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Manual 16

Follow-Up

April 21, 2011 - Version 1.1

Study website - <http://www.csc.unc.edu/hchs/>

**Follow-Up
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ANNUAL FOLLOW-UP OF HCHS/SOL PARTICIPANTS

Annual follow-up (AF) of cohort members is used to (1) maintain contact and correct address information on cohort participants, (2) update tracing information on two or more contact persons, (3) ascertain the participant's vital status, and (4) document medical events/hospitalizations and life events since the baseline examinations.

1. Overview of Follow-Up Procedures

There are four primary components to annual follow-up: (1) the generation of scheduling material by the HCHS/SOL Coordinating Center and/or the Field Centers; (2) the scheduling of the AF interview by field center staff; (3) the administration of the AF interview; (4) the ascertainment of medical information relating to hospitalizations for cardiovascular disease and documentation of fatal events. These steps are summarized in Figure 1 and described in the following sections. Although no follow-up physical examination has currently been included in HCHS/SOL, it is possible that an additional field center visit will be added in the future. If so, this manual will be expanded to include procedures for the follow-up field center examination.

Figure 1 Annual Follow-up Contact Procedures after Baseline Examination in the HCHS/SOL Cohort Study



- (a) Send Pre-AF Interview reminder letter (Optional but recommended).
- (b) Conduct Annual Follow-up telephone interview.
- (c) Send Annual Contact Letter for cohort members who cannot be contacted by telephone.
- (d) Make secondary collateral contacts if no response from participant

2. Eligibility Requirements for Annual Follow-Up

All persons meeting the minimal standards as participants in the baseline examination (Exam 1) are to be contacted annually unless they have specifically requested no further contact or they have become permanently lost-to-follow-up. This includes participants who have moved away from the community in which they were recruited. AF telephone interviews can be conducted with participants wherever they may live on the anniversary date for a follow-up interview. At the September 20, 2010 meeting of the HCHS/SOL steering committee the following rules for eligibility were adopted. The protocol specifies six study components that are required for active follow-up; otherwise the participant is not eligible for AFU interview, events collection or ancillary studies (ie, "passive follow-up" would be used instead of an "active" or direct interview contact). Full AFU eligibility is determined by the presence of six mandatory components from the baseline examination: Informed Consent, Blood draw, Anthropometry, Seated blood pressure, Medical History, and Personal identifier forms. Before an individual is assigned passive follow-up status, they will receive two invitations from HCHS/SOL to complete the missing components. Participants who are designated as "passive follow-up only" because they lack the minimum study components will be so notified via PI letter. Participants in passive follow-up would be eligible for repeat examination visits during any future SOL renewal

3. Time Window for Annual Follow-Up Contacts

Study participants are re-contacted annually as closely as possible to their baseline examination anniversary date. AF contacts begin in March, 2009 since that is one calendar year since the start of the first baseline examinations in 2008 and will continue indefinitely as long as the study is funded. Contact years are numbered sequentially, starting with the year of the baseline examination, which is contact year 1, regardless of the calendar year in which it was completed (see Appendix 1).

Because recruitment of the cohort occurs over a three year period, participants could later be in any one of three HCHS/SOL contact years (see Table 1).

Table 1 Recruitment and Follow-Up Timetable for HCHS/SOL

Calendar Year	Baseline year/Recruitment Cohort		
	2008-2009	2009-2010	2010-2011
<u>Initial Clinic Visit (start of CY01)</u>			
2008	<u>CY01</u>	--	--
2009	--	<u>CY01</u>	--
2010	--	--	<u>CY01</u>
<u>First Follow-Up Phone Interview (end of CY01)</u>			
2009	<u>CY02</u>	--	--
2010	--	<u>CY02</u>	--
2011	--	--	<u>CY02</u>
<u>Second Follow-Up Phone Interview (end of CY02)</u>			
2010	<u>CY03</u>	--	--
2011	--	<u>CY03</u>	--
2012	---	--	<u>CY03</u>

Regardless of the contact year, the targeted time for annual contact is within 3 weeks (before or after) the baseline examination anniversary date. A window, up to 3 weeks before and 6 months after the target date, is the maximum allowed for each annual contact. When the contact window expires and no contact is made, a final result code for that window is entered on the record of contacts with the participant on the Annual Follow-up Tracking (AFT) form. The next contact year window begins immediately as the previous one ends.

The contact year to which a participant death is assigned is determined by whether or not the participant has already been interviewed for a particular contact year. If the death occurs after the interview is completed, it is assigned to the next contact year. If the death occurs before the interview is completed for that year, then the death is assigned to the current contact year.

4. Participant Contact Procedures for Annual Follow-Up

HCHS/SOL field centers initiate the AF procedures by generating several times a year AF materials for use in scheduling and conducting the AF interview. The study data management system for participant follow-up has specialized reports and an interviewer work flow display panel to facilitate conducting interviews with the participant. Information about the participant from their baseline interview will be used to populate participant tracing information on the annual follow-up form. The participant tracking information includes the participant's name, address, telephone number(s), date of baseline visit; and the names, addresses, and telephone number(s) of THREE contact persons and the personal physician. The annual follow-up form for the current year will list the most recent data on file for the names and addresses of the participant and his/her contacts.

5. Informant/Alternate Responses for HCHS/SOL Participants

For purposes of the HCHS/SOL annual follow-up call (AFU) an alternate respondent is defined as a well-informed, mature individual who can answer health related questions on behalf of an HCHS/SOL cohort member if the latter is not available, or is unable to provide the information. A family member or other person age 18 or older who shares the participant's household or knows him/her well may qualify as an alternate respondent, if sufficiently well informed about the participant's health and use of health care. The circumstances in which an alternate respondent is needed are outlined in the Retention Manual 3-Appendix 1.

An alternate respondent is needed if the interviewer has indications that the participant has difficulty answering, or may have cognitive problems. The interviewer may use his/her judgment to determine if the participant is cognitively impaired and unable to answer questions reliably.

Before scheduling an AFU interview, HCHS/SOL personnel should review records from the initial interview or, in the case of a 2nd annual follow-up, the previous AFU interview. If the previous interview was conducted with an alternate respondent, the alternate respondent should again be contacted to schedule the follow-up interview. Alternate respondent information (if available) can be obtained from the ARE form in the DMS. A copy of the letter containing alternate respondent information should be available in the participants file.

Alternate respondent interviews should not be utilized when the HCHS/SOL cohort member is temporarily unavailable due to a short-term illness, travel or incarceration. In these cases, the interviewer should call back the HCHS/SOL cohort member when s/he is expected to return home. If the HCHS/SOL cohort member will be unavailable throughout their AFU window, the interviewer should report the cohort member as alive but not contactable.

6. Preparing Initial Follow-up Contact Letter(s)

Depending upon requirements of the local field center's IRB, or at the option of the FC, a letter may be sent to the participant prior to the AF call. However, a letter will always be mailed in the event that telephone contact is not completed by three weeks after the anniversary date. This letter contains:

1. A reminder that the addressee is in the study and that annual contact is involved.
2. A description of the purpose of the contact.
3. Information that the participant should obtain to assist with the interview (e.g., hospitalizations, physicians visits).
4. Any additional materials like response cards that may be needed during the interview.
5. A request to call the HCHS/SOL Study office to set up a time to complete the Annual Follow-up Interview.
6. If applicable: Alternate respondent designation form can be mailed to participants at this time. The circumstances in which an alternate respondent letter is mailed are outlined in the Retention Manual 3-Appendix 1.

Participants who do not have phones, have trouble communicating by telephone, or have special needs may be visited in their home to complete the AF interview. In this case, a letter indicating that study staff will be attempting a home visit should be mailed at least one week before the anticipated home visit. Alternate respondent letter should be completed at time of visit.

7. Verifying Participants Lost to Follow-Up

If study staff are unable to contact a participant after repeated calls within three weeks past the anniversary date, additional efforts to locate the participant should be initiated. These efforts include sending return receipt requested mail to the participant, searching printed and online directories for new addresses or phone numbers (e.g., whitepages.com [free] or 555-1212.com [fee-based]), calling the participant's contacts as listed on the tracing report, when practical, a visit to the last known address to contact family or neighbors may be undertaken, and finally, if consent has been obtained, the FC may contract with a credit reporting firm to locate a new address or phone number for the participant. When the social security number is available, the Social Security Death Index (updated every 6 months) may be searched to determine if the participant's death has been reported to the SSA (the SSDI can be searched for free at <http://ssdi.rootsweb.com/> and a fee-based service is available through ancestry.com.) Again, if the SSN is available, the National Death Index (NDI) can be searched from time-to-time. The NDI is fee-based and submissions should be conducted after consultation with the Coordinating Center.

Repeated and varied efforts to make contact with each participant should be undertaken utilizing all the information available to the FC. Only after all efforts have failed or the time window expires should a participant be declared lost-to-follow-up. On the Annual Follow-up Record of Calls form, a final contact status (result) code indicating the participant cannot be located (i.e., is lost-to-follow-up) is only to be assigned after all tracing avenues have been exhausted and supervisor approval has been obtained. Experience has shown that participants who are lost to follow-up in one year may be located in subsequent years of follow-up and only participants who die or insist on no further contact with the HCHS/SOL study should be considered irreparably lost to the study.

8. Scheduling the Annual Follow-Up Telephone Interview

Administration of the AF is carried out at each FC on a continuous and ongoing basis. The procedure involves identifying participants needing annual contact based upon the anniversary date of their baseline examination, establishing contact, administration of the AF form, and enumeration of participant-reported medical events. Scheduling reports for each year of annual follow-up are provided online as part of the HCHS/SOL DMS Report facility (see DMS Reports documentation and training slides for AFU). The procedures for event classification are described in Manual 15. Retention activities that encompass the annual follow-up contact are described in Manual 3. The first contact with a participant is suggested to be by mail because advance materials can be sent to the participant that describe the interview, outline the need to refer to current prescribed medications, and also include any bilingual response cards need during that interview. Field centers should include a number for participants to call to schedule their follow-up interview on these reminder letters. If no response occurs within 2 weeks of the mailing then contacts should be initiated by telephone

AF interviewers are to telephone study participants at their homes at optimal times (i.e., late afternoons, evenings, or weekends) to conduct the annual follow-up interview. When the timing of the initial contact is inconvenient for the participant, the interview is to be rescheduled. When a cohort member cannot be reached on the first call, the interviewer makes return calls as necessary, at varying times of the day and week until either the participant is contacted or a decision is made to initiate tracing procedures.

9. Conducting an Interview with an Alternate Respondent.

When an interview is completed by an alternate respondent, the alternate respondent is asked to answer for the participant (to the best of his/her knowledge) instead of the participant responding him/herself with the help of the "alternate respondent." If the alternate respondent does not know the answer, "Unknown" is recorded rather than a guess. During the interview the participant's name or "him/her" should replace "you" in the specific questions, where appropriate. When an interview is completed by an alternate respondent this is recorded on the AFU as the result code for - Contacted, Interview Complete (by) Alternate Respondent/Informant.

Some designated components of the AFU are skipped when an alternate respondent is utilized. Once an interview is designated as an alternate respondent interview, these skips should occur automatically in the data entry system. If an alternate respondent is fully responsible for

preparing a HCHS/SOL cohort member's food, the alternate respondent may be asked to respond to questions on the 24-hour dietary recall. ***When an alternate respondent is utilized for the 24-hour recall, a note MUST be entered in the log to indicate that an alternate respondent's responses were utilized and that the alternate respondent was fully responsible for preparing the alternate respondent's food.*** An alternate respondent should **not** be asked to provide answers for the FPQ.

10. Making Special Arrangements for Out-of-Area or Institutionalized Participants

Because all follow-up interviews are currently designed to be conducted via telephone, no special arrangements are needed for out-of-area participants. The field center that recruited a participant will continue to have responsibility for conducting the follow-up interview with that participant. Field centers will make the necessary arrangements to have staff available for follow-up telephone calls as needed for the various time zones represented in their participant list.

During the course of annual follow-up activities we will experience having participants admitted to medical rehabilitation, nursing, or assisted living facilities for either short or long term care. It is permissible to perform an AFU interview either by telephone or in-person interview depending upon individual circumstances. Participants who are incarcerated **cannot** be interviewed while in the custody of those institutions. However, those participants can and should be approached and interviewed after release in order to have complete AFU interview data on all segments of the study cohort.

11. Making Reminder Phone Calls

When the timing of the initial contact is inconvenient and the interviewer must re-schedule the AF interview, a reminder phone call prior to the day of the scheduled interview is suggested but not required. The reminder phone call should contain:

1. A reminder regarding the date and time of the follow-up interview.
2. A reminder regarding the information that the participant should have available to assist with the interview (e.g., hospitalizations, physicians visits).
3. A request to call the HCHS/SOL Study office if they have any questions.

12. Use of Text Messages and Cell Phones

In recent years there has been a shift away from the predominant use of land based phone lines to a mixture of cellular phones and land lines in the United States. Often for cost saving measures, households may use cell phones exclusively in preference to land lines because they are inherently portable and provide a flexible means of communication. However the use of text messages and cell phone calls will often cost the recipient money for each message or call. If a cell phone is the sole means of telephone contact with a study participant, then field centers should be sensitive to making calls to those numbers during off-peak hours to minimize any costs to the participant.

13. Call Back Messages on Answering Machines

Messages on respondents' and contacts' answering machines must be approved by the IRB. The message should be simple and should repeat the call back number slowly and clearly. For example, " My name is _____. I am calling from the Hispanic Community Health Study/Study of Latinos. My number is _____. Please do call me back at _____."

14. Content of Annual Follow-Up Interview

Question by question (QxQ) instructions for the record of contacts and for the Annual Follow-up form and prototype scripts for their administration have been prepared for the interview (see study web site). The interview includes the use of three forms. The record of calls should be documented using the annual follow-up tracking form (AFT) which is used to keep track of attempts to contact a participant. The Annual Follow-up Interview questionnaire, is used to ascertain their vital status (AFE/AFS, section A), hospitalizations (section B), other health information determined by the HCHS/SOL steering committee (section C), current medications (section D), and participant & contacts address update information (section E).

The components of the AF interview are usually done in the following order: (1) completion of the tracking information on AFT; (2) administration of the five-part AFE questionnaire; (3) and concludes with administration of the separate Food Propensity Questionnaire (FPE) during the first contact year of the study.

15. Record of Contacts Form

The Annual Follow-up Tracking form (AFT) is used throughout the contacting process to log each participant's interim and final contact and appointment status (when applicable). The participant's name, ID, contact year, and contact year date ranges are pre-printed at the top of the form. Space is provided to document contact attempts, pertinent information for future contacts, and the outcome of the contact. There are ten contact RESULT CODES (0 through 9). The final result code is circled and entered into the data entry system. The paper copy of the form is kept in the participant's folder to assist in future contacts.

*RESULT CODES (CIRCLE THE FINAL SCREENING RESULT CODE
(AFTA Item 2)

- 0 Pending contact/ No Action Taken
- 1 Tracing (No contact with any source, primary or secondary)
- 2 Contacted, Interview Complete with Cohort member
- 3 Contacted, Interview Complete by Proxy/Informant
- 4 Contacted, Interview partially complete or rescheduled
- 5 Contacted, interview refused
- 6 Reported Alive, Will Continue to Attempt
Contact this Year
- 7 Reported Alive, Contact Not Possible this Year
- 8 Reported Deceased
- 9 Unknown vital status

Codes 0, 1, 4, and 6 are interim codes. Codes 2, 3, 5, 7-9 are final codes. Detailed instructions for completing the tracking form are provided in the QxQs, with a description of the Results Codes for contacts. It should be noted that these codes are required for all Annual Follow-Up contacts.

16. Annual Follow-Up Interview Form

Year 1:

Once contact has been made, the entire AF interview is administered to surviving participants. When a participant has expired prior to the annual contact, the relevant portions of the AFE form (only Sections A and E) are administered to a member of the participant's household (or an alternate contact person) in order to obtain enough information to officially record the death and to obtain the date and location of death and other relevant medical information for an Informant Interview form (IIE/IIS) which is described in Manual 15, End Points.

Section A of the AFE form documents the participant's vital status and the date on which the status determination was made. The criteria for establishing participant vital status are defined in the form's instructions. Sections B-D are administered only to surviving participants and document perceptions of health and interim (since the previous AF interview) medical events. Guidelines for administering this section are provided.

Section B on the AFE form is administered to all respondents (participants and proxies) to document overnight hospitalizations in acute or chronic medical care facilities and visits to Emergency Rooms for treatment. Every participant-reported hospitalization and ER visit is verified and the discharge diagnoses recorded. Potential outcome events are reviewed further by the abstraction of participants' hospital records to document the presence/absence of HCHS/SOL Study endpoint criteria. Detailed information on diagnostic criteria and event determination of the cardiovascular, stroke, and pulmonary events is provided in Manual 15.

Section C of the AFE is administered to all respondents (participants and proxies) to document recent chronic health conditions during the past year. These conditions may have been pre-existing at the baseline visit, or have newly occurring ones requiring treatment or instructions for lifestyle modification.

Section D of the AFE is a medications interview for currently prescribed medications. The section would be difficult to obtain by proxy unless that person had permission from the participant to discuss medication use.

Section E of the AFE is administered to all respondents (both participants and proxies) to update and verify the contact tracking information obtained at baseline. The participant tracking information that is currently on the study database (IDE/IDS form) will fill this portion of the AFE form automatically if the interview is conducted online using the DMS. The interviewer simply over writes contact information for the participant or an alternate contact that is being updated so that it can be saved in the study database for use in the next contact cycle.

Year 2:

In year 2 of annual follow-up the interview was expanded to add content on self-reported events since the baseline examination in a revised Section D. This section should be completed only directly by participant interview, not by proxy or alternate respondent. Section E in year 2 is the medication survey; section F covers cigarette smoking and marital status. The usual contract tracking information is contained in the final section, G, that can be completed by an alternate respondent.

Year 3:

The interview for year 3 is a reduced set of the items from year 2. Section A on general health status was modified to clarify if the responses are participant vs. designated (alternate) respondent based. Section D on self-reported events was shortened by dropping hearing related items and items on smoking and marital status that appeared in the second year.

17. Alternate Respondent Form

In order to ensure proper recording of the Alternate Respondent information the CC has created a standalone DMS form called “Alternate Respondent Information” (ARE, version A.) Question by question (QxQ) instructions for the record of Alternate-Respondent form has been prepared and posted on the study web site.

18. Staff Training, Supervision, and Certification

Interviewers are trained and certified in general interviewing techniques and the administration of the AFE form battery. This requires familiarity with the contents and procedures for administering the AFE form battery, assigning contact and appointment status codes on the AFE Record of Calls, scheduling a field center appointment, and verifying contact information on the section E of the annual follow-up form. Staffs are certified centrally in administering the AFE interview battery after review of a standardized protocol. Recertification is required annually with the recommendation of periodic refresher courses and retraining if quality assurance analyses indicate poor performance or inconsistent results.



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Appendix 1. Guidelines for Annual Follow-up Contacts

Introduction: In order to standardize the approach made to study participants in the scheduling and conduct of the annual follow-up interviews some general guidelines are proposed. The annual follow-up interviews for the first, second, and third contacts with HCHS/SOL participants were developed so that the overall participant burden is kept to an average of 30 minutes. The length of the AFE form was shortened for the first year to approximately 10 minutes to permit the food propensity questionnaire (or FPQ) to be administered during the same phone call. Subsequent contact years 2 and 3 add questions designed to capture health outcomes that may occur with the passage of time. Those later interviews may be longer depending upon inter-current health events experienced by the participant

Scheduling the Interview:

- Make initial contact to schedule interview before the anniversary date of the baseline examination (target date + 3 weeks)
- Start of window is 3 weeks before anniversary date
- End of contact year window is 6 months after anniversary date
- Target date for each successive year is indexed to baseline
- First contacts may be by letter (suggested) or telephone
- Anticipate that full the interview will use all the time allotted

Preparing for the AF Interview:

- Produce tracing reports using the DMS for annual follow-up
- Know the contact window to structure the process and make sure that everyone is followed
- Use information on file for best time to call and occupation to inform the phone interview process
- Conduct the phone interview immediately if the participant agrees
- Interviews are designed to be computer assisted using the web based DMS

Conducting the AF Interview:

- Verify that the participant has every they might need for the interview, like access to their prescribed medications, response cards
- Completion of the 5-section AF form and the food propensity questionnaire are the goals for the first contact year interview
- Follow the scripts that are included in the English and Spanish versions of the forms
- Complete as much of the interview in one phone call as possible
- An incomplete interview is better than none at all
- If the participant tires, or has to end the call, be polite and reschedule the remainder
- Do not alienate the participant because each person is important to the cohort