

Annual Follow-Up Tracing Form and Questionnaire Instructions
AFU Version A, 8-23-2001
QxQ Date 10-16-2001

I. General Instructions

The Annual Follow-Up Form (AFU) is completed as the first of four annual follow-up forms administered each year on or near the anniversary of the participant's baseline JHS clinic examination. This form corresponds to the core AFU for the ARIC cohort and, for all ARIC/JHS participants, is entered directly into the ARIC data entry system. For all JHS participants, it is entered into the JHS Clintrial data entry system.

The interviewer must be certified and should have a working knowledge of the annual follow-up procedures. S/He should also be familiar with the data entry procedures for electronic version forms and the document titled "General Instructions for Completing Paper Forms" prior to completing this form. ID number, Contact Year, and Name should be completed as described in that document.

Forms for conducting the annual follow-up are generally completed in the following order:

- 1) Annual Follow-Up Record of Calls (ARC)
- 2) Annual Follow-Up Form (AFU)
- 3) Annual Follow-Up Other Form (AFO)
- 4) Annual Follow-Up 01, 02, or 03 (AF1, AF2, or AF3)
- 5) Appointment scheduling (if due)
- 6) Contact Form (CON): Verification of participant contact information

The Participant Contact Information Sheet generated by the Coordinating Center contains detailed information to be used in contacting the participant. This form is maintained, with the date of printing annotated, in the participant file. Refer to separate protocol section on tracing for special procedures to use in difficult cases when contact information is out of date. Any updated information is entered on the Contact (CON) form according to instructions for that form. If the participant alters any consent information, updated information is entered on the Informed Consent Tracking (ICT) form according to directions on that form.

All contact attempts, including interim and final results codes, are recorded on the Annual Follow-Up Record of Calls (ARC) form. When the contact is made with the participant or an informant, the interviewer attempts to determine the participant's present address (or address immediately prior to death) to assist in the JHS surveillance activities.

At the completion of the AFU interview, the location of the participant's address is recorded as within the JHS surveillance boundaries (YES), outside the JHS surveillance boundaries (NO), or UNKNOWN in Item 24 at the bottom of the ARC form. For participants who have expired, the place of residence refers to the person's address immediately prior to death.

II SPECIFIC INSTRUCTIONS

Before placing a phone call, the interviewer assembles the participant's computer-generated Participant Contact Information Sheet, the ARC, the AFU, AFO and appropriate year AF1, AF2 or AF3, the accompanying question-by-question instructions, and, for years when scheduling a clinic appointment only, an appointment calendar for scheduling Clinic Visit 02. If a Visit 02 Clinic appointment is to be scheduled with more than one respondent during a single call, it may be easier to conduct all interviews first and then schedule appointments together.

NOTE: Cohort participants who have moved outside of the study area are still traced and interviewed, and hospitalization or death information is obtained if necessary.

Completing the Questionnaire

Once the participant is called, the interviewer begins by reading the following script:

INTRODUCTION: "Hello, this is [INTERVIEWER NAME] from the Jackson Heart Study. May I please speak with [NAME(S) OF PARTICIPANT(S)]?"

IF THIS IS AN ARIC/JHS PARTICIPANT, SAY: "Hello, this is [INTERVIEWER NAME] calling from the ARIC and Jackson Heart Studies. May I please speak with [NAME(S) OF PARTICIPANT(S)]?"

Determine participant's availability and vital status.

If deceased, offer condolences, and then determine the date and location of death (starting with item 4) and continue with the section on hospitalizations (section H). At end of interview, inform the respondent of the possible need for someone from the JHS staff to contact a family member later on, and ask when would be the best time to call.

For years when NOT scheduling an appointment:

WHEN PARTICIPANT IS ON THE LINE, READ: "Hello, this is (INTERVIEWER NAME) from the JHS Study and I'm making our annual contact call. I would like a few minutes of your time to find out about your health in the past year (lead in to item 6.)"

OR, IF THIS IS AN ARIC/JHS PARTICIPANT, SAY: "Hello, this is (INTERVIEWER NAME) from the ARIC and Jackson Heart Studies and I'm making our annual contact call. I would like a few minutes of your time to find out about your health in the past year (lead in to item 6.)"

For years when SCHEDULING an appointment:

WHEN PARTICIPANT IS ON THE LINE, READ: "Hello, this is (INTERVIEWER NAME) from the JHS Study and I'm making our annual contact call. I would like a few minutes of your time to find out about your health in the past year and to schedule your next visit for an examination at the JHS Exam Center (lead in to item 6.)"

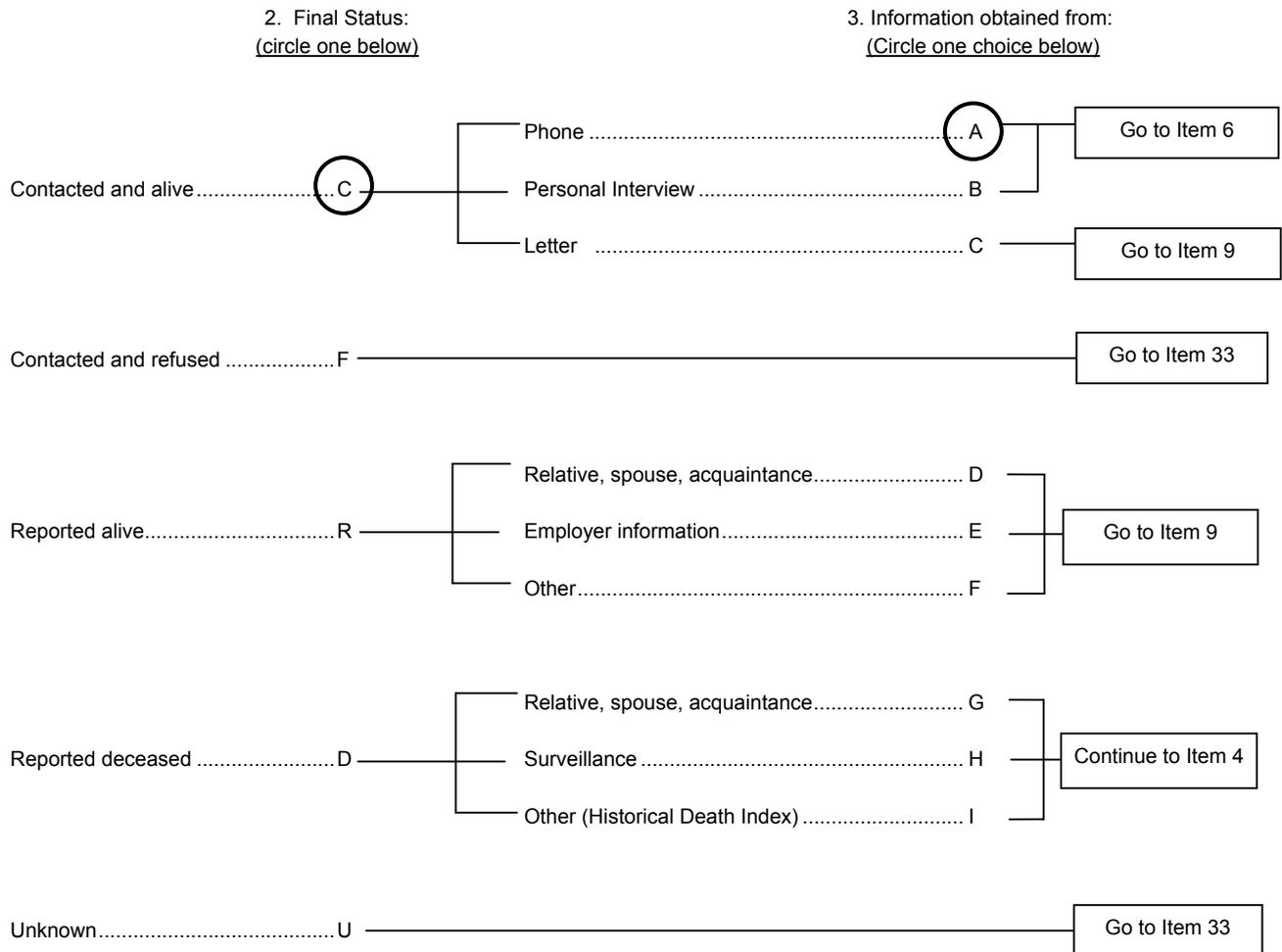
OR, IF THIS IS AN ARIC/JHS PARTICIPANT, SAY: "Hello, this is (INTERVIEWER NAME) from the ARIC and Jackson Heart Studies and I'm making our annual contact call. I would like a few minutes of your time to find out about your health in the past year and to schedule your next visit for an examination at the JHS Exam Center (lead in to item 6.)"

A. Vital Status

1. The date of status determination is the date on which the participant's final vital status became known to the interviewer (see item 2 below). This date must fall during the participant's contact year, i.e., no earlier than the "Earliest" date and no later than the "Latest" date on that form. It is generally the last date on the "Record of Calls."

2 & 3. Record the final vital status of the participant for the present contact year, and indicate the source of that information. The response to item 3 must correspond to item 2 as shown on the form. Thus, if item 2 is "C" then item 3 must be "A," "B," or "C". Similarly, if item 2 is "R", then item 3 must be "D," "E," or "F." If item 2 is "D," then item 3 must be "G," "H," or "I." After completing item 3, follow the skip rule indicated for that response.

Example: If the participant was contacted over the phone, record as:



In this situation, continue the interview by going to item 6.

If direct contact is not made, but a reliable source of information has provided a status of "Reported alive" or "Reported deceased" in item 2, then hospitalization information may be obtained from this source. It is important that the source's identity be recorded in the call record in Section B of the form. Record the source's name, street address, city, state, zip code and telephone number.

The following are the criteria for each final status:

C. Contacted and alive: The participant has been directly contacted in some way by the JHS Exam Center during the present contact year. This contact preferably takes the form of a phone call or personal interview (so that the entire questionnaire can be administered), but a letter written by the participant is also acceptable for assigning this status. In this last case, it is obviously not possible to ask the remaining questions on the form. Note that this status corresponds to a final result

code of N, O, or P on the "Record of Calls."

F. Contacted and refused: The participant has been directly contacted in some way by the JHS Exam Center during the present contact year, but s/he refused to answer the annual follow-up questions.

R. Reported alive: Reliable information indicates that the participant is living, but direct contact has not yet been made. If this is the final status, it is therefore implied that it is not possible that contact will be made during this same contact year. Since one would generally continue to make attempts at a direct contact up until the "Latest" date, it is reasonable that the "date of status determination" would fall on or just before that "Latest" date, when this is the final status. Note that this status corresponds to a final result code of R on the "Record of Calls." Reliability of the information is evaluated by supervisor review. It is therefore important to document the source in as much detail as possible.

D. Reported Deceased: Reliable information indicates that the participant has died. In this case, the "date of status determination" is the date on which the death became known to the JHS Exam Center, NOT the date of death. Note that this status corresponds to a final result code of S on the "Record of Calls." Reliability of the information is evaluated by supervisor review. It is therefore important to document the source in as much detail as possible.

U. Unknown: Neither the participant nor another source of information has been contacted in a manner sufficient to provide reliable vital status data. In this case, the "date of status determination" is either the date on which the unknown status is being assigned, or the participant's "Latest" contact date for the specified contact year, whichever is earlier. Note that this status corresponds to a final result code of T on the "Record of Calls."

Note: Once a final status has been assigned and entered into the database, it can not be changed during the same contact year without written authorization from the Coordinating Center. Therefore, a final status code should not be assigned until the end of the contact year or until it becomes obvious that the status can not change. As described elsewhere, a death occurring after a contact but before the end of the Contact Year is assigned to the next Contact Year.

Examples:

1. It is Contact Year 02. The participant cannot be contacted, nor can any reliable information be found regarding his vital status. His baseline visit was on 9/26/00, and his "Latest" CY 02 date is 3/26/02. Record as:

Contact Year 02
Date of Status Determination 3/26/02
Status T

2. It is Contact Year 03. The participant cannot be contacted, nor can any reliable information be found regarding his vital status. His status in CY 02 was "Unknown," as determined on 6/28/02. His baseline visit was on 1/23/01. Record as:

Contact Year 03
Date of Status Determination 6/28/03
Status T

3. It is Contact Year 02. The participant's baseline visit was on 2/24/01. His "Latest" date is 8/23/02. Neither the participant nor a reliable source can be located. Finally, on 8/25/02 (two days after the "Latest" date), the participant is located and interviewed. The interview must be recorded under Contact Year 3, and the status for CY 02 is "Unknown." Record as:

Contact Year 02
Date of Status Determination 8/23/02
Status T

4. It is Contact Year 2. The participant's "Earliest" date is 2/12/02 and his "Latest" date is 2/11/03. The participant was contacted on his "Target" date, 8/12/02, and the questionnaire was administered routinely. One month later, his obituary is seen in the newspaper. The death may not be reported until the next Contact Year. Record as:

Contact Year 02 03
Date of Status Determination 8/12/02 2/12/03
Status N S

A death investigation may, however, be started at any time.

B. Death Information

4-5. If the participant has died, attempt to secure the date and location (city/county, state) of death from the source of information, whether it is a relative or an obituary. Take steps to begin a death investigation by initiating a Cohort Event Eligibility Form. Obtain as much information as possible from the informant on items 4 and 5. For example, if only the year and month of death are known, record them, (and not the day). Similarly, if the state is known, but not the city/county, record as much information as is available. Continue with Item 9, Section E (OVERNIGHT ADMISSIONS).

C. General Health

The time frame for the next set of questions in Sections C - G is since the last Annual Follow-Up (AFU) call. Generally this is about 12 months. Exceptions to this could result from one or more missed AFU contacts other than during AF Year 01. The most recent contact will rarely have been the last Exam Center visit. It is important that the participant understand the time frame.

6. Read the question, gently stressing the time frame, and pausing slightly between each of the response categories. Read all four categories, and record the participant's selection. When necessary, reread the second sentence.

7. Read the questions/statements as written. Do not otherwise define the condition for the respondent. Do not define the condition yourself, based on the respondent's answer. Record ambiguous responses as UNKNOWN and enter the text response in a note log.

Enter YES, NO or UNSURE for each item that identifies a specific condition (7a-i, and l). A response is positive only if the condition was diagnosed by a physician. NO is coded if (1) the respondent was told by a doctor that s/he did not have the condition specified, (2) was never told by a doctor that s/he had the condition, or (3) was never tested for the condition. UNKNOWN is recorded if the respondent is not sure that the doctor said s/he had this condition. The code of UNKNOWN is most frequently used when the respondent can not remember accurately what the doctor said. Follow the skip patterns closely for responses of NO or UNKNOWN.

For Item 7i (cancer), go to Item 8 if the response is NO or UNKNOWN. If the response is YES, ask **“Can you tell me in what part of the body the most recently diagnosed cancer was located?”** (Item 7j) and date of diagnosis (Item 7k). Ask if the participant has had multiple diagnoses of cancer (Item 7l). If NO or UNSURE, go to Item 8. If YES, record the site (Item 7m) and date of diagnosis (Item 7n). NOTE: Space is provided for recording information on only two cancers. Do not probe to determine whether these diagnoses represent two separate malignancies or a malignancy and its recurrence.

D. Stroke / TIA

8. Here we are specifically looking for a physician/health care provider diagnosis of stroke or TIA. Light stroke, minor stroke or small stroke would all be considered appropriate synonyms resulting in a "YES" response if participant was told by a physician/health care provider. If the participant is unsure, record as "NO."

E. Overnight Admissions

9 - 11. The purpose of questions 9 and 10 is to determine whether it is necessary to complete the "Hospitalizations" section. Generally, these questions are asked directly of the participant, but the participant or the interviewer can ask to have a spouse or more knowledgeable person in the household answer the questions on hospitalization. When direct contact is not made with the participant, but a reliable source of information has provided a status of "Reported alive" or "Reported deceased" in item 2, questions 9 and 10 may be asked of this source. If speaking with an informant, replace the words "Were you" with "Was ____ (participant)". The term "hospitalized" includes staying overnight in any acute or chronic care facility which excludes nursing homes. Only inpatient care should be included, e.g., ER or outpatient visits not involving an overnight stay are coded as NO. If the participant or informant is unsure, doesn't know or can't provide information about the overnight hospitalization(s) for heart attack (Item 9) or other condition (Item 10), select the response category UNKNOWN.

9. This item is intended to specifically enhance the participant's or informant's recall about cardiovascular-related hospitalizations. The term 'heart attack' refers to the person's admitting diagnosis or discharge diagnosis. For example, the response to Item 9 would be YES for a person admitted to a hospital overnight to rule out a suspected heart attack. Frequently, such a patient is discharged with a diagnosis of something other than a heart attack, for example, tachycardia (uneven heart rate) and esophageal reflux (indigestion). In other words, admissions to "rule out," as well as discharge diagnoses of a heart attack, are both coded YES.

10. This question asks the participant/informant to recall overnight hospitalizations in acute or chronic care facilities, such as hospitals, for any condition other than a heart attack or to rule out a heart attack.

If the response to Item 9 or 10 is positive, Section F (HOSPITALIZATIONS) can be administered prior to administering Section H (FUNCTIONAL STATUS).

11. The question asks the participant/respondent to recall overnight hospitalizations in chronic care facilities such as nursing homes, for any reason since the last contact. If the answer is "Yes," ask if the participant is currently staying in a nursing home.

F. Hospitalizations

Collection of data:

If there was a positive response to Items 9 and/or 10, read the following script to the respondent/informant: "For each time you were (s/he was) a patient overnight in a hospital, I would like to obtain the reason you were (s/he was) admitted, the name and address of the hospital, and the date when you were discharged."

Abbreviations can be used for local hospitals.

37-39. Record information on all hospitalizations reported since the time of last contact. Use the Hospitalizations section of the Annual Follow-Up Form. This is a long question that will have to be obtained in parts. Use neutral probes to elicit all hospitalizations. For the (first) overnight stay, record the reason for the hospitalization (Item 37), the hospital name, city, and state (Item 38a), and the discharge date (month and year) of the hospitalization (Item 39). Probe for additional hospitalizations and follow the directions for the first hospitalization. There is space to complete 6 hospitalizations. If there are more than 6, record and enter the 6 most relevant to JHS. List the others on a separate sheet, so all can be transmitted to the JHS Surveillance Supervisor.

Linkage between annual follow-up and event investigation:

Certain procedures are necessary to insure that any deaths or hospitalizations that are encountered during AFU contact attempts are brought to the attention of the Surveillance Event Investigation staff, and vice-versa. The surveillance staff is to be notified of every cohort hospitalization and an investigation should be initiated.

40. For each hospitalization reported, enter H in Item 40a - f to indicate the information has been transmitted to the Surveillance staff. The H code may be changed to an N code if the surveillance search finds that the identified hospitalization was not an overnight stay, or there was no documentation by the hospital of an overnight staff.

G. Invasive Procedures

Read the transition statement.

12. Do not ask. Check the Participant Contact Information Sheet to determine whether the participant has previously completed version G or H of the ARIC AFU form, or version A or B of the JHS AFU form. Select the appropriate response category (YES or NO), and follow the skip patterns. Persons who have completed version G or H of the ARIC AFU or version A or B of the JHS AFU are read Item 12a; persons who have not yet completed version G or H or A or B are read Item 12b. The difference between the two versions of Item 12 part (a) and part (b) is the setting in which the questions were asked: item 12a is for participants who were last

contacted during an AFU interview; item 12b is for persons whose last contact was at a clinic visit at a field center.

12 a & b. These questions refer to “major” therapeutic surgery on the heart or arteries of the neck or legs. “Legs” refers to the entire lower extremity (not “just below the knee”, which is the restricted anatomical definition). “Surgery” does not include lower extremity arteriography, even though it is an “invasive” procedure, nor surgery for varicose veins. Note also that “abdominal aortic aneurysm repair” is not included here. When NO, go to Item 14, selecting the part (a or b) which corresponds to the part you are completing here. When YES, continue with next questions.

13 a - f. Standardized definitions and synonyms of invasive cardiac procedures are listed below in the table of Definitions and Synonyms of Diagnostic and Therapeutic Procedures. The definitions can be read to participants who are unclear as to the meaning(s) of a term, and the synonyms can be used by the interviewer to help determine whether or not the participant has had the procedure in question. Specify the type of procedure in the spaces provided when responses to Items 13b or 13e are YES.

14. Do not ask. This question is comparable to Item 12. Check the response to Item 12, or check the Participant Contact Information Sheet to determine whether ARIC version G or H or JHS version A or B has been administered. If YES, read Item 14a to the participant. If NO, read Item 14b. Carefully follow the skip patterns.

14 a & b. When the response is positive (the definition of angioplasty can be read to the participant if he or she asks for clarification), continue with item 15a. When the response is negative (unknown is also coded as NO), go to Section H (INTERVIEW).

H. Interview

This section contains questions about the use of medications used for the treatment of, or are related to, one or more cardiovascular conditions. These questions were routinely asked during the clinic visit. It is important to note that the time frames change for each set of questions. Begin this section with the following transition statement, gently stressing the time frame, as “the past two weeks.”

16. The following synonyms may be given in response to participant questions:

High Blood Pressure:.....Hypertension

High Blood Cholesterol:Hypercholesterolemia

High Blood Sugar:.....Diabetes

It is not necessary for these medications to have been prescribed by a physician. Unlike the procedures for the medication survey in the clinical exams for the ARIC and JHS cohorts, the names of these medications are not transcribed. For each of the three conditions, select a response of YES, NO, or UNKNOWN, based on the participant's knowledge. UNKNOWN could indicate that the respondent is unclear as to whether he or she has the medical condition, or whether any of the medication(s) being taken are specifically used to treat that condition.

Introduce Item 17 with a new transition statement which defines the new terms in the next question.

17. This question documents the current use of aspirin or aspirin-containing medications on a regular basis, regardless of the amount, or the reason for its use. These medications do not include Tylenol (acetaminophen), Advil (ibuprofen), etc. Select a response of "YES", "NO", or "UNKNOWN," based on the participant's knowledge.

18. Do not ask. When male, select M, and go to Section I (FUNCTIONAL STATUS). When female, select F, and continue with Item 19 to determine whether the most recent contact was the Visit 01 exam, or whether it was an Annual Follow-Up call (version G or H of the ARIC AFU or version A or B of JHS AFU). As was done for Item 12, the last contact venue determines the introduction to the next question.

19. Do not ask. Check the Participant Contact Information Sheet to determine whether the participant has previously completed version G or H of the ARIC AFU or version A or B of JHS AFU form. Select the appropriate response category (YES or NO), and follow the skip patterns. Persons who have completed version G or H of the ARIC AFU or version A or B of JHS AFU are read Item 19a; persons who have not yet completed version G or H are read Item 19b. The difference between the two versions of Item 19 part (a) and part (b) is the setting in which the questions were asked: item 19a is for women who were last contacted during an AFU interview; item 19b is for women whose last contact was at a clinic visit at the Exam Center.

DEFINITIONS AND SYNONYMS FOR THERAPEUTIC AND DIAGNOSTIC PROCEDURES

DIAGNOSTIC PROCEDURES

SYNONYMS

ECHOCARDIOGRAM	A test in which sound is transmitted into the body is electronically plotted to produce a picture of the heart's size, shape and movements.	• Echo
ELECTRO-CARDIOGRAM	A graphic record of the electrical impulses produced by the heart.	• ECG • EKG
TREADMILL CARDIAC STRESS TEST	An exercise test on a treadmill, bicycle or similar device in which people	• EST • Exercise test

increase their heart rate in order to have the function of the heart measured, usually by ECG.

THALLIUM SCAN OF THE HEART SPECTOMETRY

A computer image of the heart done by injecting in a dye into the bloodstream. Computer-generated pictures then find them in the heart. These tests show how well the heart muscle is supplied with blood, how well the heart is functioning, or identify a part of the heart damaged by a heart attack.

- Heart Scan

HOLTER MONITOR

A small, portable ECG machine worn by patients. Over one or more drugs.

HEART RHYTHM or CONDUCTION STUDIES

Invasive procedures, usually performed under anesthesia, to assess cardiac arrhythmias. Catheters are placed in the heart to map the spread of electrical impulses during each heart beat.

CAROTID ULTRASOUND STUDIES

A diagnostic method in which pulses of sound are transmitted into the neck arteries and the echoes returning from the surfaces of the artery walls are electronically plotted to produce a picture of a small portion of the carotid artery showing the amount of atherosclerosis (hardening of the arteries) that can be seen in the arterial wall.

- Ultrasound

MRI of BRAIN

A diagnostic procedure using powerful magnets to look inside the skull. Computer-generated pictures image the brain and can identify abnormalities, such as damage from a stroke or a head injury.

- Cerebral MRI

CAT SCAN of BRAIN

A non-invasive diagnostic technique which produces an image of the brain and can identify abnormalities.

- CT

DEFINITIONS AND SYNONYMS FOR THERAPEUTIC AND DIAGNOSTIC PROCEDURES

DIAGNOSTIC and THERAPEUTIC PROCEDURES

SYNONYMS

CORONARY ARTERY BYPASS SURGERY

Surgery to improve blood supply to the heart muscle. This surgery is performed when narrow coronary arteries reduce the flow of oxygen-containing blood to the heart. Vein bypass (from leg veins) 3, (4-5, etc). Vessel bypass.

- CABG
- "Cabbage" operation
- Bypass graft / operation

OTHER HEART PROCEDURES

Examples include valve replacement, ventricular aneurysm resection, Aortic Stenosis, Ventricular Stenosis. Defect repair, Patent ductus closure,

Pacemaker, Implantation of automatic defibrillator,
Coronary atherectomy.

ENDARTERECTOMY

Surgery to take out plaque from an artery, to restore blood flow in one or both of the arteries in the neck.

OTHER ARTERIAL REVASCULARIZATION

Any procedure where additional blood flow is brought to an artery via a bypass from a location elsewhere in the body.

BALLOON ANGIOPLASTY

A procedure used to dilate (widen) narrowed arteries. A catheter with a deflated balloon on its tip is passed into the narrowed artery segment, the balloon inflated, and the narrow segment widened. Angioplasties can now also be done by laser. To keep arteries from collapsing, stents (stainless steel supports) can be inserted into the artery during angioplasty.

- Percutaneous angioplasty
- Balloon dilation
- Balloon test/ procedure
- PTCA
- Stent(s)

CATHETERIZATION

A procedure used to examine the heart or an artery by introducing a thin tube (catheter) into a vein or artery(e.g., carotid artery).

- Angiography

For items 19a-22, record information on a maximum of two different hormone preparations, starting with the most recent one. "Current" means either in a cycle at the time of the interview or between cycles, or currently in a program of female hormone shots or implants. Information on the first hormone is recorded in Items 19 and 20; information on the second hormone is recorded in Items 21 and 22. If more than two hormones were used in the contact interim, only record the two which were most recent. However, this may require the use of a generic name (estrogen/progesterone) and GPI code that has been added to the medication dictionary to identify estrogen/progesterone compounds.

For example, if a woman is currently taking "Prempro" (a combined estrogen-progesterone drug which comes as one pill) but was also taking opposed estrogens for hormone replacement therapy (which was prescribed as two pills, i.e., one estrogen and one progesterone) within the time frame since the last contact, Item 19c (Name 1) would be completed as "Prempro", and Item 21a (Name 2) would be completed as "estrogen/progesterone." If, however, the participant is currently taking two separate estrogen and progesterone drugs for hormone replacement therapy (i.e., not Prempro or another combination estrogen/progesterone pill), then the name of the estrogen drug is recorded in Item 19c and the name of the progesterone drug is entered in Item 21a.

If NO, go to Section I (FUNCTIONAL STATUS).

If YES, transcribe the name of the hormone. It is not necessary to record the concentration as was done at the clinic visit. If the participant does not know the name of the medication, but knows she is taking hormone replacement therapy,

draw two horizontal lines here and through the boxes for medication code (Item 20: Code 1).

20. After the AFU interview has been completed, look up the medication code of the hormone in either the paper or data entry system versions of the Hormone Replacement Therapy Dictionary, and record the 6 digit code in the fields provided on the paper form. In selecting the code for a preparation with multiple hormones, identify the code based on the full name of the product, not just the first hormone. When the participant does not know the name of the hormone, on the paper form draw two horizontal lines through (in the Data Entry System, enter “==” in) the medication code boxes.

21. If NO, go to Section I (FUNCTIONAL STATUS). If YES, follow QxQs for Items 19.

22. Follow instructions for item 20.

I. Functional Status

23 - 29. Provide a transition statement such as, "Next I would like to find out whether you can do some physical activities without help. By 'without help,' I mean without the assistance of another person. These questions refer to the last 4 weeks."

This time frame is different from the previous section on hospitalizations. In general, you are trying to assess the participant's current functional status. This time period (i.e., the last 4 weeks rather than the day of the interview) has been chosen because we do not want to document decreases in functional ability that might be due to temporary conditions such as a headache, a cold or the flu, or a sprained ankle, etc. The intent of these questions is to record the individual's overall ability to perform the various activities covered (i.e., heavy work around the house, walk upstairs without assistance, walk half a mile, or work outside the home).

23. For this question, the examples are just guidelines. If a person can do any heavy work (not necessarily all of the things specified in the question), then record YES. Other examples of heavy work around the house could be "cutting the grass with a hand or power mower" (but not a riding lawn mower), or "painting walls or wallpapering."

24. The focus of the question is on the participant's ability to walk up and down stairs without the assistance of another person. If the participant says something like, "We have a ranch house, so I don't have to go up stairs," say that you want to know if s/he is able to walk up and down stairs. If the respondent is uncertain, code as NO.

25. Again, the emphasis is on the ability to do the activity, in this case, to walk half a mile. The concept of help in this item refers to persons helping. Therefore, the use of equipment would not be considered assistance and you would code YES for a participant who reported walking half a mile with the use of a cane. One, it keeps

the definition consistent with those in Items 23 and 24. Two, it is assumed (and was the experience in Framingham) that anyone requiring either a second individual to assist ambulating or the use of a rehabilitative device (such as a three-pronged cane or walker) is not able to walk half a mile.

26. The focus of this question is whether the ability to work outside the home has been primarily compromised due to poor health (i.e., the participant is completely unable to engage in his or her occupation).

If NO, determine if the poor health and the resultant disability were due to heart disease (Item 26b). Regardless of the response, skip Item 27 and go to Item 28a.

If YES, go to Item 27a.

If the participant (1) does not work outside the home or (2) is not capable of working but would normally not be working outside the home (e.g., a homemaker, retired, or unemployed and not looking for work), code as NOT APPLICABLE, skip Item 27, and go to Item 28a.

In 26b, if asked about the meaning of "a heart problem," do not interpret nor offer a medical explanation, but rather let the participant decide whether s/he is "unable to work because of a heart condition or heart disease."

27. The focus of question 27a is absence from work anytime within the four weeks prior to the interview for at least half a day (4 hours or more) because of personal illness. If this occurred (YES for Item 27a), determine how many days the participant was absent from work (Item 27b). The maximum number of days not worked is 28. The minimum is 1 because less than 4 hours of missed work would have been coded as NO in Item 27a and Item 27b would not have been asked. Therefore, 4 hours or more of missed work during a day is counted as 1; less than 4 hours is rounded down. For example, 3 days and 3 hours is entered as "03," whereas 3 days and 6 hours is entered as "04."

28. The focus of this question is to determine whether the ability to pursue one's normal activities around the house has been compromised by poor health.

For example:

You would code as NO a homemaker who is no longer able to clean house or perform the usual daily activities. If NO, determine if this is due to a heart problem (Item 28b), and go to Item 30, skipping Item 29. If asked about the meaning of "a heart problem," do not interpret nor offer a medical explanation, but rather let the participant decide whether s/he is "unable to work because of a heart condition or heart disease." If a participant indicates that s/he is able to carry on with the usual activities around the house but is not able to do her/his usual recreational activities -- such as bowling, walking, any form of recreational exercise -- code NO, determine in Item 28b if this is due to a heart problem, and go to Item 30, skipping Item 29.

However, you would code as YES a retired brick layer (who is physically incapable of laying bricks) but who is able *to do his usual retirement activities* such as gardening or housework. Continue with Item 29a.

29. The focus of question 29a is a reduction in the participant's usual activities (in contrast to a cessation of these activities in Item 28) during the four weeks prior to the interview because of poor health. The reduction in activities had to occur for at least half a day, i.e., 4 hours or more. If this occurred (YES for Item 29a), determine on how many days the participant had to reduce his or her activity level (Item 29b). The maximum number of days of reduced activity is 28. The minimum is 1 because less than 4 hours of reduced activity would have been coded as NO in Item 29a and Item 29b would not have been asked. Therefore, four hours or more of reduced activity during a day is counted as 1; less than 4 hours is rounded down. For example, 3 days and 3 hours is entered as "03", whereas 3 days and 6 hours is entered as "04."

J. Other items

30. If asked, "now" refers to the last 4 weeks. Current smokers are coded as YES; former smokers and non-smokers are coded as NO.

31. Read the statement, gently stressing the time frame, and pausing between each response category. Read all five categories, even if the person selects a category before you finish reading. If asked, instruct the participant to select the term which best describes her/his living situation, regardless of legal status.

K. Administrative Information

33. Enter the 3-digit JHS ID code of the person completing this form in the boxes provided.

34. This information is needed to know whether the participant's hospital records would be routinely found through community surveillance. Complete this item after the current address is verified and discussing questionable addresses with the surveillance staff. The location of the participant's residence is recorded as within the JHS surveillance boundaries (YES), outside of the surveillance area (NO), or UNKNOWN, based on the definition of community boundaries. For participants who have expired, the place of residence refers to the person's address immediately prior to death. A response of UNKNOWN is used only as a last resort; interviewers who are unsure as to whether or not an address is within the study boundary should work with the AFU supervisor.

35. If the participant has requested that JHS not access medical records, these records are assumed to be accessible through hospital permission to access through community surveillance. If this person has requested that her/his records not be accessed for cohort follow-up (see Participant Contact Information Sheet), and the surveillance staff indicates that the study will not be able to get them through community surveillance, answer NO. Otherwise, select YES.

36. When the AFU has been successfully administered, or the supervisor determines that all contact efforts have been exhausted, the final screening result code is circled in the RESULTS CODE BOX on the TRC form, and entered in this field.

NOTE: ONCE A FINAL STATUS HAS BEEN ASSIGNED AND ENTERED INTO THE DATA BASE, IT CAN NOT BE CHANGED DURING THE SAME CONTACT YEAR WITHOUT WRITTEN AUTHORIZATION FROM THE COORDINATING CENTER. THEREFORE, A FINAL STATUS CODE SHOULD NOT BE ASSIGNED UNTIL THE END OF THE CONTACT YEAR OR UNTIL IT BECOMES OBVIOUS THAT THE STATUS CAN NOT CHANGE. AS DESCRIBED ELSEWHERE, A DEATH OCCURRING AFTER A CONTACT, BUT BEFORE THE END OF THE CONTACT YEAR, IS ASSIGNED TO THE NEXT CONTACT YEAR.

L. Employment Status

32a. Read the four categories to the participant. Select the letter which most closely corresponds to the participant's choice, and follow the skip patterns for each responses category.

If the participant selects "employed," continue with Item 32b. If the participant selects "unemployed," go to Item 32c.

32b. Category B, "employed, but temporarily away from my regular work" most often refers to school teachers who work 9 or 10 months out of the year, have the summers off, and return to their regular job at the end of the school vacation.

32c. No special instructions.

32d. No special instructions.

For AFU contacts for which a clinic visit is not being scheduled, choose the appropriate ending:

END (talking to participant): "Thank you very much for answering these questions. We will call you in about a year (see you at the clinic)." Proceed to Contact (CON) form and verify participant information.

END (if participant deceased): "We may need to contact a family member later. When would be a good time to call in that case?" DO NOT proceed to the Contact (CON) form.

END (otherwise): "Thank you very much for answering these questions. We will call _____ in about a year." DO NOT proceed to the Contact (CON) form.

Verification of Contact Information and Appointment Scheduling

A. When No Scheduling of Visit 02 Appointment Is Needed

For AFU contacts for which a clinic visit is not being scheduled, choose the appropriate ending:

END (talking to participant): "Thank you very much for answering these questions. We will call you in about a year (see you at the clinic)." Proceed to Contact (CON) form and verify participant information.

END (if participant deceased): "We may need to contact a family member later. When would be a good time to call in that case?" DO NOT proceed to the Contact (CON) form.

END (otherwise): "Thank you very much for answering these questions. We will call _____ in about a year." DO NOT proceed to the Contact (CON) form.

B. When Scheduling Visit 02 Appointment Is Needed

You may want to schedule all appointments in a household together. Below is a prototype script:

"Now let's decide on your clinic appointment date(s). This JHS clinic visit will be much like the one you had three years ago. You may remember that it takes about 3 to 4 hours, and you will be asked to fast for 12 hours before you come in unless you have a medical reason not to. We also can provide a taxi, if you

need transportation. We have some openings in (MONTH). Our appointment times are at (TIMES). Is there a day or time that would be best for you?"

1. If respondent(s) is unable to schedule appointment at this time, indicate on Annual Follow-Up Record of Calls (ARC), specify reason and prospects for re-contacting, and go to closing (below).
2. If respondent is unwilling to schedule a clinic visit, indicate on Annual Follow-Up Record of Calls (ARC), and verify contact information on the Contact (CON) form.

"I'm sorry you are unwilling to come back for a fourth exam. We would, however, like to continue calling you once a year. As we've done in the past, we would like to verify the information we have on how to contact you. Let me make sure that I have your full name."
(Administer part a of the Contact (CON) verification of tracing form, then go to "Closing" below)

3. If appointment is made, record date and time on Annual Follow-Up Record of Calls (ARC). Circle the appropriate appointment code on the ARC.

Refer to Annual Follow-Up Record of Calls (ARC) Instructions for an explanation of the Appointment Code values. Refusal codes (G, H and I) should have the participant's reason for refusing entered into a notelog for item 15.

Appointment codes should be updated on the DES as appropriate, given changes in the participant's status.

a. CONTINUE WITH FASTING INSTRUCTIONS.

"We ask that you fast for the visit unless you have a medical reason not to. Do you take insulin for sugar diabetes or have any other reason that you cannot fast for 12 hours?"

IF NO _____

IF YES _____

Since your appointment is at _____, you should begin fasting the night before.

This means nothing by mouth but water and essential medications. We do encourage you to drink plenty of water. As with your previous exam, you will be given a snack at the clinic.

There is no need for you to fast.

b. ASK ABOUT SPECIAL NEEDS.

"Will you need any assistance getting around the clinic or do you have other special needs we should know about?" If yes, indicate on Annual Follow-Up (ARC) Record of Calls and inform clinic.

c. REVIEW MEDICATION SURVEY PREPARATIONS.

"We will want to ask you about your use of medicines, vitamins or supplements. This includes ALL medicines including: 1) prescription drugs from your physician or dentist; 2) prescription drugs you may have received from other people, such as friends or relatives; and 3) over the counter medicines bought at a drug store or supermarket, such as medicines for colds, vitamins, minerals, herbs and the like. We ask that you bring the containers so that we can copy information from the labels. Please bring in the bottles of any medications you have taken in the TWO weeks before your appointment. If you don't have the container, please bring the prescription or the loose pills or capsules. A bag to carry them will be in the packet mailed to you."

d. GIVE RESTRICTIONS ON DONATING BLOOD PRIOR TO THE CLINIC VISIT.

"Please do not donate blood during the week before your clinic appointment. If it becomes necessary to give a pint of blood or plasma within 7 days of your appointment, please call the Exam Center and reschedule your appointment." Provide with telephone number for the Exam Center.

e. RESOLVE ANY QUESTIONS OR CONCERNS.

"Do you have any questions?"

f. UPDATE MAILING ADDRESS (VERIFY CONTACT INFORMATION).

"Finally, this is a good time to verify your mailing address to make sure that all the material you need for the clinic appointment reaches you. This will only take a few more minutes. Let me make sure that I have your full name (Mr. ____'s full name). (ADMINISTER THE CONTACT INFORMATION FORM.) "You should receive your packet in a few days and we will see you on _____. If it is necessary to change your appointment or you think of any (other) questions, please call the clinic."

Closing

NO ADDITIONAL INTERVIEWS

"Thank you for your time.
Good-bye.

ADDITIONAL INTERVIEWS _____

"Now I would like to interview "(NAME).

Thank you for your time."

If the participant is available, return to the beginning of the Annual Follow-Up interview. If the next participant is unavailable, determine when s/he might be contacted.

"Is there a date and a time that would be best for me to speak with (NAME)?"

Record date and time on Annual Follow-Up Record of Calls (ARC)

Contact Form (CON): Verification of Contact Information

Verify the items on the Contact Form (CON) for contact next year by saying: "You have previously provided us with information on how to contact you. To help us contact you next year, please tell me if the information I have is still correct." These include the participant's name, address, and phone number(s), as well as information on three additional contacts. The current data on file appear on the left hand side of the page, with blank spaces for corrections or changes provided on the right side. Information only needs to be entered in these blanks in the case of changes to the data. For example, a change of mailing address would be recorded as:

MAILING ADDRESS:

Highland View Apts.

Apt. 73A

3465 Highland Lane

Jackson, MS 39216

MAILING ADDRESS:

423 Garaway Core

Clinton, MS 39056

Print a copy of the current CON before making any changes. Date and initial the printed version with the interviewer's 3-digit JHS code. Place paper copy in participant file. Any changes to tracing information must be recorded on the CON form.

Data should be updated on the CON as necessary immediately after the follow-up contact, but only by someone certified in use of the JHS Data Entry System. The interviewer who updated the computer file enters her/his JHS Staff Code Number on the CON.

Do not read the information on consent restrictions. If the participant introduces the topic, remind her/him of the current consent status for any items mentioned. If any changes are identified, instruct the participant that s/he will need to complete a new consent form to document changes to the consent restrictions. S/He may come by the JHS clinic to do so, or you may offer to mail another consent document to the participant. Remind her/him that changes will be made ONLY on receipt of a new signed and dated consent document. Once that document is received, the new information should be entered in the Informed Consent Tracking (ICT) form according to the directions in the QxQs for that form. The person who updated the computer file enters her/his JHS Staff Code Number on the ICT.