you identify a new neurological event.

ID#:_____ Name:_____

Date Opened: ____/____/____

Date of Event: ____/____/____ Date Type:____ (0=Exact, 1=Approximate)

Source of Referral:_____

1 = Hospital Admission
2 = Biennial Exam
3 = Offspring Exam
4 = Family
5 = Medical Records
6 = Review
7 = Other (Please specify)

Initials:_____

Reason for Referral:_____

Reason for Hospitalization:_____ (1=Neurology, 2=Other, 8=NA)

Comments:_____

_____

_____

DISPOSITION (FOR TRACKING PERSONNEL TO COMPLETE)

1. Dictation:_____ (0=Awaiting, 1=In)
2. To be Scheduled in Stroke Clinic:_____ (0=No, 1=Yes, 2=Pending)
3. Date Seen in Stroke Clinic:____/____/____
4. Reason Not Seen in Clinic:_____ (1=NA, 2=Refused, 3=Deceased, 4=Out of State)
5. Part of PSIP Follow-Up Protocol:_____ (0=No, 1=Yes, 9=Unknown)
6. Previously Seen:_____ (0=No, 1=Stroke, 2=Dementia, 3=Other)
7. Medical Records needed:_____ (0=No, 1=Yes)
8. Date:____/____/____
9. CT/MRI/MRA to be obtained:_____ (0=No, 1=Yes)
10. Date:____/____/____
11. Review Status:_____ (1=Awaiting Review, 2=Reviewed, 3=Need Info)
12. Date Reviewed:____/____/____
13. Status of Case:_____ (1=Open, 2=Closed)
14. Date:____/____/____
15. Diagnosis:_____
    (1=Stroke, 2=TIA, 3=? TIA, 4=Parkinson's, 5=No CVA, 6=Other Neuro, 7=Migraine, 10=?Stroke, 20=Recurrent TIA, 9=Unknown, 11=Multiple Sclerosis

(80)

Neurology Clinic Referral Form

Internal Use Only

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

Record Of In-Clinic Medical Encounter

(to be filed in chart)

Internal Use Only

Participant's ID#: _____ Participant's Name:_____

Date of Incident: ____/____/____

Description of Incident:

_____

_____

_____

_____

_____

_____

_____

_____

Physician:_____

Follow-Up (if any)

Date of Follow-Up: ____/____/___

_____

_____

_____

_____

_____

_____

_____

Physician/Staff:_____

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Problems/Corrective Action Log

Height/Weight

Internal use only

Date	Problem	Date	Corrective Action
1/03	Scale says 50.2 when Calibrated	2/5/03	Beam spoke to scale Company - it is still ok to use if .2 over or under (it's still accurate)

Problems/Corrective Action Log

Blood Pressures

Internal Use Only

Date	Problem	Date	Corrective Action

Internal 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**

Internal Use Only

Congnitive Function
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 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
11/00

Internal 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.	
	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.	
	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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Internal Use Only

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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Internal Use Only

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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Internal Use Only

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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Internal Use Only

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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Internal Use Only

Weight and Height
Supervisor Checklist

Date:_____ Technician #:_____

Supervisor:_____ Participant name & ID #:_____

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

Weight Measurements: ***Comments:***

y n Scale is positioned at zero.

y n Participant is not wearing shoes.

y n Participant's weight is equally distributed on both feet

y n The measurement is recorded, rounding down to the nearest pound.

Height Measurements:

y n Participant is not wearing shoes.

y n Participant is standing erect with his/her back to stadiometer.

y n Participant's heels are together and against the stadiometer.

y n Participant faces straight ahead.

y n Participant is asked to take a deep breath in

y n Examiner's eyes are level with the point of measurement.

y n The measurement is recorded to the nearest quarter inch, rounding down.

Overall Comments of Supervisor:

Instructions to technician/corrective action:

_____

Signature, Supervisor 3/02

Internal Use Only

Framingham Heart Study
Intertech Quality Control Measurements

Date: _____ Pt label: _____

First Tech ID: _____ Second Tech ID: _____

Height/Weight Measurement

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

Height Measurement: _____ Repeat Height Measurement: _____

Weight Measurement: _____ Repeat Weight Measurement: _____

Keyer: _____

Anthropometric Measurements
Neck Circumference and Waist Girth

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

Neck Circumference: _____ Repeat Neck Circumference: _____
(inches, round down to the next lower ¼ inch)

Waist Girth: _____ Repeat Waist Girth: _____
(inches, round down to the next lower ¼ inch)

Keyer: _____

Blood Pressure Measurement

Each technician, paired with a second technician and out of each other's view, performs the blood pressure measurement on the same participant. If the difference is SBP and/or DBP is greater than **4mmHg**, or if the average of the readings for each technician differs by more than **3mmHg**, the measurement is repeated.

Cuff Size: _____

Palpated Systolic Pressure: _____

Systolic Blood Pressure (SBP): _____

Diastolic Blood Pressure (DBP): _____

Repeat SBP: _____

Repeat DBP: _____

Cuff Size:
0= Pedi
1= Regular
2= Large
3= Thigh

Keyer: _____

Problems/Corrective Action Log

Cognitive Function and Physical Activity Questionnaires

Internal Use Only

Date	Problem	Date	Corrective Action

Problems/Corrective Action Log

ECGs

Internal Use Only

Date	Problem	Date	Corrective Action