

FRAMINGHAM HEART STUDY

COHORT EXAM 26

OFFSITE VISIT PROTOCOL

Start Date: 4/3/2000

Table of Contents

<u>Section</u>	<u>Title</u>	<u>Page</u>
1.	Exam Components	1
2.	Equipment for Exam Procedures	3
3.	Preparation for an Offsite Examination	5
4.	Proposed Sequence of Exam	6
5.	Interviewing the Elderly	7
6.	Visiting the Cognitively Impaired	8
7.	Informed Consent	9
8.	Nursing Home Chart Review Protocol	10
9.	Update Sociodemographic Data	12
10.	Guidelines for Coding Accuracy	13
11.	Numerical Data Sheet	14
12.	Medical History Questionnaire (Screens 1-13)	15
13.	Procedure to Determine Maximal Inflation Level	44
14.	Seated Blood Pressure	45
15.	Weight Measurement	47
16.	ECG Lead Placement	48
17.	Cognitive Function: The Mini-Mental Status Examination	51
18.	Sociodemographics and Subjective Health	59
19.	Activities of Daily Living: Self Reported Performance	61
20.	Rosow-Breslau	64

21.	Nagi	66
22.	CES-D	68
23.	Berkman Social Network Questionnaire	72
24.	Technician Obtained Measures of Observed Physical Performance	77
25.	Off-Site Visit Chart Completion	83
26.	Appendix	86
	A. Exam Forms	
	B. Exam Referral Forms	
	C. Supervisory Observation Forms	
	D. Problems/Corrective Action Log	
	E. Reference Article	

write by

Offsite Cohort 26 Exam Components

1. Obtain informed consent and update of sociodemographic information.
2. Technician Administered Medical Questionnaire (same as physician-administered Medical Questionnaire for on-site exam)
 - A. Hospitalizations, Emergency Room Visits, Physician Visits
 - B. Medications
 - C. Female Hormone Replacement
 - D. Prostate Disease
 - E. Thyroid Disease
 - F. Smoking Status
 - G. Alcohol Intake
 - H. Respiratory/CHF Questions
 - I. Chest Pain
 - J. Syncope History
 - K. Cerebrovascular Episodes
 - L. Peripheral Vascular History
 - M. Cardiovascular Procedures
 - N. Cancer History
3. Technician Obtained Resting Blood Pressure
4. Technician Administered Questionnaires
 - A. Cognitive Function/MMSE
 - B. Sociodemographics
 - C. Subjective Health
 - D. Activities of Daily Living
 - E. Use of Nursing and Community Services
 - F. Rosow-Breslau Questions
 - G. Nagi Questions
 - H. Falls/Fractures
 - I. CES-D Scale
 - J. Berkman Social Network Questionnaire

Offsite 65

5. Technician Obtained Measures of Observed Physical Performance
 - A. Hand Grip Strength
 - B. Stands
 - C. Measured Walks
 - D. Repeated Chair Stands
6. Electrocardiogram
7. Weight Measurement

Equipment For Exam Procedures

1. SECA Portable Scale Model #810/815 to measure body weight in lbs. *bs005*
2. Weight to calibrate scale: 50 lbs.
Worcester Scale Co., Inc. *bs005*
228 Brooks Street
Worcester, MA
508-853-2886
3. Microcomputer Augmented Cardiograph (MacPc) (cardiogram computer)
Marquette Electronics
100 Marquette Drive
Jupiter, FL 33468-9100
800-552-3249
800-559-7072 (Tech Support)
800-558-5544 (Sales Rep) *EKG*
bs483-bs517
4. Power module for MacPc: Part #9518-001
Marquette Electronics (See above)
5. Power Aneroid Sphygmomanometer (gauge only): Moded 5090-03
Tycos Instruments, Inc.
95 Old Shoals Road
Arden, NC 28704 *bs015, bs016*
bs312, bs313
bs479, bs480
6. Litman stethoscope tubing and earpieces with bell: Classic II
7. Blood pressure cuffs in three sizes: large, regular, and pediatric.
8. JAMAR dynamometer, stop watch
Sammons Preston *bs200-bs228*
4 Sammons Court
Bolingbrook, IL 60440
800-323-5547

8/21/07

Field Equipment Calibration Time Table

<u>Activity</u>	<u>Daily</u>	<u>Weekly</u>	<u>Monthly</u>	<u>Yearly</u>
Recharge ECG Battery			X	
Manometer			X	

8/24/05

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
- 3 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 and paperwork for Exam 26

Preparation

The day before scheduled Heart Study visit it is best to call the participant to remind them. 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 available also. If participant states he/she has not filled out the form, just ask them to try and recall their medical history for the past two years, including physician visits.

In the case of a Nursing Home visit, one should ask to speak with the nurse assigned to the participant that day. Remind the nurse of pending visit and ask if participant can be dressed in a top that opens in the front. Also 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

1. Obtain Informed Consent
2. Update Sociodemographic
3. Update Interim Medical History
4. Blood Pressures (2)
5. MMSE and Activity Questionnaires
6. Weight
7. ECG
8. Observed Physical Performance
9. Exam 25 Chart Completion

Interviewing The Elderly

In the very elderly (those over 75), fatigue tends to set in after about a half an hour (1). Even with those who are well-motivated and in good health, interviews that exceed 45 minutes may lead to the respondents giving unreliable and inaccurate information (1). An average exam 25 visit lasts about 90 minutes. The order of the exam is critical.

Those of a different generation may be unfamiliar with terms and phrases used in modern society. For instance, in the medical section, a participant may be unfamiliar with certain procedures and, or medical terminology. Being able to present an alternative description of the item or procedure is critical.

Many participants may be either visually or hearing impaired. This information may be obtained from their prior FHS visit summary or volunteered by the participant themselves. The handouts for the exam should thus be in large, bold type to facilitate reading. When reading the questions, enunciate and speak slowly. If the participant cannot understand what is being asked, they may become frustrated and this sets a negative tone for the remainder of the visit.

For many homebound elders, having a visitor is an event. They may relish the opportunity to talk and it may be difficult to obtain a response without a digression. Ironically, the more they digress, the longer the exam, and the more tired they become. In order to obtain accurate data, it is necessary to tactfully and patiently turn the conversation back to the interview.

(1) Kelsey JL, O'Brien LA, Grisso JA, Hoffman S. Issues in Carrying Out Epidemiologic Research in the Elderly. American Journal of Epidemiology 1989; 130: 860.

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	Give clear instructions instead of asking questions
Do not try to reason	Keep communication in the present
Keep information simple	Use sensitive touch when possible
Use given names	Give frequent acknowledgment and encouragement
Use eye contact	Ignore misinformation and simply acknowledge the communication
Give one direction at a time	

When a participant is not known to be cognitively impaired prior to the examination and there appears to be memory difficulties at the time of the visit, the MMSE should be performed immediately. If the total MMSE score is < 23 or if their MMSE score has decreased three or more points over the last 2 years their exam should be aborted. The dementia study should then be notified so a dementia study visit can be performed to determine the presence of a cognitive impairment requiring consent by substituted judgment before rescheduling core exam.

Informed Consent

It is imperative that before any information is gathered from the participant that he or she has signed the consent form(s).

For those cohort participants who are not cognitively impaired, an opportunity to read the consent form(s) must be given. For those who are visually impaired or who opt not to read the form(s) a detailed summary of what is contained in the consent form(s) must be given. The participant should be given the opportunity to ask any questions regarding information contained in the consent.

When the participant signs the form they must also write in the date. In the case where the handwriting of the participant does not clearly depict the date, the date may be written underneath by the interviewer and initialed.

Cognitively impaired cohort must have consent forms signed by a proxy. A consent by substituted judgment form is used. These signed consents must be obtained before the off-site visit is made, unless the proxy will be at the site at the time of the visit.

Nursing Home Chart Review Protocol

When visiting a participant in a Nursing Home, most of the necessary interim information may be obtained through the careful 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 kindly ensure that the chart will be available upon your arrival.

1. Updating sociodemographic data

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, salmon colored sheet, they should be documented, along with their addresses and phone numbers.

Check the bottom of the salmon 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, if they are legible.

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.

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 worth of information is present, always ask to see the whole interim period. This will ensure that nothing is missed.

Waste 75

Update Sociodemographic Data

Personal and family information are found on the Personal and Family History, salmon colored sheets. The information can be obtained from either the participant, the proxy, or the chart at a long term care facility.

Since this sheet, in its original form, is carried from cycle to cycle, there is a great effort to maintain its neatness. Updated information regarding the participant's current address, physician, and two contacts should be written on the photocopied sheet provided. The data is transferred over at a later time. It is very important to obtain at least one contact so that in case the cohort cannot be located, there is a way to track them.

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 life status (living or dead) and health status should be documented.

8/5/12 76

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. Do not leave any blanks on exam form. If measurements are not taken, please enter 9s in blanks, and document the reason. 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.

Numerical Data Sheet

Site of Exam

bs001

Coding

1 = Nursing Home

2 = Residence

3 = Other (living situations that would not fit into the category of either 1 or 2)

Marital Status

Confirm marital status with participant. bs003

Examiner's Number

Fill in interviewer three digit number. bs004

Weight bs005 - bs007

Record weight measurement obtained with the portable Framingham scale. If unable to obtain participant's weight on portable scale (ie the participant is not able to stand to take measurement) enter weight obtained from nursing home measurement.

Proxy Information bs009 - bs014

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 the 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.

Exam 26 Procedure Sheet bs018, bs019, bs021

ECG done

Blood drawn

Observed Performance Measure

Coding

0 = No

1 = Yes

9 = Unknown

Basic Background and Healthcare (Screen 1)

1. Hospitalization in interim *bs230*
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 two or more times

2. E.R. visit in interim *bs231*
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 and discharged from the emergency room.

Coding

0 = No, participant had no visits to the E.R.

1 = Yes, participant had only one visit to the E.R.

2 = Yes, participant had two or more visits to the E.R.

3. Day surgery in interim *bs232*
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, no day surgery

1 = Yes, participant has had one or more day surgeries

4. Illness with visit to the doctor in interim *JS233*
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 not uncommon that some participants do not have regular check-ups but only see their physician when something is wrong. If the participant had something wrong, but waited until his/her scheduled visit, that is considered a check-up. Many participants also have more than one physician, e.g. if someone visits their cardiologist every 3 months, and in the interim saw their primary care physician, these are still all check-ups. It is imperative that the reason for the visit be documented.

Coding

0 = No visits outside of regular check-ups

1 = Yes, participant had only one visit to the doctor due to illness

2 = Yes, participant had two or more visits to the doctor due to illness

5. Check-up in interim by doctor *JS234*
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 and is usually scheduled at regular intervals.

Coding

0 = No, participant did not have a check-up

1 = Yes, participant did have a check-up, regardless of number

Details of all hospitalizations, ER visits, day surgery, and physician visits must be provided as follows:

1. 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).
2. 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.

JS 234

- 65234
3. **Site of the hospital or office**
The hospital and the town are most important.
 4. **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.

First Examiner - Cardiovascular Medications (Screen 2)
First Examiner - Other Medications (Screen 3 & 4)

1. Currently Receiving Medication for Treatment of Hypertension *JS 236*
Are you taking any medications for high blood pressure?

Although this question is straightforward, many do not know what their medications are for.

Coding

0 = No

1 = Yes

9 = Unknown

2. Take Aspirin Regularly *JS 265 - JS 268*
Do you take aspirin regularly?

Regularly here refers to taking aspirin on a scheduled basis. Taking aspirin for the occasional headache is not valid, unless there is a pattern i.e. two aspirin per month for headaches. Be sure to clarify that ASA does not include Tylenol, Advil, Motrin, etc.

Coding

0 = No

If the participant answers in the affirmative, then the following three categories need to be fulfilled.

- A. Number of aspirins taken regularly
How many aspirins do you take at one time?

Try to establish whether this is the number of aspirin usually taken.

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

- C. Usual aspirin dose
How many milligrams do you take? (81 mg = baby aspirin, 325mg = regular adult aspirin, 500 mg = extra strength adult aspirin).

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.

JS237-JS264
JS269-JS311

Technician Blood Pressure Readings (Screen 4)

BS312, BS313, BS479, BS480

Two blood pressures, spaced at least ten minutes apart, should be obtained during the offsite visit. Interspaced areas are printed in the medical history portion of the exam for blood pressure documentation.

Adherence to blood pressure protocol methods should be maintained (see technician's blood pressure in this manual). On offsite visits, however, there are occasions when the participant is in a supine position and cannot be raised to the sitting position. Blood pressure should still be obtained but a note should be made of the protocol change next to recorded pressure.

NOTE: Screen 13 is the same as Screen 4.

BS 84

Medical History - Genitourinary and Thyroid Disease (Screen 5)

1. Female Hormone Replacement JS 314 - JS 321

Since (date of last FHS exam) have you taken any female hormone replacements such as:

*Estrogen – If yes probe if oral or via patch.
How many days of the month?*

Estrogen cream

*Progestin – If yes ask what the dose is.
How many days of the month?*

2. Prostate Disease JS 322, JS 323

Prostate Trouble JS 322

Since (date of last FHS exam) until today, have you experienced any trouble with your prostate?

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. Document exactly what the trouble is and code according to the participant's response. If the participant states that he has had trouble in the interim, it should be determined whether he still experiences the trouble or if it was alleviated in the interim.

Coding

0 = No, participant states that he has had no trouble

1 = Yes, now, participant states that he presently still has the trouble

2 = Yes, not now, participant presently does not have the trouble

JS He 85

Prostate Surgery 15323

Since (date of last FHS exam) until today, have you had any prostate surgery?

If the participant answers in the affirmative it again must be determined whether or not he has had the surgery in the interim, if so, it should be listed on medical encounter area of screen 1.

Coding

0 = No

1 = Yes, now

2 = Yes, not now

3. Thyroid History 15324

Since (date of last FHS exam) until now, have you been diagnosed with a thyroid condition?

Coding

0 = No

1 = Yes, he/she has been diagnosed in the interim

Probe to find the exact diagnosis and onset. Record the information in the "comments" area provided.

15324

Alcohol Consumption and Smoking (Screen 6)

1. Alcohol Consumption

Do you now consume, or have you ever consumed at least 12 drinks of any type of alcohol during the period of a year? *bs325*

Be sure participant understands question refers to the present and past.

Ever in your life did you have at least a drink a month of any type of alcohol including beer, wine, or liquor/spirits?

Coding

0 = No

1 = Yes

9 = Unknown

2. *During the past year have you consumed at least 12 drinks of any type of alcohol (beer, wine, or spirits)?* *bs326*

Coding

0 = No

1 = Yes

9 = Unknown

If yes: Determine what type of alcohol and usual consumption

In the past year, have you had any beer? *bs327*

Circle No or Yes on the form.

If Yes, ask participant if they usually drink at least one beer per week. *bs328, bs329*

Coding

0 = Less than 1 per week

1-7 = For average number of days per week participant drinks beer

99 = Unknown

Write 87

If participant drinks less than 1 beer per week:

bs330

Ask participant average number of beer consumed per month.

Coding

0 = More than 1 per week

99 = Unknown

Repeat the same series of questions for:

bs331-bs346

- White wine including rose, champagne
- Red wine including port, sherry
- Other wine
- Liquor/Spirits (often participants will refer to these drinks as cocktails or highballs)

Fill in each corresponding section of the form.

2. Smoked Cigarettes in the Last Year

Have you smoked cigarettes regularly in the last year?

bs347

Coding

0 = No, have not smoked

1 = Yes, have smoked regularly in the last year

Ask the participant how many cigarettes do or did they smoke a day and record the number in the area provided.

bs348

White 88

Respiratory Questions (Screen 7)

All of the following questions should be asked in the exact wording. Exceptions can be made if the participant had difficulty understanding the question in its original form.

1. *Do you usually cough on most days for 3 consecutive months or more during the year?* *bs349*

Coding

0 = No

1 = Cough is new since their last FHS exam

2 = Cough is old, meaning had it at time of last FHS exam

9 = Unknown

(Alternative Inquiries: *Have you had a chronic cough, one that would not go away, that lasts for three or more months? 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?* *bs350*

Coding

0 = No

1 = Yes

9 = Unknown

(Alternative Inquiry: *Do you bring up phlegm from your chest on most days for at least three months out of the year?*)

3. *Have you had asthma in the interim?* *bs351*

Coding

0 = No

1 = Yes, if asthma was new in interim

2 = Yes, if cohort had asthma in interim but also had it at time of last FHS exam

9 = Unknown

(Alternative Inquiry: *Have you had any asthma attacks or been diagnosed with asthma since (date of last FHS exam)?*)

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

bs352

Coding

0 = No
1 = Yes
9 = Unknown

5. Night cough

Do you experience a night cough? bs353

Coding

0 = No
1 = Yes
9 = Unknown

6. Dyspnea on exertion

Do you experience shortness of breath when you exert yourself? bs354

Depending on the physical state of the participant, what is defined as exertion can vary. It is best to ask then, *What is the least amount of exertion that makes you short of breath?*

Coding

0 = No dyspnea
1 = Dyspnea that occurs when climbing stairs or vigorous exercise
2 = Dyspnea that occurs with rapid walking or moderate exercise
3 = Dyspnea that occurs with any slight exertion
9 = Unknown

7. Dyspnea has increased over the past two years

Has your shortness of breath increased over the past two years? bs355

This can also be phrased as: *Has your shortness of breath worsened over the past two years? Has your breathing become more difficult 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? *bs 356*

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.*)

9. Have you awakened suddenly, very short of breath, gasping or choking for air?
If yes: How often does this occur? *bs 357*

Coding

0 = Never experience it
1 = Experience this once or twice a year
2 = Experience this a few nights a month/or under special circumstances
3 = Experience it at least once a week, but irregular pattern
4 = Experience it 3 to 5 nights a week
5 = Experience it 5 to 7 nights a week
9 = Unknown

10. Ankle edema bilaterally
Do both of your ankles swell? *bs 358*

Coding

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

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? *bs 359*

Coding

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

12. Been hospitalized for heart failure in interim *JS360*
Since (date of last FHS exam) until today, have you been hospitalized for heart failure?

Coding

0 = No

1 = Yes

2 = Maybe

9 = Unknown

If yes: should be detailed on screen 1.

The last area containing "Respiratory Examiner Opinions" are not to be filled out by offsite interviewer, but to be filled out by the physician completing the chart. *JS361, JS362*

First Examiner-Coronary Heart Disease Opinions In Interim (Screen 8)

Any chest discomfort since last exam? *bs 363*

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)

When the participant states that they have not experienced any chest discomfort, ask further *chest pain, tightness, pressure*. If none have been experienced, 0 = No can be coded and the interviewer can move on to screen 8.

When the patient responds that they have experienced chest discomfort, descriptive characteristics of the discomfort must be obtained.

For "Yes" responses:

1. Chest discomfort with exertion or excitement *bs 364*
Have you experienced chest discomfort with exertion or when excited, such as times of emotional upset?
2. Chest discomfort when quiet or resting? *bs 365*
Have you experienced chest discomfort when quiet or resting?

Coding

0 = No

1 = Yes

2 = Maybe

3 = Unknown

Chest Discomfort Characteristics:

To answer these, interviewer must have coded either 1 or 2 at top.

- a. Date of Onset *bs 366, bs 367*
When did the discomfort first begin?

Code as month and year.

Coding

99/99 = Unknown

bs 4e 93

- b. Usual Duration *65368*
How long does the discomfort usually last?

Code in minutes.

Coding

999 = Unknown

- c. Longest Duration *65369*
What is the longest amount of time the discomfort lasted?

Code in minutes.

Coding

900 = 15 hours or more

999 = Unknown

- d. Location *65370*
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 *65371*
Does the pain (or pressure) move around at all?

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 *bs372*
How many episodes of chest discomfort have you experienced in the past month?

Code as number of episodes.

Coding

999 = Unknown

- g. Frequency *bs373*
How many episodes of chest discomfort have you experienced in the past year?

Code as number of episodes.

Coding

999 = Unknown

- h. Type *bs374*
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 *bs375*
Does taking Nitroglycerin resolve the discomfort in less than 15 minutes?

Be sure to code **8** not **0** if the participant has never used Nitroglycerin.

Coding

0 = No

1 = Yes

8 = Not tried

9 = Unknown

- j. Relief by rest in less than 15 minutes *bs376*
Does rest relieve the discomfort in less than 15 minutes?

Coding

0 = No

1 = Yes

8 = Not tried

9 = Unknown

- k. Relief spontaneously in less than 15 minutes *bs 377*
Does the discomfort relieve itself spontaneously in less than 15 minutes?

Coding

- 0 = No
1 = Yes
8 = Not tried
9 = Unknown

- l. Relief by other cause in less than 15 minutes *bs 378*
Is the discomfort relieved in any other way in less than 15 minutes?

Coding

- 0 = No
1 = Yes
8 = Not tried
9 = Unknown

NOTE: The "First CHD Opinions" section at the bottom of screen 7 is not to be filled out by the interviewer. It is to be filled out by the physician. *bs 379 - bs 382*

NOTE: It is critical to use the comment section to write a narrative description of the chest discomfort.

At the very bottom of screen 7 is an area for the interviewer to write comments about the chest discomfort. This should be very descriptive of the discomfort, how it is relieved and any other relevant details, including specific activities or situations that bring on 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.

Write 9/6

First Examiner-Syncope History In Interim (Screen 9)

Have you fainted or lost consciousness in the interim? *bs 383*

This may be asked exactly as written.

Coding

0 = No

1 = Yes

2 = Maybe

9 = Unknown

If participant has experienced loss of consciousness due to a stroke, skip to screen 9.

If the participant has experienced no episodes of fainting or loss of consciousness in the interim, move to screen 9.

If the participant has fainted or lost consciousness or is unsure, record the descriptive data regarding the events.

1. Number of episodes in past two years *bs 384*
How many times in the past two years have you fainted or lost consciousness?

Code as number of events.

Coding

99 = Unknown

2. Date of first episode *bs 385, bs 386*
Do you recall the first time you fainted or lost consciousness (in past 2 years)?

Code as date: month and year.

Coding

99 = Unknown

3. Usual duration of loss of consciousness *bs 387*
How long are you usually unconscious for?

Code in number of minutes.

Coding

999 = Unknown

4. Injury caused by the event *bs 388*
Did you have any injury caused by the event?

May be asked as written.

Coding

0 = No

1 = Yes

2 = Maybe

9 = Unknown

5. ER/Hospitalized or saw M.D. *bs 389*
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. or the medical facility where he/she was seen.

NOTE: The area entitled "Syncope Opinions" at the bottom of the page is not to be completed by the interviewer but by the physician. *bs 390 - bs 394*

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

First Examiner-Cerebrovascular Episodes In Interim (Screen 10)

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 *bs395*
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 in an arm or leg?

Coding

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

2. Sudden Speech Difficulty *bs396*
Since (date of last FHS exam) until today, have you experienced any sudden difficulty with your speech?

Coding

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

3. Sudden Visual Defect *bs397*
Since (date of last FHS exam) until today, have you experienced any sudden visual defect?

Coding

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

4. Double Vision *bs398*
Since (date of last FHS exam) until today, have you experienced any double vision?

Coding

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

Write 99

5. Sudden Loss of Vision in One Eye *bs399*
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?

Coding

0 = No

1 = Yes

2 = Maybe

9 = Unknown

6. Unconsciousness *bs400*
Since (date of last FHS exam) until today, have you experienced any episodes of unconsciousness?

Coding

0 = No

1 = Yes

2 = Maybe

9 = Unknown

7. Numbness, Tingling *bs401, bs402*
Since (date of last FHS exam) until today, have you experienced any numbness or tingling anywhere in your body?

Coding

0 = No

1 = Yes

2 = Maybe

9 = Unknown

8. CT Scan or MRI (of head) Since Last Exam *bs403*
Since (date of last FHS exam) until today, have you had either a CT Scan or an MRI done of your head?

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.

9. Seen by Neurologist Since Last Exam *bs 404*
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 *bs 405*

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 = None took place
1 = An event did take place
2 = Perhaps an event took place
9 = Unknown

If this is 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? *bs 406, bs 407*

Coding

- 99-99 = Unknown

Was it observed by anyone?

Document who witnessed event.

- b. Onset time *bs 408*
What were you doing when the event took place?

Coding

- 1 = Active
2 = During sleep
3 = While rising
9 = Unknown

bs 404

- c. Exact/approximate time *65409*
Do you recall at what time the event occurred?

Code time by using 24-hour military time.

Coding

99-99 = Unknown

- d. Duration *65411-65413*
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. *65414*
Did you see your physician or go to the hospital?

Coding

0 = No

1 = Hospitalized

2 = Saw M.D.

9 = Unknown

- f. Number of days stayed at..... *65415*
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

“Cerebrovascular Disease Opinion” is not be completed by the interviewer. It is to be filled out by a physician. *65416-65419*

NOTE: Use the comment section to provide a narrative description of any symptoms that occurred.

offsite 102

First Examiner-Peripheral Vascular History And Opinion (Screen 11)

1. *Can you walk 50 feet without any help?* *bs420*

Coding

0 = Able to walk 50 feet without any help

1 = Need of help

2 = Cannot walk

9 = Unknown

2. *Do you have lower limb discomfort while walking?* *bs421*

Coding

0 = No

1 = Yes

2 = Cannot walk

9 = Unknown

If Yes:

a. *Discomfort in calf while walking?* *bs424, bs425*

Coding

0 = No

1 = Yes

9 = Unknown

Code left and right legs separately.

b. *Discomfort in lower extremity (not calf) while walking?* *bs426, bs427*

Coding

0 = No

1 = Yes

9 = Unknown

As above, here also code separately for left and right legs.

c. *Occurs with first steps?* JS428

Coding

0 = No

1 = Yes

9 = Unknown

d. *After walking a while?* JS429

Coding

0 = No

1 = Yes

9 = Unknown

e. *Related to rapidity of walking or steepness?* JS430

Coding

0 = No

1 = Yes

9 = Unknown

f. *Forced to stop walking?* JS431

Coding

0 = No

1 = Yes

9 = Unknown

g. *Time for discomfort to be relieved by stopping (minutes)?* JS432

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

Coding

00 = No discomfort.

88 = Non-applicable or participant walks through the discomfort without relief with rest

h. *Number of days out of a month of lower limb discomfort?* JS433

Code as number of days out of a month that cohort experiences leg discomfort.

Coding

00 = No

88 = Non-applicable.

99 = Unknown.

3. Venous Disease *bs434, bs435*

Have you had a blood clot in the veins in your legs or arms since we saw you last?

Coding

0 = No

1 = Yes

9 = Unknown

“Intermittent Claudication Opinions” is to be coded by the reviewing physician. It is not to be coded by interviewer. *bs436*

NOTE: It is critical to provide a narrative description of the leg discomfort under comment section.

bs434 105

Cardiovascular Procedures (Screen 12)

bs437 - bs459

Cardiovascular Procedure (in the interim only, not lifetime)

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

The procedures are all cardiovascular in nature:

- a. *Coronary arteriogram*
- b. *Bypass surgery*
- c. *Carotid surgery etc.*

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.

Cardiovascular Procedures in Interim Summary:

This area is provided for interviewer to list all subsequent cardiovascular procedures. Data to be obtained is date of procedure, location and type of procedure.

bs site 106

First Examiner-Cancer Site or Type (Screen 13)

65460-65478

Have you, since your last clinic visit, had cancer or a tumor?

The answer will be coded by the examiner as:

- 0 = No
- 1 = Yes
- 9 = Unknown

For code 1, more information must be obtained.

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

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.

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.

Site 107

Procedure To Determine Maximal Inflation Level
For Blood Pressure Measurement

BS015, BS016, BS312, BS313, BS479, BS480

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

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

Technician's Seated Blood Pressure

JS015, JS016

A. Equipment:

1. One standard Litman stethoscope tubing and earpieces with bell: Classic II 3M
2. One standard mercury column sphygmomanometer: Baumanometer
3. BP cuffs in three sizes

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. 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.

65015, 65016

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.

D. Blood Pressure Readings:

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

Weight Measurement

65005

1. The participant should remove slippers or shoes.
2. Prior to asking participant to step onto the scale, turn scale on, check to make sure it reads 0.0.
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 him/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 .**
8. Calibrate the scale with each visit.

ECG Lead Placement

65482 - 65517

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

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.

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.

bs482 - bs517

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. Record the **E** measurement on the ECG log sheet. Record the measurement to the nearest **0.5** cm (e.g. 16). Log the reading where the two sections of the Heart Square meet (e.g. 12) under **V6** on the log sheet (see Heart Square diagram for reference).

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

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

6. **V3**: Exactly halfway between **V2** and **V4**.
7. **V5**: Exactly halfway between **V4** and **V6**.
8. Attach limb leads in the following order: right leg, left leg, right arm, left arm. This will avoid lead reversal.
9. 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.
10. 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.

bs482-bs517

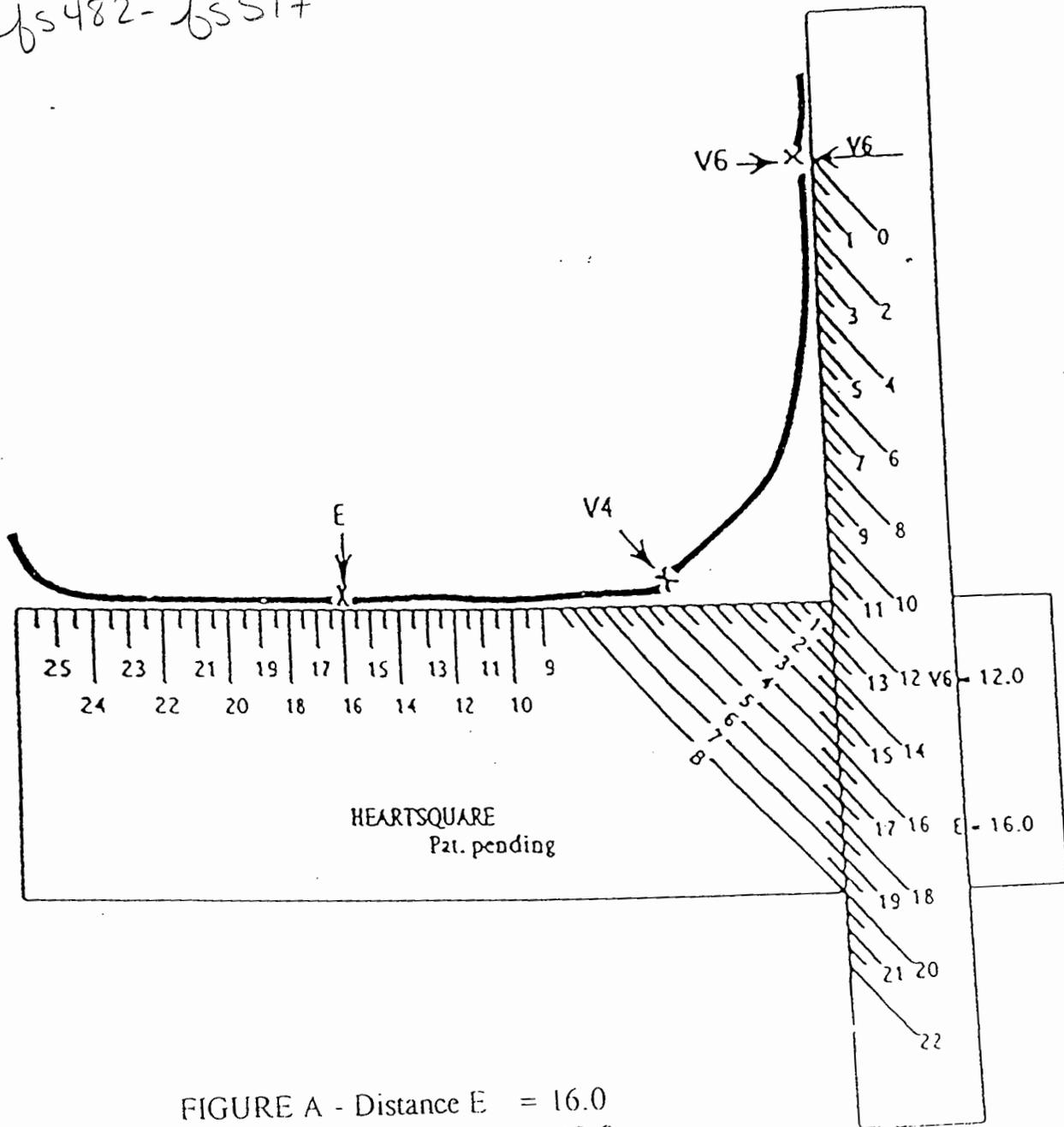


FIGURE A - Distance E = 16.0
- Distance V6 = 12.0

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

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

bs482-114

Mini-Mental State Exam

165023 - 165048

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 Senile Dementia of the Alzheimer's Type (SDAT).

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

B. Definitions:

1. **Alert Level:** Participant scoring 23 or less on the MMSE may have a cognitive impairment and will be referred for further evaluation. Referral forms may be obtained from the clinic. They should be filled out and sent to Maureen Valentino, Research Assistant.
2. **Mini-Mental State Exam Scoring:** The MMSE will be computer scored.

C. Methods:

1. The MMSE asks questions to ascertain cognitive status. Responses are scored **correct** or **incorrect**.
2. If a response is ambiguous, the interviewer records the response in the margin so a decision can be made on its appropriateness.
3. When a participant is incapacitated by blindness, has a functional disability, is illiterate, or is otherwise unable to respond to all questions, the interviewer should specify the problem and questions involved (see "Examiner's Impression" later in the section).

D. Expanded Scoring Instructions for Mini-Mental Exam:

Important note: 0 is meant to represent whenever subjects demonstrate the inability to correctly answer a particular item. They refuse to listen to the question, they have not demonstrated that they can answer the question, they have

165023-115

65023-65048

only indicated they do not want to answer it. If subjects give no response it will not always be clear why, again, it has been demonstrated that they have not answered it.

1 - 5 = Correct response(s). Note that the scoring method for spelling WORLD backwards has been standardized. (Scoring is shown later in this section.)

Important note: Sometimes 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). 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.

6 = When a test item is administered and no response is given, regardless of why (such as when a person is too severely demented, or refuses to respond to that single item (but does respond to other items on the test -- right or wrong).

Important note: The single exception to scoring **6** for no response is if a subject is in a coma (this circumstance would be encountered in a nursing home visit, not in a clinic 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 (if subject refuses entire test, then all items were not administered and should be scored **9**).

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. Remember, 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).

Write 116

65023-65048

Scoring Entire Test:

Add up all correct responses. The total score must be less than or equal to **30** (give **6** or **9** scores a value of **0**). EXCEPT:

Score

- 99** If ALL items are scored **9**
- 66** If ALL items are scored **6**
- 99** If MOST items are scored **6** and or **9** and it is unclear whether the participant was able to answer questions.

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. No response, but participants attempted to respond (i.e. they are demonstrating that they heard the question and are making an attempt to respond to it).

Examiner's Impression:

The examiner's impression for Cohort Cycle 26 will include the following:

<u>NO</u>	<u>YES</u>	<u>MAYBE</u>	<u>UNKNOWN</u>	
0	1	2	9	Illiteracy or low education
0	1	2	9	Not fluent in English
0	1	2	9	Poor eyesight
0	1	2	9	Poor hearing
0	1	2	9	Depression/possible depression
0	1	2	9	Aphasia
0	1	2	9	Coma
0	1	2	9	Parkinsonism/other neurologic disorder
0	1	2	9	Other

E. Questions: Scripts and Procedures for Each Question:

Introductory Script: *I would like to ask you a few questions dealing with concentration and memory. Some questions may seem easy and others may be a bit more difficult.*

88 site 117

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

1. *What is the date today?* (3 = correct score for month, day and year) JS023

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

2. *What is the season?* JS024

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

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

3. *What day of the week is it?* JS025

4. *What town, county, and state are we in?* JS026

- a. Ask the participant what town, county, and state we are in. Then ask

5. *What is the name of this place?* JS027

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

6. *What floor of the building are we on?* JS028

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. JS029

- 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. Participant should repeat the items in the same order.
- e. Read *Apple, Table, Penny.*
- f. Script: *Could you repeat the three items for me?*
- g. Record the score for the first trial.
- h. 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.
- i. If, items are repeated in correct order, score 3 points.

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 scored later). JS030

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

9. What are the 3 objects I asked you to remember a few moments ago? JS031

- a. Items may be repeated in any order.

10. What is this called? (Watch) JS033

11. What is this called? (Pencil) JS034

- a. Show the wrist watch/pencil to the participant. NOTE: the pencil should be a standard sharpened wooden pencil with eraser.
- b. Correct responses include: watch, wristwatch, timepiece.
- c. Code 1 = correct for correct answer.

12. Please repeat the following: No ifs, ands or buts. JS 035

- 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.

13. Please read the following and do what it says. JS 036

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

14. Please write a sentence. JS 037

- 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 0 = 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.

JS 120

15036

PLEASE CLOSE YOUR EYES

12/14/05

15. Please copy this drawing. 65038

- a. Script: *Here is a drawing. Please copy the drawing on the same piece of paper.*
- b. If the participant asks if the figures should be drawn separately or together the examiner should respond, *Draw the figures as you see them.*
- c. To be correct, each pentagon must have 5 sides, 5 sides that point outward. The two figures must be overlapping.
- d. The overlap figures must have 4 sides.
- e. Code "0" = incorrect when the participant's figure did not match.

16. Take this piece of paper in your right hand, fold it in half with both hands, and put it in your lap. 65039

- 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 each correctly performed act (code **6** if low vision).

Sociodemographics and Subjective Health

A. Sociodemographics

1. *Where do you live?* 65050

Coding

0 = Private residence

1 = Nursing home

2 = Other facility, such as continuing care, retirement community or assisted living facility

9 = Unknown

2. *Does anyone live with you?* (NOTE: Code nursing home resident as NO to these questions.) 65051

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:

Spouse 65052
Significant other 65053
Children 65054
Friends 65055
Relatives 65056
Pets 65057

Coding

0 = No

1 = Yes, less than 3 months per year

2 = Yes, more than 3 months per year

9 = Unknown

65051, 123

3. *Are you currently working at a paying job?* J5058

Coding

0 = No

1 = Yes, full time (\geq 32 hours)

2 = Yes, part time ($<$ 32 hours)

9 = Unknown

4. *Do you currently do unpaid volunteer or community work?* J5059

Coding

0=No

1=Yes

9=Unknown

5. *During the past 6 months (180 days) how many days were you so sick that you were unable to carry out your usual activities?* J5060

Coding

999 = Unknown

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

5. *In general, how is your health now?* J5061

Coding

1 = Excellent

2 = Good

3 = Fair

4 = Poor

9 = Unknown

6. *Compare your health to most people your own age:* J5062

Coding

1 = Better

2 = About the same

3 = Worse than most people your own age

9 = Unknown

Activities of Daily Living: Self Reported Performance

65064-65074

Activities Part I

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:

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

The answers will be coded by the examiner as:

- 0 = No help needed, independent
- 1 = Uses device, independent
- 2 = Human assistance needed, minimally dependent
- 3 = Dependent
- 4 = Does not do during a normal day.
- 9 = Unknown

The activities include:

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

8546 125

65064-65074

4. Transferring
 - Getting in and out of a chair
 - Arising from a sitting position to a standing position and back
 - Devices such as: sliding board, grab bars, special seat.
5. Toileting activities
 - Using the bathroom facilities and handling clothing
 - Devices such as: special toilet seat, commode.
6. Bladder continence
 - Ask if person has "accidents" (code =5 if use special products)
 - Devices such as: external catheter, drainage bags, ileal appliance, protective device.
7. Bowel continence
 - Ask if person has "accidents" (code=5 if use special products)
 - Devices such as: suppositories, bedpan, regular enemas.
8. Walking on a level surface about 50 yards (length of Thurber St.)
 - Devices such as: cane, crutches, or walker.
9. Walking up and down one flight of stairs
 - Can climb front steps of 5 Thurber Street
 - Devices such as: handrail, cane.
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, amplification.
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.

Activities Part II

1. *Are you in bed or a chair for most or all of the day (on the average)?* 65076
2. *Do you need a special aid (wheelchair, cane, or walker) to get around?* 65077-65081

A. Use of Nursing and Community Services:

Coding for the following questions is:

- 0 = No
- 1 = Yes
- 9 = Unknown

Ask the participant, *In the past two years have you been admitted to a nursing home (or skilled facility)?*

65083

In the past two years, have you been visited by a nursing service, or used home, community or outpatient programs?

65084

Ask which services were used and how often.

65085 - 65111

1. Home health aides
2. Homemaker visits
3. Visiting nurses
4. (PCA) Personal Care Attendant
5. Rehabilitation services (such as physical therapy, occupational therapy, speech therapy)
6. Cardiac rehabilitation
7. Meals on wheels
8. Community day programs
9. Other (Specify _____)

Coding

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

Site 127

Rosow-Breslau Questions

BS113 - BS119

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.

Definitions:

This section contains definitions of the activities, symptoms, and diseases identified in the Assessment of Physical Functioning Form.

Activities:

1. Walking one half mile or four to six city blocks. Walk this distance without stopping for more than five minutes.
2. Walking around home, walk from room to room, or within one room within the participant's principal residence.

Questions:

Scoring

0 = No

1 = Yes, independent

2 = Does not do

9 = Unknown

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). BS113

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). BS114

If you had to, could you do all the housekeeping yourself (like washing clothes and cleaning)? BS115

821 2/12/8

If you had to, could you do all the cooking yourself? JS116

If you had to, could you do all the grocery shopping yourself? JS117

Do you drive? JS118

Reason for not driving now: JS119

Scoring for not driving:

1 = Health

2 = Other non-health reason

3 = Never licensed

8 = N/A, current driver

9 = Unknown

Nagi Scale

65121-65131

1. Show and explain the answer sheet *before* administering the test.
2. Ask each question individually. Start with, *For each item, tell me whether you have. . .*

15121-15131

No difficulty

A little difficulty

Some difficulty

A lot of difficulty

Unable to do

Do not do on MD orders

Procedures For CES-D Interview

bs157 - bs176

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.

The scale is given at each exam. The scale is not given if the patient is: sedated, aphasic, 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.

C. CES-D Scoring:

Responses are circled on the form. The score is the sum of 20 weighted responses and the final score is calculated by the computer. Score ranges from 0 to 60 by totaling all responses. Code 9 = *refused or do not know* is not included in the score. Values for each question range from 0 to 3.

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.

JS157- JS176

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 categories. The following definitions should be given:

Code

0 = Rarely or none of the time (< one full day)

1 = Some or a little of the time (1 to 2 days in the past week)

2 = Occasionally or moderate amount of time (3 to 4 days in the past week, or about 1/2 the time)

3 = 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.

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. When a participant asks for an interpretation of a particular response, reread the definitions to him/her.
5. 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 form.
6. Check the response on the form.
7. When the participant refuses to respond to the statement, check 9 = refused or do not know.

js157-js176

8. 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?*

9. 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.

NOTE:

Do not ask why the participant appears depressed. However, if that information is volunteered, briefly document the reason.

Do not score positive for *restless sleep* if the participant wakes to go to the bathroom and is able to get back to sleep easily.

This is a self-reported questionnaire and answers should be accepted as given.

js157-js176

- 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 moderate amount of time
(3 - 4 days)**

- 3 = Most or all of the time
(5 - 7 days)**

Berkman Social Network Questionnaire

BS177 - BS189

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

Before administering the BSNQ, read the following statement, *The following questions ask about your social support. Please choose the response that best describes your situation over the past year. The first two questions refer to **close friends**, and the second two refer to **family**.*

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

<i>None</i>	<i>6 to 9</i>
<i>1 or 2</i>	<i>10 or more</i>
<i>3 to 5</i>	<i>Unknown*</i>

* **Unknown** only to be used if participant is unable to answer or refuses, or question was not asked.

1. *How many **close friends** do you have; people that you feel at ease with, can talk to about private matters?* BS177

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

2. *How many of these **close friends** do you see at least once a month?* BS178

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.

3. *How many **relatives** do you have; people that you feel at ease with, can talk to about private matters? (See #1 above)* BS179

4. *How many of these **relatives** do you see at least once a month? (See #2 above)* BS180

5. *Do you participate in any groups such as a senior center, social or work group, church connected group, self-help group, or charity, public service or community group?* JS181

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

6. *About how often do you go to religious meetings or services?* JS182

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.

Questions 7 and 8 ask about insurance coverage.

7. *Do you have either Medicare or Medicaid?* JS183

8. *Do you have health insurance other than Medicare or Medicaid?* JS184

The intent of questions 9-13 is for friends and family, not mental health specialists. They should be answered with the following responses:

<i>None of the time</i>	<i>Most of the time</i>
<i>A little of the time</i>	<i>All of the time</i>
<i>Some of the time</i>	<i>Unknown*</i>

* **Unknown** to be used only when participant is unable to answer or refuses, or question was not asked.

Be sure to preface each question with the statement *How much of the time.*

9. *How much of the time is there someone available to you whom you can count on to listen to you when you need to talk?* JS185

10. *How much of the time is there someone available to give you good advice about a problem?* JS186

11. *How much of the time is there someone available to you who shows you love and affection?* JS187

12. *How much of the time can you count on anyone to provide you with emotional support (talking over problems or helping you make a difficult decision)?* JS188

13. *Do you have as much contact as you would like with someone you feel close to, someone in whom you can trust and confide?* JS189

JS189

JS177 - JS180

None

1 or 2

3 to 5

6 to 9

10 or more

1. How many *close friends* do you have: people that you feel at ease with, can talk to about private matters?
2. How many of these *close friends* do you see at least once a month?
3. How many *relatives* do you have; people that you feel at ease with, can talk to about private matters?
4. How many of these *relatives* do you see at least once a month?

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

9. How much of the time is there someone available to you whom you can count on to list to you when you need to talk?
10. How much of the time is there someone available to give you good advice about a problem?
11. How much of the time is there someone available to you who shows you love and affection?
12. How much of the time can you count on anyone to provide you with emotion support (talking over problems or helping you make a difficult decision)?
13. How much of the time do you have as much contact as you would like with someone you feel close to, someone in whom you can trust and confide?

Observed Physical Performance Measures

- A. Equipment: *bs200 - bs228*
1. Data sheets
 2. Pencil (pen)
 3. Stopwatch
 4. 4 Meter measured walk
 5. 2 Armless straight back chairs measuring approximately 18" high from floor to top of seat

B. 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, do not encourage them any further.

C. 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.

D. Stands: *bs200 - bs211*

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: JS200 - JS203

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: JS204 - JS207

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.

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

3. Tandem: JS208 - JS211

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.

E. 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.

1. Walk #1: JS213-JS215

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: JS216-JS218

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: JS219-JS222

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.

JS 213

F. Repeated chair stands: JS223A - JS228

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.

Single chair stand:

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

If participant feels it is unsafe, skip the chair stands

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 participants 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.

Repeated chair 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".

JS-144

JS223A - JS228

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.

G. JAMAR hand grip strength test: JS191 - JS198

1. Equipment:
 - A. JAMAR dynamometer
 - B. Pencil (pen)
 - C. Data sheet
 - D. Straight back chair
2. Technician tells the participant: ***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 it to move very much.***
3. Participant is seated in chair with arms, forearm resting on chairarm, elbow at about a 90 degree angle.
4. Participant should hold JAMAR in upright position, wrist in neutral position, JAMAR facing the technician.
5. Make sure that red peak-hold needle is set to zero.
6. Tell participant to squeeze as hard as s/he can, and squeeze until you tell s/he to stop. Hold squeeze for a 3 to 5-1000 second count.

JS 191-198

65191-65198

7. 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.
8. Repeat steps until three measurements are recorded.

Off-Site Visit Chart Completion

65482 - 65517

After returning to the Heart Study building there is a procedure to ensure that the chart is processed in an efficient manner. Below is a guide to assist in this process.

Portable ECG Transmission Protocol

A. ECG Transmission:

1. The Marquette Muse information system is in Room 112. This system is used for storing and transmitting ECGs.
2. In order to transmit, one must first enter a password, user # and site #. This information is confidential and individualized.
3. Stored in the top, right hand drawer of the desk with the Muse, is a double ended silver phone line.
4. In the lower right hand corner of the computer is a phone like jack labeled "MAC 6 and MAC PC". One end of the line should be plugged into this outlet and the other end should be plugged into the receptacle located in the left side of the portable ECG machine.
5. Turn on the ECG machine.
6. Press the double arrow button (↵) and while holding it, press **F1**.
7. The next screen should be the *System Functions* screen.
8. Press **F1** again to choose the storage option.
9. Press **F4** to transmit. This should lead to the *Transmission Type* screen.
10. Press **F2** to choose local transmission.
11. The machine asks whether you want to select patients by number. Select **NO** and hit **r** (return).
12. Next, the screen will display all the ECGs stored. If there were five ECGs on one person, that person's name will appear five times with the option of transmitting that recording or not. Hit the corresponding yes or no as to whether you want to choose a hard copy of that tracing.

JS482- JS517

13. Transmission of the data is rapid, but it should take a few minutes to print the hard copy of the tracing. Wait until all the ECGs that were selected are printed before disassembling the apparatus.
14. After ECG printing is complete, carefully remove it from the machine and stamp the top (white margin) of the page with the appropriate exam cycle number.

B. After Transmission is Completed:

1. On the liquid crystal window, the portable machine should show: Transmission Completed, Press any key to continue.
2. At this time you should delete any ECGs that were not transmitted.
3. Return to the *Storage Functions* screen, then press **F5** to choose the More option.
4. Press **F1** to choose delete.
5. The machine asks if you want to Select by patient ID. Choose NO.
6. The names of the patients who still have ECGs stored will appear. To delete, press **F1** until there are no more ECGs in storage.
7. You are then asked if you want to delete that number of ECGs. Choose YES.
8. The machine will return to the *Storage Functions* screen. To return to the main screen keep striking the return key.
9. When the process is completed, reconnect the portable ECG machine to the power source.

C. ECG Physician Review:

The tracing of the portable ECG(s), full size tracing of the ECG, and the ECG from the participant's previous exam should be presented to a FHS physician for comparison and reading. This step ensures that should there be any marked ECG changes, the participant's personal physician will be informed immediately.

If the FHS physician determines that the participant's physician should be notified, he/she should be given the whole chart. After a contact is made, the physician should complete a phone encounter sheet to document his/her actions.

If there is no need for notification of an outside physician, the ECGs should be returned to the participant's chart and the interviewer may complete the chart.

D. Chart Review Protocol: For Internal Use Only

Utilizing a check list is the best way to ensure that nothing is overlooked in the chart review process.

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 received a bone density measurement, ensure that the printout is taped to the Quantitative Ultrasound Measurement (QUS) sheet, which should be completed and returned to the bone study coordinator.
3. If the participant has suffered a hip fracture since their last visit, write that person's name, FHS ID number, and type of fracture on a piece of paper and give it to the study coordinator.
4. Document the participant's heart square measurements in the appropriate location.
5. If the participant has had a stroke since their previous exam or has shown marked cognitive changes in the interim, ensure that a referral is made to the proper FHS study. After completing the referral forms, paper clip them to the outside of the chart.
6. Before submitting the chart to the cohort participant coordinator, do one more review to ensure that nothing was overlooked.

Stroke Tracking Referral Form

The Framingham Study

Tracking Purposes 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

5 = Medical Records

2 = Biennial Exam

6 = Review

3 = Offspring Exam

7 = Other (Please specify)

4 = Family

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)

2014 150

Neurology Clinic Referral Form

Tracking Purposes Only

ID#: _____

Name: _____

Date: ___/___/___

Person Making Referral: _____

Source of Referral: _____

1 = Hospital Admission

5 = Medical Records

2 = Biennial Exam

6 = Other (Please specify)

3 = Offspring Exam

7 = Review

4 = Family

Reason for Referral: _____

Reason for Hospitalization (if applicable): _____

Living Situation (if applicable): _____

1 = Own Home

4 = Relative's Home

2 = Elderly House

5 = Nursing Home

3 = Hospital

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

151
4-20-04

Standard Blood Pressure Examination Supervisor Check List

Internal Use Only

Date: ___/___/___ Technician #: _____ Supervisor: _____

Instructions: For each item, circle Y (yes) or N (no) to indicate whether the procedure is carried out correctly. Record any comment in the blank space between that item and the next. For certain items, specific parts of the procedure which are important are listed separately.

The following items apply throughout the exam:

- | | | |
|---|---|--|
| Y | N | Participant 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 | Technician bares participant's arm to allow proper placement of cuff. |
| Y | N | Technician assesses participant's arm for correct cuff size. |
| Y | N | Technician palpates brachial artery. |
| Y | N | Technician wraps cuff center of bladder over brachial artery. |
| Y | N | Instructs participant on posture. |
| Y | N | Finds palpated systolic pressure using standard manometer. |
| Y | N | Calculates maximal inflation level, standard manometer. |
| Y | N | Waits at least 30 seconds before proceeding. |
| Y | N | Keeps work station free of excessive noise. |
| Y | N | Places stethoscope in ears, earpieces forward. |
| Y | N | Inflates rapidly to maximal inflation level. |
| Y | N | Places bell on brachial pulse. |
| Y | N | Deflates cuff 2 mmHg per second. |
| Y | N | Deflates cuff 10 mmHg below diastolic. |
| Y | N | Opens thumb valve or disconnects tubing. |
| Y | N | Records readings. |

153

Internal Use Only
Overall comments of supervisor:

Instructions to technician/corrective action:

Signature
Blood Pressure Supervisor

Site 1534

12 - Lead ECG Quality Control Supervisor Check List

Internal Use Only

Date: ___/___/___ Technician #: _____ Supervisor: _____

Instructions: Please circle Y (yes) or N (no) to indicate if the technician correctly performed the specific maneuver.

-
- | | | |
|---|---|---|
| Y | N | The participant's correct name and ID number are entered into the MAC. |
| Y | N | Participant's arms are resting comfortably on the bed alongside the body. |
| Y | N | Technician has established a rapport with the participant so the participant is at ease with the procedure. |
| Y | N | Electrode location V2 is located in the 4th intercostal space at the left sternal border. |
| Y | N | V1 is at the same level as V2 but at the right sternal border. |
| Y | N | The E point is located at the intersection of the 5th intercostal space and the mid-clavicular line. |
| Y | N | V6 is located in the mid-axilla at the same level as the E point. (The DAL-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 E-0 measurement and the 0-V6 measurement is calculated. |
| Y | N | The measurements (in the item directly above) are accurately recorded on the log sheet. |
| Y | N | The difference from the above calculation is located on the DAL-square and V4 is located on the chest . |
| Y | N | V3 is located midway between V2 and V4. |
| Y | N | V5 is located midway between V4 and V6. |
| Y | N | RL is located on the inside right ankle. |
| Y | N | LL is located on the inside left ankle. |
| Y | N | RA is located on the outside right wrist. |
| Y | N | LA is located on the outside left wrist. |
| Y | N | The electrode labels are checked before positioning to guard against lead misplacement. |
| Y | N | The paper ECG record is reviewed for quality and corrective action is taken if necessary. |

155

Internal Use Only

Overall comments of supervisor:

Instructions to technician/corrective action:

Signature, Supervisor

White 156

Interview Supervisor Check List

Internal Use Only

Date: ___/___/___ Technician #: _____ Supervisor: _____

Using the scale key below, evaluate the interviewer's performance for each of the following procedures. Write any comments in the spaces provided.

- Key: N/A Not applicable
- 1 Unsatisfactory (failed to meet standards)
 - 2 Below expectations (did not meet some standards)
 - 3 At expectation (met standards)
 - 4 Above expectation (met all standards and in some instances exceeded them)
 - 5 Outstanding (distinguished performance, consistently exceeded all standards)

N/A 1 2 3 4 5 Answers respondent's questions and concerns.
Comments: _____

N/A 1 2 3 4 5 Speaks slowly and distinctly, reading the questions at neutral/even pace.
Comments: _____

N/A 1 2 3 4 5 Maintains the focus of the interview but allows participant to express thoughts.
Comments: _____

N/A 1 2 3 4 5 Follows instructions/reads questions as they are written.
Comments: _____

N/A 1 2 3 4 5 Initiates (where needed) appropriate non-leading questions.
Comments: _____

N/A 1 2 3 4 5 Records/codes answers correctly (follows skip patterns as needed).
Comments: _____

N/A 1 2 3 4 5 Reviews forms.
Comments: _____

N/A 1 2 3 4 5 General overall rating.
Comments: _____

Signature of Reviewer: _____

FSI 2/15/98

Problems/Corrective Action Log

Height/Weight

Internal Use Only

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

Boite 158

Problems/Corrective Action Log

Blood Pressures

Internal Use Only

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

Site 159

Problems/Corrective Action Log

ECGs

Internal Use Only

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

Waste 1100

Problems/Corrective Action Log

Cognitive Function and Physical Activity Questionnaires

Internal Use Only

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

Write 1/6/1