YEAR 3 TELEPHONE FOLLOW-UP

1   **Background and Rationale**

The Eighteen Month Follow-Up Telephone Call will be administered approximately six months following the participant's Year One Clinic Exam. It's purpose is to collect a) tracking information, b) ascertain interim hospitalizations, nursing home stays and new cardiovascular events, c) document changes in social relations and contact persons since the last contact, and to d) assess the extent to which respondents experienced any major life disruptions in the previous six months or since there previous CHS clinic exam.

2   **Definitions**

2.1   <u>Time Frame</u> Life events questions are asked of occurrences that may have happened in the last six months prior to the questionnaire, or since the participant's Year One Clinic Visit.

2.2   <u>Spouse/Partner</u> Questions about a person's spouse/partner, include both married spouses and unmarried partners who live together and have an intimate relationship.

2.3   <u>Specific Life Events Questions</u>

         Q 4   <u>Moving</u> -- changing houses, apartments, or rooms(s) within the same residential care unit.

         Q 17   <u>Caring</u> -- defined by participant.

         Q 18   <u>Significant change in personal finances</u> -- a major change in income status (e.g. retirement, new employment, social security benefits, retirement benefits) or a major increase in debt or expenses.

         Q 19   <u>Very close friend or close family member</u> -- defined by the participant.
                   <u>Serious accident or illness</u> -- one which required bed rest or hospitalization.

         Q 21   <u>Relationship</u> -- a bond or communication between two people.
                   <u>Significantly worse</u> -- defined by the participant.

         Q 23   <u>Other important things</u> -- events not previously covered which are significantly different from the participant's normal routine. For example: loss of a pet, taking a major trip/vacation, having problems with neighbors, etc.

3   Methods

3.1   The Follow-Up Telephone Call is administered by a CHS certified interviewer. The average time for administration is 10 minutes. However, if the participant wishes to prolong the conversation, the interviewer will continue the call in the interest of maintaining good rapport with the participant.

3.2   Communication involving Events: Prior to your first attempt at contacting the participant, it is important to check with your site's Events Coordinator regarding the possibility of death or any recent changes in health status of the participant or his/her spouse. Knowledge of and sensitivity to these issues will aid in collecting information from the participant more smoothly and help eliminate any awkwardness that may be caused by ignorance of the situation. If the participant is unable to provide the information him/herself, be aware that the form may be filled out by the designated proxy.

In this version of the Follow-Up Telephone Interview, more details regarding self-reported events are being collected. On a weekly (or other periodic basis), the information collected on the Events Physician/ Hospital Information Form referred to in Questions 11-16 in the questionnaire should be forwarded to the CHS Events Coordinator. The Events Coordinator can then ascertain if the event has been reported yet and initiate Events procedures if they are not already underway.

3.3   Contacting the Participant / Using the Contact Log

A one-month window has been calculated as the ideal time for conducting the interview with each participant (the window was determined from date of the Baseline Visit rather than the Year-One Visit). This window is shown on the 18-Month Telephone Follow-Up Contact Log. If you are not able to administer the interview during the window, however, attempts may be continued UNTIL THE SUBSEQUENT CLINIC VISIT. Every attempt should be made to locate and speak to the participant him/herself.

Documentation of the results of the 18-Month Telephone Call will be the same as methods and codes used at the Year-One Follow-Up Visit. A Contact Log will be provided for each participant indicating the window within which the interview should be conducted. On the form, one line should be used for each attempted contact. For each attempted contact, a pending result code is assigned during the period in which contact attempts are continuing. Once the interview is done or it is clear that the interview will not be completed, a final result code is to be assigned. Only final codes are entered into the data base; they should be entered ONLY IF THE CALL IS NOT COMPLETED.

Information collected includes:

- Date of Contact
- Day of Week

- Time
- Pending Result Code
- Final Result Code

The Result Codes are:

■ Pending Codes

- 1 - No Answer: For this date and time, the telephone attempt resulted in no answer.

- 2 - Bad Number/Disconnected: After dialing the telephone number listed on the 18-Month Contact Log, the number was reported as a non-working or disconnected number. This code implies further investigation by the interviewer to identify another telephone number for the participant.

- 3 - Unable to Reach by Telephone - Letter Sent: If after repeated attempts to reach the participant have failed, a letter is to be sent to the participant at the address listed on the 18-Month Contact Log (or at a more recent address if known).

- 4 - Contacted but Not Scheduled: This code is to be used when the participant has been contacted but the interview has not yet been administered. This code implies that further attempts to schedule the interview will be made.

- 5 - Temporarily Unavailable, Contact after __/__/__ : If information becomes available that the participant is temporarily unavailable (e.g. on jury duty, out-of-town, minor illness or injury), this code is to be used. The date at which the participant will be available again should be reported on the form.

- 6 - Refused, Conversion Attempt Pending: When a participant initially refuses the 18-Month Telephone Call, additional efforts to change his/her mind will be attempted. This code is to be used in the interim while conversion attempts are being made.

■ Final Codes

- 10 - 18-Month Telephone Call Completed: The participant was successfully contacted by phone, letter or in person and the clinic visit has been scheduled.

- 12 - 18-Month Telephone Call Refused - Reason Unknown: The participant was successfully contacted by phone, letter or in person but the

interview was refused by the participant without an explanation.

- 13 - 18-Month Telephone Call Refused for Non-Health Reason: The participant was successfully contacted by phone, letter or in person but the interview was refused for a reason not relating to the health of the individual. These are reasons exclusive of other Final Codes.

- 14 - 18-Month Telephone Call Refused, Participant Too Ill - No Proxy - Do Not Contact: The participant or his/her family has refused the interview due to a major injury or illness and does not want it completed by a proxy.

- 15 - Participant Out of Area for Extended Period: Reliable information or contact with the participant has indicated that the participant will not be in the catchment area for the remainder of time that the 18-Month Telephone Call will be done. Report return date to the area, if known.

- 16 - Participant Deceased: Reliable information indicates that the participant has died.

- 17 - Unable to Locate Participant: Attempts to contact either the participant or proxies by phone, mail or in person have failed. No further attempts to schedule the interview will be made.

- 18 - Participant Incapacitated - Proxy Has Completed the Interview: The participant is unable to complete the interview due to physical or mental incapacitation. A proxy has completed the interview.

- 19 - Participant in Hospital, Contact after __/__/__ : When participant has been hospitalized but expresses a willingness to complete the interview at a later time, this code should be used. The date at which to re-contact the participant should be noted.

- 20 - Participant in Nursing Home, Contact after __/__/__ : When participant has entered a nursing home or skilled care facility but expresses a willingness to complete the interview at a later time, this code should be used. The date at which to re-contact the participant should be noted.

- 21 - Participant Ill at Home, Contact after __/__/__ : When participant is too ill to take part in surveillance but expresses a willingness to complete the interview at a later time, this code should be used. The date at which to re-contact the participant should be noted.

- 22 - Participant Moved Out of Area: Reliable information or contact with the participant has indicated that the participant has permanently moved

out of the study catchment area.

- 24 - Participant Caring for Ill Person, Contact after ___/___/___: If the participant is unable to complete the interview due to responsibilities of caring for another ill person, this code is to be used. The date at which to re-contact the participant should be noted.

3.4 **Preliminary Investigation**

The Participant Tracking Sheet provided by the Coordinating Center for the 18 Month Follow-up Telephone Call has listed the marital status of the participant reported at Baseline. Search through any other records that you may have on the participant (Events, clinic notes, etc.) to determine if a spouse's death may have occurred recently. If either the Tracking Sheet or other investigation reveals that the participant is widowed, you may omit the word "spouse" in Questions 27, 28 and 30 from the interview scripts. If RECENT information on marital status is definitely known, you may also complete Question #5, marital status, and skip over the question during the interview.

3.5 <u>Introductory Script</u>

Questions 1 through 3 deal with the script used to introduce the interview.

- ■ Question 1 - (script): Hello, this is (your name) from the Cardiovascular Health Study. May I please speak with (participant's name)?

  - Code "1 - Participant answers" if the participant him/herself answers or comes to the phone. Then skip to Question 2.

  - Code "2 - Participant not in" if participant is not at home or unavailable to answer the phone. Follow-up with person who answered the phone by asking when would be a good time to reach the participant. Enter day and time that is suggested.

  - Code "3 - Participant deceased" if you are informed that the participant has died. If possible, ask the following questions to ascertain if an Informant Interview is required:

    - Has CHS been notified? If yes, has an interview with a family member been conducted?

    - Did the participant die in the hospital?

    - What was the cause of death?

If the death occurred

- out-of-hospital or
- in-hospital with a cardiovascular cause,

an informant interview is required (if not already conducted). If possible, conduct or schedule the interview now.

■ Question 2 - Did you receive our letter?

- Code "1 - Yes" if the participant answers that s/he has received the letter.

- Code "2 - No" if the participant cannot recall receiving a letter. Then follow with script:

I'm sorry you didn't receive our letter since it told about this telephone call. We told you when you came to the CHS clinic for your last examination that we would be calling you in about six months. Six months have now passed and we are calling to say hello and to find out how you have been since we last saw you. Do you have a few minutes to speak on the phone now?

■ Question 3 - Interview

Record the result of initiating the interview:

- Code "1 - Interview started" if the participant agrees to begin the interview. Fill in the time of day (hour, minute, and am or pm) at which the interview begins.

- Code "2 - Participant refuses interview" if the participant refuses to be interviewed even after attempts to reschedule. Check with your supervisor to determine if another call may help in persuading compliance. If it is determined that the refusal is final, write in the reason for the refusal in the space provided.

- Code "3 -Participant wants to reschedule interview" if the current time is not convenient for the interview and another time is requested. Record the date and time of the rescheduled interview in the space provided.

3.6 **Tracking** - Question 4

Refer to the specific Participant Tracking Information Sheet. Verify the participant's name and address as listed on the sheet. If the participant notes that a change in address has occurred during the last six months (or since his/her Follow-Up Clinic Visit), record

this on the Telephone Interview form and document changes on the Tracking sheet. If the participant has moved, ask if the move has taken place during the last month. Record the response on the form.

3.7 **Marital Status** Update - Question 5

■ This question may be skipped if current marital status is definitely known; interviewer may code the answer.

■ Question 5 - What is your current marital status? Are you (read the alternatives and code the response given):

- "Married", Code 1
- "Widowed", Code 2
- "Divorced", Code 3
- "Separated", Code 4
- "Never Married", Code 5
- If participant replies that he/she does not fit in any of the responses provided, code 8, "Other", and write response given in the space provided.

3.8 **Changes in Health Status** - Questions 6 - 10

■ Script: I would like to ask you some questions that we also asked you six months ago. The reason for asking them again is that we are interested in possible changes that might have occurred.

■ Question 6 - Would you say, in general, your health is (read the alternatives and code response given):

- "Excellent", Code 1
- "Very Good", Code 2
- "Good", Code 3
- "Fair", Code 4
- "Poor" , Code 5
- Code "9 - Refused/Don't Know" if participant refuses to answer or doesn't know.

■ Question 7 - How would you say your health compares to other persons of your age? Would you say your health is (read the alternatives and code response given):

- "Better than others your age?" - Code 1
- "About the same as others your age?" - Code 2
- "Worse than others your age?" - Code 3
- Code "9 - Don't Know" if participant doesn't know the answer.

■ Question 8 - How does your health compare to when we say you in (state month participant visited the clinic for CHS Follow-Up exam)? Would you say your health is (read alternatives and code response given):

- "Better", Code 1
- "About the same", Code 2
- "Worse", Code 3
- Code "9 - Don't Know" if participant doesn't know.

■ Question 9 -During the past two weeks, how many days have you stayed in bed all or most of the day because of illness or injury? Do not include days in a hospital or nursing home.

- Record the number of days participant cites, from 00 to 14.

- If none (00), skip to Question 11.

■ Question 10 - What illness caused you to stay in bed?

- Do not read responses to participant, but code in response that best describes answer given.

- Choose from the following alternatives:

  - Heart attack/heart failure
  - Diabetes
  - Arthritis
  - Stroke
  - Mental illness
  - Cold or flu
  - Cancer
  - Injury
  - General fatigue or weakness (including old age)
  - Lung disease, emphysema, bronchitis
  - Recovering from surgery
  - Other (specify)
  - Don't know

3.9 **Events Documentation** Questions 11 - 21

■   <u>Myocardial Infarction:</u> Question 11a - Has a doctor told you that you had a new myocardial infarction or heart attack since we saw you about six months ago?

- Code '1 - Yes' if the participant responds yes.

  - Ask participant to provide the name and address of the physician who made the diagnosis and report this information on the Physician/Hospital Information Form.

- Code '2 - No' if the participant responds no and skip to Question 12.

■   Question 11b - Date of event or diagnosis

- Ask the participant to recall the date that their doctor told them they had the event. Complete as much information as possible here. If the exact date is not known, please ask the participant to estimate the approximate date. An estimate is better than missing information. If the participant will not provide a day, please fill in the month and year given and fill in '99' in the area for 'day'.

■   Question 11c - How many times altogether did you see a doctor for this condition over the last six months, that is since (month of Year One Clinic Exam)?

- Count the number of physician office or outpatient visits made FOR THIS DIAGNOSIS or problem only. Record in the space provided.

■   Question 11d - Were you in the hospital at least one night for this condition over the last six months?

- Code '1 - Yes' if the participant responds yes and continue to Question 11b.

  - Ask participant to provide the name and address of the hospital into which they were admitted and report this information on the Physician/Hospital Information Form.

- Code '2 - No' if the participant responds no and skip to Question 12.

■   Question 11e - How many different times were you in the hospital for this condition?

- Record the number of different hospitalizations for this condition.

- This number should reflect the number of admissions for this condition IN THE LAST SIX MONTHS (or since Year-One Clinic Exam) ONLY.

■ Question 11f - Please tell me the admission dates of the hospitalizations.

- Record the admission dates for each hospitalization for this condition. If the exact date is not known, please ask the participant to estimate the approximate date. An estimate is better than missing information. If the participant will not provide a day, please fill in the month and year given and fill in '99' in the area for each 'day'.

■ Question 11g - How many days altogether were you hospitalized for this condition?

- Record sum of all days hospitalized for this condition.

■ Angina: Question 12a - Has a doctor told you that you had a new incident of angina pectoris or chest pain due to heart disease since we saw you about six months ago?

- Code '1 - Yes' if the participant responds yes.

  - Ask participant to provide the name and address of the physician who made the diagnosis and report this information on the Physician/Hospital Information Form.

- Code '2 - No' if the participant responds no and skip to Question 13.

■ Question 12b - Date of event or diagnosis

- Ask the participant to recall the date that their doctor told them they had the event. Complete as much information as possible here. If the exact date is not known, please ask the participant to estimate the approximate date. An estimate is better than missing information. If the participant will not provide a day, please fill in the month and year given and fill in '99' in the area for 'day'.

■ Question 12c - How many times altogether did you see a doctor for this condition over the last six months, that is since (month of Year One Clinic Exam)?

- Count the number of physician office or outpatient visits made FOR THIS DIAGNOSIS or problem. Record in the space provided.

■ Question 12d - Were you in the hospital at least one night for this condition over the last six months?

- Code '1 - Yes' if the participant responds yes.

    - Ask participant to provide the name and address of the hospital into which they were admitted and report this information on the Physician/Hospital Information Form.

- Code '2 - No' if the participant responds no and skip to Question 13.

■ Question 12e - How many different times were you in the hospital for this condition?

- Record the number of different hospitalizations for this condition.

- This number should reflect the number of admissions for this condition IN THE LAST SIX MONTHS (or since Year-One Clinic Exam) ONLY.

■ Question 12f - Please tell me the admission dates of the hospitalizations.

- Record the admission dates for each hospitalization for this condition. If the exact date is not known, please ask the participant to estimate the approximate date. An estimate is better than missing information. If the participant will not provide a day, please fill in the month and year given and fill in '99' in the area for each 'day'.

■ Question 12g - How many days altogether were you hospitalized for this condition?

- Record sum of all days hospitalized for this condition.

■ CHF: Question 13a - Has a doctor told you that you had a new incident of heart failure or congestive heart failure since we saw you about six months ago?

- Code '1 - Yes' if the participant responds yes.

    - Ask participant to provide the name and address of the physician who made the diagnosis and report this information on the Physician/Hospital Information Form.

- Code '2 - No' if the participant responds no and skip to Question 14.

■ Question 13b - Date of event or diagnosis

- Ask the participant to recall the date that their doctor told them they had the event. Complete as much information as possible here. If the exact date is not known, please ask the participant to estimate the approximate

date. An estimate is better than missing information. If the participant will not provide a day, please fill in the month and year given and fill in '99' in the area for 'day'.

■ Question 13c - How many times altogether did you see a doctor for this condition over the last six months, that is since (month of Year One Clinic Exam)?

● Count the number of physician office or outpatient visits made FOR THIS DIAGNOSIS or problem. Record in the space provided.

■ Question 13d - Were you in the hospital at least one night for this condition over the last six months?

● Code '1 - Yes' if the participant responds yes.

- Ask participant to provide the name and address of the hospital into which they were admitted and report this information on the Physician/Hospital Information Form.

● Code '2 - No' if the participant responds no and skip to Question 14.

■ Question 13e - How many different times were you in the hospital for this condition?

● Record the number of different hospitalizations for this condition.

● This number should reflect the number of admissions for this condition IN THE LAST SIX MONTHS (or since Year-One Clinic Exam) ONLY.

■ Question 13f - Please tell me the admission dates of the hospitalizations.

● Record the admission dates for each hospitalization for this condition. If the exact date is not known, please ask the participant to estimate the approximate date. An estimate is better than missing information. If the participant will not provide a day, please fill in the month and year given and fill in '99' in the area for each 'day'.

■ Question 13g - How many days altogether were you hospitalized for this condition?

● Record sum of all days hospitalized for this condition.

■ Intermittent Claudication: Question 14a - Has a doctor told you that you had a new incident of intermittent claudication or pain in your legs from a blockage of

the arteries since we saw you about six months ago?

- Code '1 - Yes' if the participant responds yes.

  - Ask participant to provide the name and address of the physician who made the diagnosis and report this information on the Physician/Hospital Information Form.

- Code '2 - No' if the participant responds no and skip to Question 15.

- Claudication may also be defined as "pain in your legs from a DECREASE IN BLOOD FLOW".

■ Question 14b - Date of event or diagnosis

- Ask the participant to recall the date that their doctor told them they had the event. Complete as much information as possible here. If the exact date is not known, please ask the participant to estimate the approximate date. An estimate is better than missing information. If the participant will not provide a day, please fill in the month and year given and fill in '99' in the area for 'day'.

■ Question 14c - How many times altogether did you see a doctor for this condition over the last six months, that is since (month of Year One Clinic Exam)?

- Count the number of physician office or outpatient visits made FOR THIS DIAGNOSIS or problem. Record in the space provided.

■ Question 14d - Were you in the hospital at least one night for this condition over the last six months?

- Code '1 - Yes' if the participant responds yes.

  - Ask participant to provide the name and address of the hospital into which they were admitted and report this information on the Physician/Hospital Information Form.

- Code '2 - No' if the participant responds no and skip to Question 15.

■ Question 14e - How many different times were you in the hospital for this condition?

- Record the number of different hospitalizations for this condition.

- This number should reflect the number of admissions for this condition IN

THE LAST SIX MONTHS (or since Year-One Clinic Exam) ONLY.

■ Question 14f - Please tell me the admission dates of the hospitalizations.

- Record the admission dates for each hospitalization for this condition. If the exact date is not known, please ask the participant to estimate the approximate date. An estimate is better than missing information. If the participant will not provide a day, please fill in the month and year given and fill in '99' in the area for each 'day'.

■ Question 14g - How many days altogether were you hospitalized for this condition?

- Record sum of all days hospitalized for this condition.

■ Stroke: Question 15a - Has a doctor told you that you had a new stroke or cerebrovascular accident since we saw you about six months ago?

- Code '1 - Yes' if the participant responds yes.

  - Ask participant to provide the name and address of the physician who made the diagnosis and report this information on the Physician/Hospital Information Form.

- Code '2 - No' if the participant responds no and skip to Question 16.

■ Question 15b - Date of event or diagnosis

- Ask the participant to recall the date that their doctor told them they had the event. Complete as much information as possible here. If the exact date is not known, please ask the participant to estimate the approximate date. An estimate is better than missing information. If the participant will not provide a day, please fill in the month and year given and fill in '99' in the area for 'day'.

■ Question 15c - How many times altogether did you see a doctor for this condition over the last six months, that is since (month of Year One Clinic Exam)?

- Count the number of physician office or outpatient visits made FOR THIS DIAGNOSIS or problem. Record in the space provided.

■ Question 15d - Were you in the hospital at least one night for this condition over the last six months?

- Code '1 - Yes' if the participant responds yes.

- Ask participant to provide the name and address of the hospital into which they were admitted and report this information on the Physician/Hospital Information Form.

- Code '2 - No' if the participant responds no and skip to Question 16.

■ Question 15e - How many different times were you in the hospital for this condition?

- Record the number of different hospitalizations for this condition.

- This number should reflect the number of admissions for this condition IN THE LAST SIX MONTHS (or since Year-One Clinic Exam) ONLY.

■ Question 15f - Please tell me the admission dates of the hospitalizations.

- Record the admission dates for each hospitalization for this condition. If the exact date is not known, please ask the participant to estimate the approximate date. An estimate is better than missing information. If the participant will not provide a day, please fill in the month and year given and fill in '99' in the area for each 'day'.

■ Question 15g - How many days altogether were you hospitalized for this condition?

- Record sum of all days hospitalized for this condition.

■ TIA: Question 16a - Has a doctor told you that you had a new transient ischemic attack or TIA or silent stroke since we saw you about six months ago?

- Code '1 - Yes' if the participant responds yes.

- Ask participant to provide the name and address of the physician who made the diagnosis and report this information on the Physician/Hospital Information Form.

- Code '2 - No' if the participant responds no and skip to Question 17.

■ Question 16b - Date of event or diagnosis

- Ask the participant to recall the date that their doctor told them they had the event. Complete as much information as possible here. If the exact date is not known, please ask the participant to estimate the approximate date. An estimate is better than missing information. If the participant will not provide a day, please fill in the month and year given and fill in

'99' in the area for 'day'.

■ Question 16c - How many times altogether did you see a doctor for this condition over the last six months, that is since (month of Year One Clinic Exam)?

- Count the number of physician office or outpatient visits made FOR THIS DIAGNOSIS or problem. Record in the space provided.

■ Question 16d - Were you in the hospital at least one night for this condition over the last six months?

- Code '1 - Yes' if the participant responds yes.

    - Ask participant to provide the name and address of the hospital into which they were admitted and report this information on the Physician/Hospital Information Form.

- Code '2 - No' if the participant responds no and skip to Question 17.

■ Question 16e - How many different times were you in the hospital for this condition?

- Record the number of different hospitalizations for this condition.

- This number should reflect the number of admissions for this condition IN THE LAST SIX MONTHS (or since Year-One Clinic Exam) ONLY.

■ Question 16f - Please tell me the admission dates of the hospitalizations.

- Record the admission dates for each hospitalization for this condition. If the exact date is not known, please ask the participant to estimate the approximate date. An estimate is better than missing information. If the participant will not provide a day, please fill in the month and year given and fill in '99' in the area for each 'day'.

■ Question 16g - How many days altogether were you hospitalized for this condition?

- Record sum of all days hospitalized for this condition.

■ Question 17 - If one or more physician visits were reported above, ask: In addition to the doctor visits you have already told me about, how many times altogether since we saw you six month ago have you seen a doctor because of your health?

If no physician visits were reported, ask: How many times altogether since we say

you six months ago have you seen a doctor because of your health?

- Record total number of physician visits reported (These are non-cardiovascular or non-CHS endpoint visits).

- Record '00' if none are reported.

■ Question 18 - If one or more hospitalizations were reported above, ask: In addition to the hospitalizations you have already told me about, how many times altogether have you stayed overnight as a patient in a hospital since we saw you six months ago?

If no hospitalizations were reported, ask: How many times altogether have you stayed overnight as a patient in a hospital since we say you six months ago?

- Record total number of hospitalizations reported (These are non-cardiovascular or non-CHS endpoint hospitalizations).

- Record '00' if none are reported. If there were no additional hospitalizations, skip to Question 20.

■ Question 19 - Please tell me the reason you were admitted and the date of each admission for each time you stayed overnight in a hospital.

- For each non-cardiovascular hospitalization, record the reason and date of admission in the spaces provided.

- You may record information for up to five hospitalizations on the form itself. If there have been more than five stays, record the additional information on a separate piece of information and attach to the questionnaire.

- Ask for the name and address of the hospital for each stay and record this information on the Physician/Hospital Information form.

- After the participant has completed giving you information, you may probe further saying, "Were you an overnight patient in a hospital at any other time during the past six months?" If additional stays are reported, complete information in the space provided above.

- If a hospitalization was reported, remind the participant of CHS investigation into events by stating the following:

  As explained at your original clinic visit, records of these

hospitalizations will be reviewed for medical information that may apply to the CHS study.

- Remind participant of the importance of notifying the Field Center of any future hospitalizations:

  So that we can better understand any changes that may occur in your health, please remember to call us if you are admitted to a hospital for any reason.

■ Question 20 - Have you stayed overnight as a patient in a nursing home or rehabilitation center since (month participant made clinic visit)?

- Code "1 - Yes" if participant states that s/he has stayed overnight in a nursing home or rehabilitation center; code "2 - No" if s/he has not.

- If participant responds "No", skip to Question 22.

■ Question 21 - Please tell me the reason you were admitted and the date you were admitted as a patient for each time you stayed overnight in a nursing home or rehabilitation center.

- For each stay, record the reason and date of stay in the spaces provided.

- You may record information for up to five separate stays on the form itself. If there have been more than five, complete the remaining information on a separate piece of paper and attach to questionnaire.

- After the participant has completed giving you information, you may probe further saying, "Were you an overnight patient in a hospital at any other time during the past six months?" If additional stays are reported, complete information in the space provided above.

- If a nursing home stay was reported, remind the participant of CHS investigation into events by stating the following:

  As explained at your original clinic visit, records of these nursing home or rehabilitation center admissions will be reviewed for medical information that may apply to the CHS study.

- Remind participant of the importance of notifying the Field Center of any future admissions to a nursing home or rehabilitation center:

  So that we can better understand any changes that may occur in your health, please remember to call us if you are admitted to a

nursing home for any reason.

3.10   Life Events

■   Questions 22 to 30 - The Life Events Questionnaire consists of nine questions in addition to the one regarding moving (Question 4).

   ●   Script - "I am now going to ask you about a number of events that commonly happen in people's lives and that can affect your health. In some cases, I will ask whether the event has happened to you or a member of your family during the past six months. In other cases, I will ask only whether it happened to you. When I ask a question about your spouse, I am referring to both married spouses and unmarried partners who live together. Please respond "yes" if the event happened and "no" if it didn't."

   ●   Read each question from the form. For greater detail on this section see Stressful Life Events and Depression Scale in the Manual of Operations.

   ●   Check the response on the form.

   ●   When the participant refuses to answer the question, check   "9 - Unknown".

   ●   If the participant reports any other changes that have happened in the past six months, record the specific event(s) in Question 30.

   ●   Definitions for terms used in the questionnaire are as indicated under "Definitions" above. These should be provided when the participant asks for clarification.

3.11   Physical Function Questions

These questions were designed to measure changes in major physical function categories for the time period between clinic visits. Each question asks the participant if there has been a change in ability to perform a specific function. If yes, it then asks the participant to clarify whether the change was an increase or decrease in the level of difficulty of performing the action.

■   Question 31a - In the last six months, have you had any change in your ability to walk a half-mile (about 5-6 blocks)?

   ●   Code "1 - Yes" if the participant responds yes.

   ●   Code "2 - No" if the participant responds no and skip to Question 32.

■ Question 31b - In what way has your ability to walk changed?

- Code "1 - Less difficulty walking" if the participant responds that he/she is having less difficulty than before or that his/her ability has improved.

- Code "2 - New onset of difficulty walking" if the participant responds that he/she has begun having difficulty, i.e. the change has been from no difficulty to some difficulty.

- Code "3 - More difficulty walking" if the participant responds that the ability to function has decreased or worsened.

- Code "4 - Can no longer walk" if the participant responds that he/she is no longer able to walk, i.e. the change has been from no or some difficulty to no ability to walk.

■ Question 32a - In the last six months, have you had any change in your ability to walk up ten steps?

- Code "1 - Yes" if the participant responds yes.

- Code "2 - No" if the participant responds no and skip to Question 33.

■ Question 32b - In what way has your ability to walk up ten steps changed?

- Code "1 - Less difficulty" if the participant responds that he/she is having less difficulty than before or that his/her ability has improved.

- Code "2 - New onset of difficulty walking" if the participant responds that he/she has begun having difficulty, i.e. the change has been from no difficulty to some difficulty.

- Code "3 - More difficulty walking" if the participant responds that the ability to function has decreased or worsened.

■ Question 33a - In the last six months, have you had any change in your ability to do heavy housework, like scrubbing floors or washing windows... or yardwork, like raking leaves or mowing?

- Code "1 - Yes" if the participant responds yes.

- Code "2 - No" if the participant responds no and skip to Question 34.

■ Question 33b - In what way has your ability to do heavy housework or yardwork changed?

- Code "1 - Less difficulty" if the participant responds that he/she is having less difficulty than before or that his/her ability has improved.

- Code "2 - New onset of difficulty walking" if the participant responds that he/she has begun having difficulty, i.e. the change has been from no difficulty to some difficulty.

- Code "3 - More difficulty walking" if the participant responds that the ability to function has decreased or worsened.

■ Question 34a - In the last six months, have you had any change in your ability to take care of your personal care needs, such as eating, bathing, dressing or getting around the home?

- Code "1 - Yes" if the participant responds yes.

- Code "2 - No" if the participant responds no and skip to Question 35.

■ Question 34b - In what way has your ability to do heavy housework or yardwork changed?

- Code "1 - Less difficulty" if the participant responds that he/she is having less difficulty than before or that his/her ability has improved.

- Code "2 - New onset of difficulty walking" if the participant responds that he/she has begun having difficulty, i.e. the change has been from no difficulty to some difficulty.

- Code "3 - More difficulty walking" if the participant responds that the ability to function has decreased or worsened.

■ Question 35a - In the last six months, have you had any change in your ability to do tasks with your arms and hands, such as reaching out, gripping, lifting or carrying something as heavy as ten pounds (a bag of groceries)?

- Code "1 - Yes" if the participant responds yes.

- Code "2 - No" if the participant responds no and skip to Question 36.

■ Question 35b - In what way has your ability to do heavy housework or yardwork changed?

- Code "1 - Less difficulty" if the participant responds that he/she is having less difficulty than before or that his/her ability has improved.

- Code "2 - New onset of difficulty walking" if the participant responds that he/she has begun having difficulty, i.e. the change has been from no difficulty to some difficulty.

- Code "3 - More difficulty walking" if the participant responds that the ability to function has decreased or worsened.

■ Question 36a - In the last six months, have you had a fall?

- A "fall" if defined here as an event which results with a person coming to rest inadvertently on the ground or other lower level (e.g. onto a chair, stairs, etc.).

- Code "1 - Yes" when the participant had the condition as described.

- Code "0 - No" when the participant did not have the condition as described and skip to Question 37.

■ Question 36b - How many times have you fallen in the last year?

- Record the number of times participant has fallen during the past year.

- When the exact number is not known, record an estimate.

3.12   Proxy and Contacts Tracking

■ Questions 37 and 38 request verification of the proxy and contacts (Contact 1 and Contact 2) previously provided to CHS.

- For current information, go to the hard copy of the Participant Tracking Information Sheet.

- Changes should be made directly onto the Participant Tracking Information Sheet.

■ Question 39 - Do you plan to be out of the area 6 months from now?

- Code "1 - Yes" or "0 - No".

- If the participant is planning to be out of the area, it is important to ascertain if the relocation will be permanent or temporary. Temporary relocations include vacations, business, trips, alternate (e.g. summer) residences, or other travel. Code "1 - Permanently" or "2 - Temporarily out of the area".

- If the participant is moving out of the study area permanently, ask for the address and telephone number of the new residence. If this level of detail is not known as yet, record the general area into which the participant will be relocating.

- If the participant is only leaving the area temporarily, record the month and year in which s/he will return. Ask him/her to please call CHS to make an appointment for the annual visit upon his/her return.

3.13   Closing

■ Closing script: "Thank you very much for answering these questions. I enjoyed talking with you. Please call us if you move or if you should have to go to a hospital or nursing home, even if you have moved from the area. You are always welcome to call collect. I look forward to talking with you and seeing you in the CHS clinic during your annual visit six months from now."

■ Question 40 - Record the time (hour and minutes) at which the interview ended.

■ Question 41 - If another participant is scheduled to be interviewed, ask to speak with him/her. If the individual is not in or it is not a convenient time for him/her, reschedule the interview for another time. If the participant agrees, begin the interview using another Follow-Up Telephone Interview form.

■ Following each interview, record your Interviewer ID Number and date of the interview in the spaces provided on the bottom of each form.

3.14   Proxy Procedures

In the event that a participant is physically incapacitated (e.g. comatose, hearing impaired, etc.), no longer able to function cognitively, or unable to be contacted during the telephone follow-up period, the interview may be conducted with the participant's proxy. For the Follow-Up Telephone Interview, the following guidelines apply:

- The person who is interviewed must be the proxy named on the Participant Tracking Information Sheet. If the proxy has changed, information on the new proxy must be entered on the sheet.

- Instruct the proxy to answer <u>for the participant</u> (to the best of his/her

knowledge) in lieu of the participant responding him/herself. If the proxy does not know the answer, "Don't Know" or "Unknown" is to be recorded rather that a guess. Also, keep in mind that the participant's name or "him/her" should replace "you" in the specific questions where appropriate.

- Record on the form whether the interview was completed by the participant or a proxy.

- If a proxy was interviewed, please record the reason for the use of the proxy.

  - Code '1 - Hearing' if the participant had a hearing problem;
  - Code '2 - Cognitive' if the participant was not able to complete the interview due to cognitive function ability;
  - Code '3 - Hospitalized' the participant was unavailable due to a hospitalization;
  - Code '4 - Other Illness' if another physical illness prevented the participant's ability to complete the interview;
  - Code '5 - Other, specify' if any other reason was involved. Please record the specific reason in the space provided.

3.15   Physician/Hospital Information Form

This form was designed to collect information which may be needed at the Field Centers to track events but which is not going to be entered into the CHS data base. If a CHS endpoint is reported by a participant, the interviewer asks for the name and address of the physician and/or hospital providing the diagnosis. This form may then be forwarded to the site Events Coordinator for follow-up activities. This form is to be used internally by the Field Centers; there is no need to send a copy to the Coordinating Center.