Manual 3:
Retention and Follow-up

3/4/2025 –Version 3.6

Study website - https://sites.cscc.unc.edu/hchs/

Tracking of Revisions to HCHS/SOL V3 MOP #3

[Previous Manual, Date, Version]	Date(s) of Revisions; source	Approved by, Date	Revisions	Previous Page #s section changed etc.	Distribution Date
Version 3.5	10/4/2024	SG	Clarified language used when respondent other than participant responds to an interview. Established consistent use of Alternate Designated Respondent (ADR).	Changes made throughout MOP	01/22/2025
Version 3.6	2/7/2025	SG	GHE(S)1 added to informant line in Table 1. Information about interim vs. final codes updated. Updated AFT version Updated information on coding "don't know' responses from ADR	Pg 14	

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A. RETENTION OF HCHS/SOL PARTICIPANTS

1. OBJECTIVES: RETENTION OF HCHS/SOL PARTICIPANTS

Through retention activities we aim to achieve maximum possible retention of study participants throughout the follow-up period. A separate manual outlines the follow-up process with participants and activities designed to capture annually information that will help detect outcome events (i.e., endpoints).

2. PROCEDURES FOR RETENTION OF HCHS/SOL

To best retain HCHS/SOL participants, we aim to have at least one contact with participants every quarter (i.e., 3 months). Contacts with participants will include a post-visit thank-you card or call, a bi-annual newsletter, a birthday or greeting card, and a holiday or end-of-year card. We aim to design both culturally and religiously appropriate contact documents. Therefore, these contacts will be initiated by each field center and will be conducted in the language of choice (i.e., English or Spanish) of the participant. In addition, because some religions (e.g., Jehovah's Witnesses) may not celebrate birthdays or holidays, specialized cards will be designed to accommodate these participants. All newsletters and cards sent to HCHS/SOL respondents will be targeted for a 5th grade reading-level in English and Spanish.

2.1. Initial Visit Change of Address Card

To assist the field centers with obtaining change of address information, each field center should provide respondents with a self-addressed and stamped change of address card that the respondent can drop in the mail if they move. A "forever stamp" should be used to eliminate need for postage. Alternatively, some Field Centers may be able to set the cards up to be charged to the site only when returned by the respondent. This card should be provided to the respondent at the end of the initial visit.

2.2. Post-Visit Thank-You Card with Optional Evaluation Component

Currently, there are no requirements for a thank you call after the respondent completes the study. Respondents are called on several occasions and for the 24hr dietary recall. Therefore, an additional call is likely to be seen as a burden by respondents.

After completing their initial visit respondents will be sent a thank-you card. These cards should be mailed within 5 weeks of a respondent's initial field center visit. The 5-week time frame should allow coordination with the 24hr dietary recall, and if available, the study results report.

Study sites may, as an option, provide participants with a combined thank-you card and evaluation card at the completion of the initial visit. The thank-you/evaluation card will have an evaluation component that can be torn off and mailed back to the site. The evaluation card will be anonymous and will provide the site with information regarding the quality of the participant's visit. To monitor visit quality, we encourage each site to provide these thank- you/evaluation cards to at least a small subset of participants. This card should be provided to the respondent at the end of the initial visit.

Although thank you calls are not being made. All sites should be aware that approximately one week after result letters are mailed, respondents who have an alert result are to receive a separate call to verify that the results have been received, answer any questions that the participant may have, and to discuss options for referrals if necessary.

2.3. Biannual Newsletter and Fact Sheet

A newsletter will be produced and distributed to respondents biannually (Summer, and Winter). The newsletter will be provided in English and Spanish. With careful design, it should be possible to have English on one side and Spanish on the other. The newsletter should contain 2 articles: (1) feature article (2/3-page), and (2) information for all study participants (1/3 page). Therefore, each site will have responsibility to prepare one article every two years. The dissemination schedule will be as follows.

- Summer – June 1 (San Diego and Chicago)
- Winter – December 1 (Bronx and Miami)

The first newsletter to HCHS/SOL participants was established on June 1, 2008. A quarterly newsletter was prepared until end of baseline visit. Biannual newsletters started after end of baseline recruitment in January 2014.

A fact sheet will be produced and distributed to respondents biannually (Fall and Spring). The fact sheet will summarize findings from past HCHS/SOL publications. These fact sheets will be produced by the HCHS/SOL Ad Hoc Science committee.

The Coordinating Center will post newsletters and fact sheets on the HCHS/SOL website. Each site will then be responsible for downloading and distributing the newsletter and fact sheet to respondents. Please note that this newsletter and fact sheet are intended for HCHS/SOL respondents and NOT the community. The field centers may choose to send the newsletter and fact sheet to other interested parties and stakeholders. However, the content of the newsletter and fact sheet should be directed to HCHS/SOL respondents as a part of the study's retention process.

2.4. Birthday/Greeting Card

Field Centers will send a birthday card to each respondent 1-2 weeks prior to their birthday. For respondents who indicate that they do not celebrate birthdays, a greeting card will be sent in place of a birthday card. A template for these cards is provided.

The Annual Follow-Up (AFU) Participant Tracing Information Sheet (see section 5.1) will include information from the baseline survey on the religion of the respondent (Catholic, Protestant, Other Christian, Other Religion, Secular). Those respondents who indicate that they are other Christian will receive greeting cards instead of birthday cards.

2.5. Holiday/New Year's Greeting Card

Field Centers will send a New Year's card to each respondent in January. A template for these cards will be provided.

2.6. Primary Contact Notification Card and Letter

The respondent should be provided with a letter to give to each of his/her 3 primary contacts. These letters will indicate that the participant has provided his/her name as a contact person to the HCHS and has given permission to the HCHS to contact him/her to obtain updated address, phone, and/or e-mail information on the participant. This letter should be provided to the respondent at the end of the initial visit.

2.7. At the initial visit, the HCHS/SOL participant will also be asked to sign a card addressed to his/her contact. The card will also indicate that the participant has HCHS/SOL permission to contact him/her to obtain updated address, phone, and/or e-mail information on the participant. This card will be retained by the site and may be mailed to contacts before a site calls the contact. This will help improve responsiveness of the contact to queries from HCHS/SOL.USPS Address Service and Returned Mail Log

All mailings to participants should follow USPS standards for address correction/return services. Specifically, the words "ADDRESS SERVICE REQUESTED" or "RETURN SERVICE REQUESTED" should appear on the face of the card or envelope to ensure that any address changes are reported back to the Field Center (see USPS Quick Service Guide 507d, Additional Services, Ancillary Service Endorsements http://pe.usps.com/text/qsg300/Q507d.htm for further information).

To assist with identifying respondents who have moved and may be more difficult to follow, a returned mail log is kept by each field center for all cards and newsletters that are marked returned to sender. Each field center designs and maintains its own returned mail log. The Coordinating Center does not require a copy of these field center logs.

2.8. Retention Timeline

At the end of the initial visit, HCHS/SOL participants should be given the following: (1) a change of address card, (2) a notification letter for each of their contacts, and (3) a thank-you card with evaluation tear-off card to mail back (optional). During the exit interview, HCHS/SOL participants should also be asked to sign the contact notification card in either Spanish or English. This will be kept on file by each site and sent out only as needed.

Within 5 weeks of the initial visit, HCHS/SOL participants should be mailed a thank-you card. They will receive birthday cards within 2 weeks of their birthday. They will receive New Year's cards within 2 weeks of January 1. They will receive quarterly newsletters as indicated in section 2.3.

ITEM (Timing of item)	MAILINGS	CALLS	IN-PERSON	ALL SUBJECTS	SUBSET OF SUBJECTS	OPTIONAL
CY1						
Baseline Exam	X	X	X	X		
Change of Address Card (**End of initial visit**)	X		X	X		
Thank you card **(5 weeks after initial visit**)	X			X		
Thank you with evaluation card (**End of initial visit)**			X		X	As per site
Contact Notification Card (**Signed at initial visit)**	X					As per participant
Contact Notification Letter (**End of initial visit)**			X	X		
Alert call		X			X	
Lab results mailing	X					
Birthday/Hello card **(On birthday**)	X			X		As per participant
Newsletter 1 **(June 1**)	X		X	X		Via email
Newsletter 2 (**September 1)**	X		X	X		Via email

ITEM (Timing of item)	MAILINGS	CALLS	IN-PERSON	ALL SUBJECTS	SUBSET OF SUBJECTS	OPTIONAL
Newsletter 3 (**December 1**)	X		X	X		Via email
Newsletter 4 (**March 1**)	X		X	X		Via email
New Year's Card (**January 1**)	X		X	X		As per participant
AFU 4 to 9 (closed)		X	X	X		
AFU 10, 11, 12, 13, 14, 15, and subsequent yrs		X	X	X		
Reminder Call to AFU		X		X		
GEE/S (3/2017-4/2018)					X	
GTE/S (4/2019-3/2020)					X	

2.9. Translations of Newsletters, Letters, and Cards

All newsletters, thank you letters, and cards are translated by the field centers. The HCHS/SOL Translation committee will not be responsible for reviewing and/or approving these translations. The Coordinating Center and Translation Committee only have responsibility for approving the translation of data collection instruments and participant consent forms.

To help promote standardization of the HCHS/SOL retention letters and cards, English and Spanish versions of these letters and cards will be reviewed and approved by the Retention Committee. Approved English and Spanish versions will be posted on the HCHS/SOL website, where they can be downloaded and tailored by each field center. To ensure that all necessary elements of the document have been included, any tailored versions of these letters and cards must be submitted to the retention committee for final approval.

2.10. Tailoring of Newsletters, Letters, and Cards

The biannual newsletter should be downloaded from the Coordinating Center website and distributed as is. The wording of letters and cards should not be modified without prior approval from the retention committee. Letters and cards may be tailored to sites by changing or adding (1) graphical designs or pictures to the card, (2) providing site specific address information, (3) providing site specific phone contact information, (4) changing colors of the text, and (5) changing the order of Spanish and English text where it is provided in the same card.

3. CLINIC ENVIRONMENT AND RETENTION-RELATED RESOURCES

A culturally and linguistically appropriate environment can improve retention efforts. Therefore, field centers are encouraged to use various strategies to help make the examining center waiting rooms welcoming. For example, artwork by local Hispanic/Latino artists can be shown in the waiting room. Examining center clinic areas can be named after persons of interest and importance to the local community.

3.1 Educational Materials and Referral Lists

The waiting rooms for each examining center should be stocked with key educational materials and promotions relevant to the local Latino/Hispanic community. Most importantly, each field center should develop and maintain a referral list for respondents. Referral lists should include (1) information on medical providers (English and Spanish-speaking), (2) childcare services, (3) educational resources, and (4) other services that respondents might need and might ask about during the course of their interviews. These referral lists should be available in the examining center waiting rooms. All study staff should be aware of these materials and be able to provide them to participants as necessary before, during, or after the clinic visit.

3.2 Payment of Monetary Incentives

Field centers will make every effort to ensure that monetary incentives are given to each respondent at the time of their visit to the field center. If this is not possible, field centers will ensure that monetary incentive are given to the respondent within 3 weeks of their visit. Timely payment of incentives will help promote a positive experience and relationship between participants and field center staff.

Field centers may choose to offer additional monetary incentives to participants who call field centers between scheduled AFU calls to report hospitalizations and emergency room visits. By encouraging participants to report these events as soon as they happen, sites may be able to collect more accurate and complete information. See Appendix 6 for more detailed information and scripts to encourage participants to report hospitalizations and ER visits.

3.3 Publicity and Coordination with Community Relations Committee

To enhance participation, the Field Centers should maintain active contact with the media in their communities. Periodic attempts will be made to provide the media with updates of the study and to enhance community support. The Community Relations committee will have primary responsibility for the development and coordination of publicity activities.

As funding permits, it is also recommended that each Field Center work with its community relations group to establish opportunities in-person community events as part of the retention strategy. These might include symposia on key issues facing the community; and these might be coordinated with or tied to other events in the community such as health forums, health fairs, community conventions, etc.

B. ANNUAL FOLLOW-UP OF HCHS/SOL PARTICIPANTS

Annual follow-up (AFU) 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 for each participant, (3) ascertain each participant's vital status, and (4) document medical events/hospitalizations and life events since the baseline examinations.

4. 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 AFU interview by field center staff, (3) the administration of the AFU interviews, and (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-AFU 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

5. ELIGIBILITY REQUIREMENTS FOR ANNUAL FOLLOW-UP

All persons meeting the minimal standards as participants in the 2008-2011 baseline examination (Visit 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. AFU 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 (i.e., "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 at Visit 2 and at any subsequently funded exams.

6. TIME WINDOW FOR ANNUAL FOLLOW-UP CONTACTS

Study participants are re-contacted annually as closely as possible to their baseline examination anniversary date. AFU contacts first began in March 2009, since that was one calendar year since the start of the first baseline examinations in 2008, and will continue indefinitely as long as the study is funded. AFU 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 2). Because recruitment of the cohort occurred over a three-year period, participants could later be in any one of three HCHS/SOL contact years (see Figure 2 on following page).

Regardless of the contact year, the targeted time for annual contact is within 5 weeks (before or after) the baseline examination anniversary date. A window, up to 5 weeks before and 28 weeks (6.5 months) after the target date is the maximum allowed for each annual contact. AFU contact years are administratively closed for all participants in the 3-year long wave for an AFU interview at the end of each calendar year. For example, the last person being interviewed for AFU-6 had their data closed on December 31, 2017. 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 the latest AFU year contact is made. If the death occurs after the interview is completed, and there is no future AFU year available in CDART, a second occurrence of the GHE form is completed. So, for example, if AFU 15 was completed before the participant dies, and AFU 16 is not available, a second occurrence of the GHE form for year 15 would be completed. If the death occurs before the interview is completed for that year, then the death is assigned to the current contact year.

7. PARTICIPANT CONTACT PROCEDURES FOR ANNUAL FOLLOW-UP

HCHS/SOL field centers initiate the AFU procedures by generating AFU materials several times a year for use in scheduling and conducting the AFU interview. The study data management system for participant annual follow-up has specialized reports and an interviewer workflow display panel to facilitate conducting interviews with participants. Information about each 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.

Figure 2 Recruitment and Follow-Up Timeline for HCHS/SOL (2009-2024)

<table>
<tr><td>2009-2014</td><td>2015</td><td>2016</td><td>2017</td><td>2018</td><td>2019</td><td>2020</td><td>2021</td><td>2022</td><td>2023</td><td>2024</td></tr>
<tr><td>Follow up 1-3</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="2">Follow up 4: Mar 2012 – Dec 2015</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="3">Follow up 5: Mar 2013 - Dec 2016</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="4">Follow up 6: Mar 2014 - Dec 2017</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td colspan="4">Follow up 7: Mar 2015 - Dec 2018</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="2"></td><td colspan="4">Follow up 8: Mar 2016 –Dec 2019</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="3"></td><td colspan="4">Follow up 9: Mar 2017 – Dec 2020</td><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="4"></td><td colspan="4">Follow up 10: Mar 2018 – Dec 2021</td><td></td><td></td><td></td></tr>
<tr><td colspan="5"></td><td colspan="4">Follow up 11: Mar 2019 – Dec 2022</td><td></td><td></td></tr>
<tr><td colspan="6"></td><td colspan="4">Follow up 12: Mar 2020 – Dec 2023</td><td></td></tr>
<tr><td colspan="7"></td><td colspan="4">Follow up 13: Mar 2021 – Dec 2024</td></tr>
</table>

Note: the chart illustrates complete contact years for interviews; closure of the AFU interview dates extends for an additional six months per interview cycle

8. ALTERNATE DESIGNATED RESPONDENTS (ADR) FOR HCHS/SOL PARTICIPANTS

For purposes of the HCHS/SOL annual follow-up call (AFU) an **Alternate Designated Respondent (ADR)** 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 aged 18 or older who shares the participant's household or knows him/her well may qualify as an ADR, if sufficiently well informed about the participant's health and use of health care. The circumstances in which an ADR is needed are outlined in Appendix 1.

An ADR is needed if the interviewer has indications that the participant has difficulty answering or may have sensory or cognitive problems. The interviewer may use his/her judgment to determine if the participant is cognitively impaired and unable to answer questions reliably. If there is concern about cognitive challenges, then use the screening protocol outlined in Appendix 1 for the six-item screener instrument.

Before scheduling an AFU interview, HCHS/SOL personnel should review records from the last completed interview with the participant. If the previous interview was conducted with an ADR due to cognitive impairment, the ADR should again be contacted to schedule the follow-up interview. Historic ADR information (if available) can be obtained from the CIE(S) form from AFU years 4 onwards.

ADR interviews should not normally 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, and attempt to complete the HOE(S) and CIE(S) with an ADR. The OPE(S) should not be completed in this case.

Other (non-designated) informant:

If interviewer can reach neither the participant nor an alternate designated respondent, they may complete some questions with a non-designated, "other" informant. This informant may or may not be a quality source of

information and has not been designated as an ADR by the participant. In this case, interviewers should attempt to complete only GHE(S)1 and the CIE(S) form and continue to attempt to reach participant.

9. 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 AFU 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:

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

Participants who do not have phones, have trouble communicating by telephone, or have special needs may be visited in their home or in a long-term care facility to complete the AFU 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 designated respondent letter should be completed at time of visit.

10. 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]), and/or 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. Finally, if consent has been obtained, the FC may contract with a credit reporting form 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) will be searched from time-to-time by the Coordinating Center. The NDI is fee-based, and submissions should be conducted in collaboration with the Coordinating Center where centralized searches are being performed for individuals who have been lost to follow-up for two years or longer.

Repeated and varied efforts to contact 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.

11. SCHEDULING THE ANNUAL FOLLOW-UP TELEPHONE INTERVIEW

Administration of the AFU 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, administrating of the AFU questionnaire, and enumerating participant-

reported medical events. Scheduling reports for each year of annual follow-up are provided online as part of the HCHS/SOL CDART Report (see CDART Reports documentation and training slides for AFU). The procedures for event classification are described within Endpoints Manual 15. Retention activities that encompass the annual follow-up contact are described previously in chapters 1-3 of this manual. 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 include any bilingual response cards needed during the 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

AFU 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.

12. CONDUCTING AN INTERVIEW WITH AN ALTERNATE DESIGNATED RESPONDENT (ADR).

An alternate designated respondent (ADR) is someone the participant identifies who is well informed on their health history and can answer questions ***on behalf*** *of* the participant. They may be a spouse or adult child or another person who is designated by the participant.

A **Proxy** is a person authorized to act on behalf of an adult not capable of giving consent, thus allowing them to participate in HCHS/SOL. They are also known as a legally authorized representative (LAR). They may be a spouse, child or adult sibling; or another person who is designated by the participant. A proxy may serve as an alternate designated respondent (ADR) depending on how familiar they are with the participant's health history.

An **informant** is someone who knows the participant and can answer some questions ***about*** the participant, but who is not designated as a proxy or ADR. They could be a contact provided by the participant or a person (relative or close friend) contacted at the participant's phone number or home, who knows the participant but may not know details about their health history.

When an interview is completed by an Alternate Designated Respondent, the ADR is asked to answer for the participant (to the best of his/her knowledge) instead of the participant responding him/herself. If the ADR 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 ADR this is recorded on the AFT form as the result code for - Contacted, interview completed w/ADR (AFT5=3) and on the GHE(S) forms as GHE(S)1=3.

Some components of the AFU are skipped when an ADR is utilized. Table 1 shows which components should be completed depending on who the respondent is for the current AFU year. Once an interview is designated as a ADR interview, follow the QxQ instructions for the specific contact year of annual follow-up.

Table 1. Current AFU Forms to Complete Based on Respondent Type

Respondent	Complete forms
Participant	Entire AFU battery: GHE(S), HOE(S), OPE(S), CIE(S)
Alternate Designated respondent who is also Proxy	GHE(S)1, HOE(S), CIE(S), maybe OPE(S)*
Alternate Designated Respondent	GHE(S)1, HOE(S), CIE(S)
Other Informant	GHE(S)1, CIE(S) only

*If ADR is taking care of participant full time due to participant's cognitive impairment, they can complete OPE(S) form on participant's behalf.

13. 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, some participants will be 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. Obtain an alternate designated respondent for all cohort members living in a nursing home or assisted living institution. That ADR can be used to perform the AFU interview in the event the participant is unable. 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.

14. MAKING REMINDER PHONE CALLS

When the timing of the initial contact is inconvenient and the interviewer must reschedule the AFU 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, physician visits).
3. A request to call the HCHS/SOL Study office if they have any questions.

15. 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. Field centers may reimburse participants for costs incurred by the AFU interview phone call at a rate that is consistent with research practices and approved by their local IRB.

16. 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 _____."

17. 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 two primary forms: the interview form and the record of contacts made to complete the interview. 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 (GHE/GHS, section A), hospitalizations (HOE/HOS, section B), other health information determined by the HCHS/SOL steering committee (OPE/OPS, section C), and participant & contacts address update information (CIE/CIS, section G).

The two components of the AFU interview are usually done in the following order: (1) completion of the tracking information on AFT; (2) administration of the multi-part AFE/AFS questionnaire; Administration of other content such as COVID-19 questionnaires (CPE/S and CVE/S at Wave 1, CPEB/S and CVEB/S at Wave 2, CVEC/CVSC at Wave 3) or the script for the invitation to study visits during AFU interviews will vary according to study requirements over time.

18. RECORD OF AFU 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 (AFT Item 5)	
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 Alternate Designated Respondent
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, and 6 are interim codes. Codes 2, 3, 5, and 7-9 are final codes. Code 4 may be used as either an interim code or a final code. 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.

19. CODING ANNUAL FOLLOW-UP INTERVIEW SCHEDULING FAILURES

Background:

All pending interviews need to be closed at the end of a contact window. During the AFU-Y4 Re-Certification training session, the question was raised on how to code AFU scheduling failures, also called “soft refusals”, on the General Health Status part of the questionnaire. These instructions are for those cases where scheduling and completing the interview was incomplete after repeated attempts with the study participant and/or their alternate designated respondent.

Participants who emphatically refuse an interview and all further contact with HCHS will not be contacted for the study again. Therefore, it is important that we distinguish between a scheduling failure for the current year AFU interview, a hard refusal for the current year AFU interview, a case where participant insists on no future contact, either for future AFU years or for all HCHS study matters.

To ensure consistency in CDART data entry for scheduling failures for any given AFU period, the CC has prepared the following guidelines for completing the forms. The goal is to code refusals in a way that will allow them to reappear in future AFU, Exam Visit, and Ancillary Study contact lists. Below is the coding scheme by

AFU year for the Hard-Refusals, Soft-Refusals, AFU withdrawals, and all contact withdrawals using the following working definitions:

Withdrawal from all future contact: Occurs when participant clearly states that he/she does not want to be called ever again for any HCHS/SOL study related matter. This includes Visits, Annual Follow Up and Ancillary Studies.

AFU Withdrawal: Occurs when participant states that they do not want to be contacted for AFU ever again.

Hard refusal: Participant states that they do not wish to complete the current year's AFU interview; however, they do not state a desire to withdraw from AFU entirely.

Soft refusal: A case where the participant says they are not available for an interview at the time of call but does not directly state that they do not want to be contacted ever again. They may even propose one or more alternate days/times for the interview, which fails to be completed.

How to Complete the Interview Forms for Hard vs. Soft Refusals:

Withdrawal from all future contact: For current AFU year and going forward, code these as: **"Contacted and refused interview"**; GHE(S)1=2. Complete Withdrawal form (WTD) making sure to enter date of withdrawal. This action effectively withdraws the person from the cohort study but is reversible should the participant change their mind and/or a family member convinces them to reactivate their status. Reactivation is a rare occurrence.

AFU Withdrawal: For current AFU year, code these as: **"Contacted and refused interview"**; GHE(S)1=2. Create new occurrence of ICT form, setting ICT0c=2 and ICT1=0 to indicate withdrawal from AFU.

Hard Refusals: For current AFU year, code these as: **"Contacted and refused interview"**; GHE(S)1=2. Participant will remain on the AFU contact list for future AFU years.

Soft Refusal (participant alive, but elusive): code these cases as follows:

AFU Y1-Y2: **"Contacted and alive"**; GHE(S)A1=1

AFU Y3 to current AFU year: **"Contacted and alive, agrees to interview";** GHE(S)1=1

Soft Refusals, special data entry instructions:

1) **Code for GHE(S)**: **"Contacted and alive, agrees to interview**" GHE(S)1= 1. Complete CIE(S) form whenever possible. If forms HOE(S), OPE(S), and/or CIE(S) cannot be completed by the end of the participant's AFU window, set these forms to Permanently Missing.

2) **Code for AFT version C (AFTC)**: Use AFT-version C for all AFU interviews. If the participant was contacted but does not complete the interview in the year window, proceed to code the AFTC-Q5=4 "Contacted, Interview partially complete or rescheduled".

Site Judgement

It may be challenging in some cases to distinguish between a hard refusal and a soft refusal/evasion, or between withdrawal from AFU and withdrawal from all future study contact. Sites are encouraged to use their best judgement to determine how to code these cases, with the goal of maximizing the participant's potential future involvement with the study.

20. ANNUAL FOLLOW-UP INTERVIEW FORM

Year 1:

Once contact has been made, the entire AFU 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 another 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 AFU 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 overwrites contact information for the participant or an alternate designated respondent 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 designated 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 designated 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. alternate designated 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.

Years 4 and 5:

The interview for years 4 and 5 administers the similar content as in Year 3. The single change in the questionnaire for these years was to drop the series of questions on place of birth for the participant since those were intended to be administered only once.

Year 6 and 7:

The interviews for years 6 and 7 are a reduced set of the items from year 5. Because the sixth year of AFU coincides with the invitations to attend the second examination the intent is to make this contact as short as possible and still inform the study about participant vital status and hospitalizations. Year 7 continues to collect the core information to learn about potential outcomes of interest and to minimize the participant interview time.

Years 8, 9, 10, 11, 12, and 13:

The interviews for years 8 through 13 have minor changes from year 7 with the addition of an email address for the participant on the contact form. The address fields for the other contacts are simplified. These 6 years of AFU interviews are identical in content.

Years 14 and 15:

Address details in CIE/S form was simplified by removing information deemed unnecessary.

Year 15 and onward:

A second occurrence of the GHE form is to be filled out if a participant passes away after they have completed the last AFU year available in CDART.

21. ALTERNATE DESIGNATED RESPONDENT FORM

The Alternate Designated Respondent form was introduced and used from AFU YR2 until the contact interview periods for AFU YR5, YR6, and YR7 onwards. The form has been replaced by the procedures outlined in Appendix 1. Current CIE(S) forms all have a question for the participant to designate one or more contacts as an alternate designated respondent capable of completing the interview if the participant is unavailable.

22. RECALL PROCEDURES FOR VISIT 3 EXAMINATION

The third HCHS/SOL examination cycle started in January 2020 and will extend for at least 36 months to February 2023. All participants on the eligibility lists provided by the Coordinating Center will be contacted except those who have permanently withdrawn consent to participate (i.e., ICT8=0). Participants who have moved out of the immediate area of the field center or who are lost to follow-up since baseline are still eligible to participate in the third visit and should be contacted as a normal part of AFU. Participants who have moved to within the immediate area of one of the HCHS/SOL field centers are eligible to be seen at that nearby location (e.g., a Chicago participant who moves to Miami). See Appendix 3 of this manual for detailed procedures and a description of the Visit 3 activities.

23. STAFF TRAINING, SUPERVISION, AND CERTIFICATION

All interviewers are trained and certified in general interviewing techniques and the administration of the Annual Follow-up form battery. This requires familiarity with the contents and procedures for administering the AFU form battery, assigning contact and appointment status codes on the AFU Record of Calls, scheduling a field center appointment, and verifying contact information on the section E of the annual follow-up form. Staff members are certified centrally in administering the AFU 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.

Interviewers will be trained to answer basic questions about referrals and health education issues that may arise during the interview. While HCHS/SOL staff will not be able to provide medical or social services consultations, respondents will inevitably have questions and interviewers must be trained to answer them and help refer respondents to services. Interviewers will also be trained to develop cultural competence skills that focus on strategies to connect and engage effectively with HCHS/SOL respondents and maintain a culturally appropriate examination environment (*afecto* / warmth).

23.1 Re-training and Information Sharing Between Interviewers and Field Center Staff

To maintain data collection quality, retraining opportunities or opportunities for refresher courses will be developed. HCHS/SOL will also create telephone and internet forums for exchange and conversation between staff across each site. This will ensure that ideas and strategies for working with our communities are shared and refined across the sites.

23.2 Supervision

Throughout the entire process from initial interview to final examination or refusal, close supervision helps maximize recruitment, retention, and rate of response for follow-up.

Supervisors will record reasons for non-response and examine performance trends by interviewer and by area. As appropriate, supervisors will initiate re-contact with refusing participants to attempt their conversion. Detailed records of all contacts will be maintained.

To facilitate retention, staff working in every branch of a field center, including both recruitment and clinic staff, must be responsive to study participants. Calls and e-mails should be returned within 72 hours. Equipment used by study participants in their home should be picked up within 72 hours after they are no longer needed, and incentives should be paid within 4 weeks.

APPENDIX 1. ALTERNATE DESIGNATED RESPONDENTS (ADR) FOR HCHS/SOL COHORT MEMBERS

For purposes of the HCHS/SOL annual follow-up call (AFU) an alternate designated 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 who shares the participant's household or knows him/her well may qualify as an ADR, if sufficiently well informed about the participant's health and use of health care. The circumstances in which an ADR is needed are outlined in this document. Although technically often called an "informant," this term should not be used in communication with the HCHS/SOL participant or the potential respondents. When talking to the person use terms such as: stand-in, substitute respondent, or alternate designated respondent.

A person authorized to sign a release of medical records or other protected health information on behalf of the study participant is called a "proxy." An ADR may or may not be a proxy. Examples of a proxy include a legal next-of-kin (spouse, son or daughter, brother or sister), their doctor or power of attorney, or a Legal Health Care Informant. If a Power of Attorney (POA) has been designated, a photocopy of the documentation is necessary for a medical records department to release records in the event the participant becomes cognitively impaired and the ADR signs a release form.

When is an ADR Needed? If the interviewer has indications that the participant has difficulty answering the interviewer or may have cognitive problems, the interviewer may be reluctant to use his/her judgment to determine if the participant is cognitively impaired and unable to answer questions reliably. If the interviewer is unsure or unable to make this determination through applying the screening criteria below, the supervisor should be contacted before proceeding with the interview. If the participant appears to be cognitively impaired, an ADR should be utilized. Additionally, an ADR may be utilized if the participant will be institutionalized in a nursing home, or long-term for medical reasons.

1. Need for an Alternate Designated Respondent (ADR)

Cognitive deficits may affect the ability to accurately respond to interviews and questionnaires. Access to a knowledgeable respondent who can assist with interviews and questionnaires is requested for participants whose self-reported information may be suspect. An ADR is a person sufficiently familiar with the participant's health history to be able to provide information on the participant's performance. An ADR may or may not be a medical proxy (able to sign informed consent) for participant.

Unless impairment is obvious, recognizing diminished cognitive ability in a participant is difficult, particularly since social skills can remain intact for participants who otherwise do not perform well during interviews. Cognitive abilities are frequently task specific. As a result, depending on the type and extent of impairment, cognitively impaired individuals can remain fully capable of making a variety of decisions, including whether or not to participate in a study, although they may subsequently exhibit some difficulties during an interview. SOL personnel need to be attentive to indicators of potential cognitive impairment in the course of interviews, such as repetition (i.e., repeating questions/stories over the course of just a few minutes) and empty or poor responses (e.g., the participant who frequently responds with "I don't know"). Individuals who repeatedly wish to engage their spouse or a companion for answers to historical questions or their medical history also may exhibit a reduced capacity to answer all SOL questionnaires.

2. Standardized Assessments to Assist Staff in Defining the Need for a Respondent

Because of the complexity of assessing impairments in cognitive domains, a standardized instrument is used to assess disorientation to time and impaired memory as a screening tool for participant safety and the need for consent by proxy and/or an alternate designated respondent. This tool is the Six-item Cognitive Screener, previously used in the SOL as part of the neurocognitive assessment (NEE/NES forms) in Visit 1. It is important to note that the Six-item Cognitive Screener (SIS) is not a diagnostic tool and that the HCHS/SOL personnel do not make diagnoses. The SIS is used to assist SOL staff to identify cognitive impairment if

deemed necessary, and to assist the study participant accordingly. The results of the SIS are recoded in the SOL database but are not reported as a SOL study result to the participant. If the study participant's performance on the SIS prompts SOL staff to notify the field center clinician for consultation, the latter may include the SIS test results as part of a referral to the participant's health care provider if this is warranted in the opinion of the field center clinician.

This use of a standardized administration of the six-item screener is harmonized study-wide and is incorporated in the procedures by which SOL personnel conduct annual follow-up calls, recruitment calls, and interviews during a field center examination. The factors that trigger the use of the six-item screener, the administration of the instrument, the scoring thresholds, and the actions prompted by the participant's performance are equivalent and harmonized to the setting in which SOL personnel interact with a study participant.

3. Administration of the Six-item Cognitive Screener.

If SOL staff have doubts about the study participant's capacity to provide informed consent, or the participant appears to experience difficulty during the exam visit, a trained SOL staff person administers the Six-item Cognitive Screener using the SIE/SIS form. SOL staff can use the following script:

"Before we continue, I would like to ask you some questions that will help us to decide the best way to conduct the SOL visit. Specifically, I will ask you to use your memory. I am going to name three objects. Please wait until I say all three words, then repeat them.

Remember what they are because I am going to ask you to name them again in a few minutes. Please repeat these words for me: BLUE – PEAR – SOFA." (Interviewer may repeat names 3 times if necessary but repetition not scored.) The interview then continues with items 1-3 ("What year is this?"; "What month is this?"; "What is the day of the week?") and proceeds to ask: "What were the three objects I asked you to remember?" See the six-item screener (SIE/SIS) question-by-question instructions for administration of this form.

4. Scoring of the Six-item Cognitive Screener.

The sensitivity and specificity of the six-item screener relative to psychometric and clinical diagnosis of impaired cognitive functioning are excellent (Callahan CM, Unverzagt, FW, Hui SL, et al. Six-item screener to identify cognitive impairment among potential subjects for clinical research. Medical Care. 2002; 40:771-781). The desired performance of the six-item screener can thus be optimized to the study by selecting cut-point thresholds that best match the study objectives. Consistent with other population-based studies, in the HCHS/SOL impaired memory is operationally defined by a score < 2 on memory items from six-item cognitive screener. Disorientation to time is similarly defined by a score of < 2 on orientation items from six-item cognitive screener.

With very few exceptions, administration of the six-item screener occurs in the setting of the online HCHS/SOL data entry and management system (CDART). Scoring is performed by the automated system with real-time feedback to the interviewer. Instead of numeric scores the system displays information on the recommended action to follow based on the participant's performance on the six-item screener, with scripts that can be used to that effect. Hand calculations are avoided to reduce staff burden as well as inadvertent bias associated with awareness of a participant's individual scores.

5. Criteria for Recruiting an Alternate Designated Respondent (ADR)

Classifying decision-making capacity is challenging and may be task specific. Given the minimal risk associated with the HCHS/SOL AFU interviews or Visit 3 procedures, the following conservative criteria are suggested as **triggers for requiring an ADR**. These include (any of):

- **Staff assessment**, at the time of annual follow-up interview, the examination visit scheduling call, or at the time of in-person informed consent. Because no mental status screen will identify all cases of cognitive impairment, the need for an ADR will be informed by the judgment of the SOL interviewers.
- **Impaired memory** (score less than 2 on the memory items from the six-item cognitive screener).
- **Disorientation to time** (score less than 2 on the orientation items from the six-item cognitive screener).

  Note: Difficulties in cognitive functioning reported by a family member or a self-reported diagnosis of dementia/Alzheimer's Disease (affirmative response to MHE questionnaire item on history of dementia) are not by themselves a reason for requiring an ADR. Instead, they are a trigger to administer the six-item screener. If administration of the six- item screener is impractical or not possible, a report of cognitive functioning difficulties by a family member or caretaker should lead to the recruitment of an ADR.

The need for a respondent will most often be ascertained during an annual telephone interview with the HCHS/SOL participant. The procedures to be followed during a telephone interview are consistent with those described in Manual 2 for the in-person field center setting. If at the time of the annual follow-up call preceding the Visit 3 examination, or at the time of scheduling the examination visit, it is determined that the participant likely requires proxy consent and participation by proxy as described in Manual 2, arrangements are made at that time to identify a proxy to accompany the participant to the examination visit. Similarly, if at the time of the HCHS/SOL examination visit it is determined that the participant requires an ADR, arrangements are made to identify and contact the ADR prior to the subsequent yearly contacts and interviews.

6. Recruitment of the Alternate Designated Respondent (ADR)

If recruitment of an ADR is necessary, the following script can be used: “We think that it might be helpful to have someone [come with you to the clinic/be with you while we complete your SOL examination visit]. This person could assist you in your participation in the study. Do you agree to have someone [coming with you to the clinic/being with you during the exam]?”

If YES:

“This person should be someone who can answer questions for you during an interview in case you do not feel comfortable providing the answers. Who would this person be?” Verify whether this is one of the participant’s contacts and record/update the name, street address, phone number and email address if available, and continue: “We ask you to tell [ALTERNATE DESIGNATED RESPONDENT’S NAME] about your decision. In the next few days, we will also contact [HIM/HER] to provide information about the exam.” Record the ADR’s contact information in the Contact Information Update (CIE/CIS) form. Confirm that the participant agrees to communicate with the respondent to request his/her engagement to assist the continued participation in SOL of the study participant. The ADR is then contacted by SOL staff a few days afterwards.

[Note: Participant can designate more than one ADR in the CIE form, if such is the case].

If NO:

Point out that having a trusted someone would help to make decisions about participation in the study. If the participant still does not agree, consult the supervisor or Principal Investigator.

7. Updated Record of the Use of an Alternate Designated Respondent (ADR)

The use of an ADR is recorded in the SOL central database at the time of conducting an annual follow-up call or noted on the examination checklist (CHK) if the interview with an ADR is conducted at the SOL field center as part of a cohort re- examination (several field center interviews are not suitable for administration via an ADR). The use of an ADR is thus recorded (and updated) in the SOL database and is accessible to SOL staff for any type of encounter with a SOL participant.

Before scheduling an AFU interview, HCHS/SOL personnel should review records from the previous AFU interview. If the previous interview was conducted with an ADR due to cognitive impairment, the ADR should again be contacted to schedule the follow-up interview.

ADR interviews should not normally 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 and attempt to complete the HOE(S) and CIE(S) with an ADR. The OPE(S) should not be completed in this case.

Role of an Alternate Designated Respondent (ADR). It is important not to confuse the role of an ADR with that of an informant. Study participants at times request the help of a family member or friend to answer some of the questions. An informant might be a spouse or relative living in the house who keeps track of the participant's activities. The informant's role is different than that of the ADR identified by the participant in that the informant merely helps the participant locate or remember needed information. The informant does not respond to opinion questions for the participant. On the other hand, an ADR responds to both the factual and assessment questions on behalf of the study participant.

Conducting an Interview with an Alternate Designated Respondent (ADR). When an interview is completed by an ADR, the ADR 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 "ADR". If the ADR does not know the answer to a given question, "Unsure" or a field status of "Don't know" should be 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 ADR this is recorded on the AFU as the result code for - Contacted, Interview Complete (by) Alternate Designated Respondent.

Identification and Tracking of the Alternate Designated Respondent (ADR). The ADR may be one of the persons initially named by the study participant as a contact. During the follow-up interviews for AFU years 4 onwards, interviewers obtaining contact information should ask if one of the contacts provided would be able to provide basic health information in the event that the participant is unavailable. If none of the contacts would be able to provide this information, the interviewer should ask who else might be able to provide the information and should record their name, phone number and address as an additional contact and potential ADR.

This information is recorded and updated as needed on the Contact Information Tracking Form (CIE/CIS) which is completed at the time of an alternate designated respondent nomination and updated at subsequent contacts as needed. If at any time the ADR has changed, the Contact Information Tracking Form is updated with the correct name and contact information for the new ADR. If more than one person in the household can be an ADR, state so in the Contact Information Tracking Form.

If no ADR has been previously designated and the interviewer determines that an ADR is needed at the time of the AFU call, the interviewer may ask an adult who answers the respondents' telephone if they or anyone in the household can provide answers to a few brief questions about the respondent's health. In this case the interviewer attempts to complete GHE(S)1, HOE(S), and CIE(S) with the respondent. If unable to complete any part of the CIE(S) and/or HOE(S), mark these forms as Permanently Missing in CDART.

Other informants:

If interviewer is able to reach neither the participant nor an ADR, they may complete some questions with non-designated, “other” informant. This informant may or may not be a quality source of information and has not been designated as an ADR by the participant. In this case, interviewers should attempt to complete only GHE(S)1 and the CIE(S) forms and continue to attempt to reach participant.

Request for Alternate Designated Respondent Letter English

HCHS/SOL Study

Dear HCHS/SOL participant,

Thank you for participating in the HCHS/SOL study. It is our hope that your participation will help make a positive change in the future lives of Hispanic/Latinos living in the United States.

As you know, we need to stay in touch with you every year to find out how you are doing. Occasionally, participants are unavailable to answer our questions due to illness or prolonged absence. In these cases, we need to speak to another person who knows how you are. This person can be your husband/ wife, adult child and/or any person you believe can give us reliable information about your recent health and any hospitalizations.

To help us know who we should talk to if you are not available, please take a moment of your time to fill out the form below and provide us with the name, address, and phone number of someone who will know how you are. We call this person an alternate designated respondent, appointed by you. When you are done, please return this form to us in the pre-addressed stamped envelope.

We greatly appreciate your support and continued involvement in Project HCHS/SOL. We are looking forward to hearing from you in the future.

As always, thank you for staying in touch! Sincerely,

CASEID#

If I am not available due to illness, the HCHS/HCHS/SOL study may speak with:

_____ _____

Alternate Designated Respondent's First Name **Alternate Designated Respondent's Last Name**

_____

Alternate Designated Respondent's phone number

_____ _____

Alternate Designated Respondent's street address **City** **State** **Zip Code**

Request for Alternate Designated Respondent Letter Spanish

Estudio HCHS/SOL

Estimado participante del Estudio HCHS/SOL,

Gracias por participar en el estudio HCHS/SOL. Es nuestro deseo que su participación haya tenido un impacto positivo en la comunidad Hispana/Latina que reside en los Estados Unidos.

Le recordamos que es importante que nos mantengamos en contacto con usted. En ocasiones los participantes del estudio no están disponibles para nuestras entrevistas de seguimiento, por razones fuera de su control. En estos casos es importante que podamos hablar con alguna persona de confianza designada por el participante. Esta persona puede ser la(el) esposa/o, hijo/a, o cualquier familiar que nos pueda dar información precisa sobre su salud.

Por favor, tome un minuto de su tiempo y provea el nombre de la persona que podamos contactar para que nos dé información sobre su salud. Sólo contactaremos a la persona que usted designe en caso de que usted no esté disponible. Nosotros llamamos a esta persona representante-alterno designado nominado por usted para darnos información sobre su salud. Luego de llenar la información por favor envíela en el sobre pre-dirigido incluido con esta carta.

Estamos sumamente agradecidos por su participación, apoyo y compromiso con el Estudio del SOL. Esperamos saber de usted en un futuro cercano.

¡Como siempre, gracias por mantenerse en contacto! Sinceramente,

---

CASEID#

Si no estoy disponible por razones de enfermedad, el representante del estudio HCHS/HCHS/SOL puede contactar a:

_____ _____

Nombre del Representante Alterno Designado **Apellido del Representante Alterno Designado**

_____

Número De Teléfono Del Representante Alterno Designado

_____ _____

Dirección del Representante Alterno Designado **Ciudad** **Estado** **Código Postal**

APPENDIX 2. GUIDELINES FOR ANNUAL FOLLOW-UP CONTACT

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 AFU Questionnaire 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 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 + 5 weeks)
- Start of window is 3 weeks before anniversary date
- End of contact year window is 6.5 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 the full interview will use all the time allotted

Preparing for the AFU Interview:

- Produce tracing reports using CDART 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 CDART

Conducting the AFU Interview:

- Verify that the participant has everything they might need for the interview, like access to their prescribed medications, response cards, etc.
- Completion of the 5-section AFU 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

APPENDIX 3. PROCEDURES FOR VISIT 3 EXAMINATION CONTACTS (2019-2022)

1. Pre-contact activities

The UNC Chapel Hill IRB will be the IRB of record for AFU and Visit 3 related activities. Each Field Center will be required to obtain reviewing and local IRB approval for the clinic examinations and the basic consent by early November 2019 in order to initiate the Visit 3 pre-contact activities. The Visit 3 recall working group works collaboratively with other committees including the Retention & Follow Up committee and the Community Relations committee. These committees will develop the most effective ways to reach the HCHS/SOL participants including activities such as community canvassing, annual follow up scripts and planning the distribution of retention materials such as the Salud SOL newsletter.

2. Visit 3 Timeline

SOL Visit 3 recall contact will begin in late autumn 2019 and end in February 2023 or later. Each Field Center will start to contact participants 1 to 6 months in advance of the beginning of their Visit 3 recall window. The wide window is necessary in order to re-distribute some visits that occurred late in the second examination cycle into the 36-month Visit 3 period.

The Coordinating Center will open the window for the three waves of participant recalls for the third examination earlier than the usual AFU interview scheduling. It is projected that 80% of our participants will agree to a third examination based on response rates from other large cohort studies. Based on those assumptions, each site will see 5-6 participants per day to meet study goals over the 36-month examination period. However, there is no upper limit to the number of participants who can be examined at each field center because the intent is to retain and re-examine as many of the HCHS/SOL cohort as possible. The eligibility window does not close for Visit 3 until the end of the examination cycle in order to maximize attendance.

A brief pilot study of up to 9 volunteer subjects per field center will be conducted in October 2019 before the first scheduled third visit in December 2019. Note that 9 is the maximum allowed for a pilot study at a single location.

Important: The HCHS/SOL Visit 3 recall examination window will never close, making it possible for all participants to return, whenever logistically possible. Should a drop-out participant want to re-engage with the study, re-consent, and attend the Visit 3 examination they will be welcome.

3. Contacting HCHS/SOL Participants

A. Visit 3 participant eligibility

Recall lists

The HCHS/SOL Visit 3 recall lists were generated in yearly waves by the Coordinating Center (CC) and distributed to the field centers. The first wave of participant recall lists for V3 will include the first wave of V1 recruitment and part of V1, wave 2. Visit 3 recall lists will mirror the initial study recruitment waves to preserve the randomness of the sample. To compensate for the initial slow recruitment start, which peaked during the first HCHS/SOL visit, some wave shifting will be needed. The CC will work with each field center to get an invitation list for Visit 3 with a primary focus on participants that have not produced hard refusals. Each site will carefully track any changes in addresses for participants locally since it will not be possible for the CC to know whether or not participants have moved from their original recruitment areas. Due to these limitations, it is expected that the ability to contact participants who have moved out of the recruitment areas will vary from site to site. The first wave of participants expected to be recalled will be those that meet the study eligibility criteria for literacy and willingness to participate.

Forms

ELE (Participant eligibility form): This form is designed to identify factors that may affect the participant's ability to complete a study visit. It captures information such as preferred language and ability and interest to attend the third examination. The ELE form will be used to document the scheduled appointment date and time for the second exam and will be used by the coordinating center to track recruitment at each center. All participant contacts for Visit 3 will be recorded, including refusals, ineligibles, and those who turn out to be lost to AFU at the time of examination scheduling. If, prior to any Visit 3-related contact, the participant withdrew from all future HCHS-related contact (and did not subsequently re-consent to be contacted), the ELE form should be coded as a refusal (ELE3=1), even though the participant is not contacted at any point for Visit 3.

B. Recruitment materials

The HCHS/SOL will use several materials, including those that were reported as most effective recruitment tools during the baseline study to reach out to study participants. Each participant who is invited to return to complete a third study visit will receive an invitation packet.

C. Types of Recall contacts:

Mailings

A Visit 3 invitation packet will be mailed to each participant identified on the recall lists approximately 2 weeks prior to the time that either telephone or in-person contact is planned. The invitation packet will consist of an invitation letter. This letter will contain an effective recall message which hopes to capture the initial motivation for participation in the study and continued participation as well as the address, telephone number, and email address of the local research center. The mailings can also include a self-addressed, stamped envelope and a change of address form with an option to indicate the preferred time to be contacted to schedule the Visit 3 exam.

Telephone contact

All field centers plan to conduct Visit 3 contact attempts in a similar fashion as conducted during baseline, Visit 2, and ancillary study recruitment. Careful coordination will ensure that minimal contact attempts are made to participants for all areas of the project, to minimize participant burden.

Social Media

In the event that participants do not respond to the aforementioned modes of contact, an attempt will be made to contact through the use of social media.

Electronic Mail

Approved contact materials may be transmitted electronically to the participant if that is their preferred mode of contact established through the AFU interviews. The initial contact should start with the core content of the invitation letter, asking that the participant contact the field center if they would like to know more about Visit 3 and are interested in the re-examination.

In-Person contact (Home visits)

If telephone screening is not successful, or if no telephone number is available for a participant or their identified contacts, an in-person contact will be attempted. A minimum of 2 in-person contact attempts at different times of the day will be made which include an evening/weekend and weekday home visit. When no response is obtained, a note ("Sorry I missed you" card) informing the participant that a HCHS/SOL staff member was there, should be left at the door.

D. Recalling difficult-to-reach participants

There are expected limitations to contacting participants who do not respond to the study contact attempts. Approaches to overcoming those barriers can and will vary at each field center as strategies are implemented to re-engage those hard-to-contact individuals.

Participants with known addresses

Participants with confirmed addresses within a reasonable distance from the field center location who do not respond to a minimum number of contact attempts by paper mail, phone, or email will receive an in-person visit by a study staff member. The number of contact attempts may vary due to local IRB guidelines. A balance must be struck between persistence versus perceived harassment because the study does not want to annoy participants during this recall process.

Participants with non-working numbers

Telephone calls should be attempted during different days of the week, different times of day (mornings, evenings, late hours), and during different times of the month (i.e., beginning, middle and end). After these contact attempts have been exhausted, participants with non-working numbers will be identified and the next steps should be taken to confirm the number including using non-paid public searches such as white pages and reverse look up searches.

Participants who have moved/no forwarding address/non-working numbers.

Participants with no reported updates in contact information including phone numbers, addresses, emails addresses, and other contacts' information will be tracked using advanced search engines including Thompson Reuters Westlaw (People Search) or Lexis Nexus. Although these engines come with a fee attached, they are reported to provide reliable updated information.

Participants who have withdrawn consent for all contact

Participants who have withdrawn consent for future contact with the study will not be contacted by study staff for re-examination. Participants who have asked to be withdrawn from the study cannot be contacted for Visit 3.

4. Coordination of V3 contact

The initiation of the recall process begins with AFU interviewers who will use the following script as they reach participants for their Year-13, Year-12, and in some cases, Year-11 annual interview contact. The timing of the regular AFU interview and the opening of an individual's invitation window for Visit 3 will determine if the introductory script should be used at Year-11 instead of the expected AFU-12 or AFU-13. Visit 3 recall ends in November 2022 and stops being part of AFU calls.

AFU Script (2019-2022):

The following script to introduce Visit 3 has been developed to set the stage for scheduling the visit. If the participant wishes to try to schedule the third examination while on the phone with the AFU interviewer, the interviewer can note preferred days and time and let the field center scheduler know. A call back may be preferred instead of scheduling during the AFU interview because of the need to coordinate the visit with the ancillary studies for which the participant is eligible, depending upon their age and prior participation.

AFU Introduction script: Hello my name is (interviewer name). I am calling to follow up with (participant name) about the Hispanic Community Health Study/Study of Latinos (SOL), a study that s/he is currently enrolled. Is s/he available?

No: When would it be convenient to call back …Thank you. I will call back.

Yes: Hello (participant name), this is (interviewer name), with the Hispanic Community Health Study/Study of Latinos (SOL).

VISIT 3 Script:

"We can't thank you enough for the contributions that you are making in the understanding of Hispanic/Latino health. This information is so important that NIH has extended the study so we will be inviting you to the third in person HCHS/SOL center visit very soon. This third visit will include health exams, questionnaires, and if you are eligible, you may be invited to participate in one or more ancillary studies."

I'm calling now to see how you have been since our last telephone interview and to update our HCHS/SOL records. Do you have a few minutes to speak on the phone?

No: When would it be convenient to call back …Thank you. I will call back.

Yes: We would like to gather information about your general health and about specific medical conditions that you may have had in the past year. I will ask you some questions about your health since the last telephone interview with you on (date of last follow-up call). I want you to focus on what happened from (date of last follow-up call) until today.

AFU Interview occurs

Other study related contact (ancillary studies, etc.) scripts will be developed when those studies are approved and funded.

5. Scheduling the HCHS/SOL Visit 3

When the telephone is answered, ask to speak to the participant being recalled for Visit 3. Once contact is made with the participant, the telephone screening proceeds in four steps, following the eligibility checklist and scheduling form question by question instructions (QxQs) and scripts, as follows.

- Introduce yourself, and the HCHS/SOL study
- Refer to the Visit 3 letter of invitation that the participant should have received
- Check that you are speaking to the participant or alternate designated respondent
- Administer the eligibility form (ELE) and schedule the appointment time and date

If you confirm that the phone call is with someone who is not the participant, then try to find an alternate time for a call back and reach the participant to discuss Visit 3 participation. It is important to enter an ELE form for every participant screened for Visit 3, including participants excluded due to distance from the field center (ELE3=3), or lost to follow-up (ELE3=2) if call attempts are made. Known out of country/ out of state participants can be coded as ELE3=3 for moved out of area. Accurate Visit 3 response rates cannot be calculated unless all participants eligible for follow-up have a final participation status code from screening.

6. Mailings prior to HCHS/SOL Visit 3

After the examination visit is scheduled, a clinic visit packet is sent to the participant. The clinic packet includes but is not limited to: card with date and time of clinic visit, directions to the clinic, contact information for clinic staff, and any instructions that a participant might need to follow prior to the clinic visit (e.g., fasting instructions). This packet should be sent in a timely manner to participant.

In addition to the packet, a confirmation phone call should take place one or two days before the scheduled clinic visit. During that reminder phone call for the Visit 3, field center staff will administer a brief safety screening questionnaire. Any participant safety screening concerns for the exam will be noted on the participant safety screening form (PSE form, see Manual 2- Field Center Operations for more details) and, as needed, discussed with the clinic manager or clinician.

APPENDIX 4. COMPLETION OF CORE AFU INTERVIEW

The core interview scenarios. The core interview consists of GHE(S)1, the HOE(S) form, and the CIE(S) form.

Participant answers and does not have time, they are in a rush to get off the phone:

- The interviewer should attempt to at least get the core interview. Then they should try to schedule a future call to complete the interview. The interviewer can continue to call, until the end of window, to try to complete the full interview with the participant.

Completion of Core AFU with Alternate Designated Respondent (ADR) (see Appendix 1, section 7)

When the interviewer finds an ADR that continually provides excuses for why the study participant is not available, this is an opportunity to complete the core, instead of having no AFU information. After multiple attempts without reaching the participant, the completion of a core interview should be considered within the first three months of unsuccessful call attempts. It is important to verify that the respondent is well informed about the participant's health and is willing to answer the core questions. The number of calls allowed by local IRBs can vary by center, for this reason they are site specific. Respondent cooperation may decline over multiple calls so it is important to capture as much information as possible early in the call attempt process. If the site chooses to continue to call to try to complete the full AFU interview, they can do so until the end of window.

Home Visits

Home visits are performed at the discretion of each site based on staff availability, environmental factors, etc. They may be appropriate in instances where the participant has an active address but no phone numbers, or no successful contact is made after three months of repeated and varied contact efforts.

Refusals from Alternate Designated Respondents (ADR)

Study refusals are accepted directly from the participant. If an ADR (non-proxy) informs study staff of a participant refusal, study staff will advise the ADR to have the participant reach out to the study and communicate their refusal directly. Study staff will further advise the ADR that study staff is only allowed to accept refusals directly from the participant.

If the participant has a cognitive impairment and their proxy refuses, then this should be coded as a hard refusal.

Coding for Core interview

Completed with cohort member:

AFT5= 2 or 4 (Partials), GHE(S)1= 1

Completed by ADR or Proxy (who is also ADR):

AFT5= 3, GHE(S)1= 3

APPENDIX 5. COMPLETION OF COVID-19 PSYCHOSOCIAL IMPACT SURVEY

HCHS/SOL will assess the impact of the COVID-19 pandemic upon the health and well-being of our predominantly urban cohort. The existing AFU protocol of one annual phone interview will not sufficiently document the onset and time course of this event upon study participants. Therefore, the study investigators and sponsor added a short phone administered survey to be implemented as soon as possible from May 2020 onwards, until all cohort members or their designated respondent or next of kin have had an opportunity to respond to this survey. Verbal consent is obtained from the HCHS participants or designated AFU respondent first, before administration of the survey.

Wave 1 of the COVID-19 survey battery was administrated from April 2020 through May 2021. Wave 2 will be administered from August 2021 through September 2022. Wave 3 will be administered starting May 2023.

The COVID-19 survey battery consists of two survey forms administered sequentially, in the preferred language of the participant (Spanish or English). The content of the questionnaires covers the psychosocial and socio-economic impact on HCHS cohort participants since January 2020, and subsequently inquires about COVID-19 health status, testing, hospital admissions and recovery as applicable to the SARS-COV-2 disease experience since that time. The average length of time for this phone contact is 15-30 minutes. A telephone script and verbal consent language appear below and are also included in the question by question (QxQ) instructions for the Wave 2 COVID Psychosocial and COVID Signs & Symptoms forms (CPEB/CPSB and CVEB/CVSB). The COVID forms can be administered at the conclusion of the AFU interview call for the year, or as a separate stand-alone telephone contact with the participant. Below are the English scripts to follow for each of those situations.

Wave 3 consists of one form, CVEC/CVSC. The COVID19 Wave 3 Questionnaire is designed to collect data on the diagnosis and symptoms associated with COVID-19, caused by infection with the SARS-CoV-2 virus. This Wave 3 survey is to be implemented from May 2023 onwards, until all cohort members, or a designated respondent or next of kin, have had an opportunity to respond to this survey. Items from NIH's C4R questionnaire have been included.

If the participant agrees, the COVID form can be administered at the conclusion of the AFU interview call for the year. It can also be administered as a separate, stand-alone telephone contact with the participant, or administered in-person if the opportunity arises during on site exams or ancillary study visits. This flexible strategy will help maximize the number of forms completed. Field centers will work with their staff to operationalize the administration of the forms with their AFU team and clinic staff.

AFU Call Introduction Script:

Thank you for completing the Annual Follow-up Call. To help us understand how the COVID-19 pandemic is affecting participants and their families, we would like to ask you a few additional questions. These will take about 15 minutes.

Separate Call Introduction Script:

Hello, my name is (interviewer name), and I am calling to talk to (participant name) about the Hispanic Community Health Study / Study of Latinos (SOL), a health study in which s/he is currently enrolled. Is s/he

available?

No *When would it be convenient to call back? ..... Thank you. I will call back.*

Yes *Hello, (participant name), this is (interviewer name) with the Hispanic Community Health / Study of Latinos.*

We are calling to check in with you and find out how you are doing. To help us understand how the COVID-19 pandemic is affecting SOL participants and their families, we would like to ask you a few questions. The interview will take about 15 minutes.

This information will be handled the same way as the other data we have collected by phone. Your participation continues to be voluntary. You may refuse to participate or may withdraw your consent to participate at any time, and for any reason, without jeopardizing your future care at this institution or your relationship with the study principal investigator.

If the participant answers that they do not have time to respond, or seem to be in a rush to get off the phone:

- The interviewer should attempt to find a date and time to call back and complete the COVID interview. Then they should try to schedule a future call to complete the interview. The interviewer can continue to call, until the end of current AFU year, to try to complete the full COVID-19 interview with the participant.

If the participant is not available, and the designated AFU respondent answers the call, only section A of the CPEB/CPSB can be completed (contact information). The CVEB/CVSB portion of the interview on COVID-19 related experiences should be completed as much as is possible.

If the participant is deceased, then extend condolences to the family. If the death occurred less than 8 weeks prior to the call, make a note to call back in 8 weeks to follow-up with the COVID experiences (CVE/CVS) questionnaire and complete as much of that form with the respondent as is possible. If the death occurred more than 8 weeks ago, ask whether the respondent is willing to answer a few questions about any experience the decedent may have had with COVID-19. If the respondent is not familiar with the decedent's history, ask whether it is possible to speak to a person who can answer these questions.

See the HCHS Endpoints manual for instructions on how to handle informant interviews respectfully and sensitively with next of kin when discussing the circumstances of a participant's death. Report the death to the AFU endpoints investigation team at your field center per the usual AFU procedures.

The Spanish language scripts for these check-in phone call scenarios follow below:

AFU Call Introduction Script:

Gracias por participar en la llamada de seguimiento de SOL. Para ayudarnos a entender como la pandemia del COVID-19 (coronavirus) está afectando a nuestros participantes y sus familias, nos gustaría hacerle algunas preguntas adicionales. Esto tomará algunos 15 minutos.

Separate Call Introduction Script:

Buenos días/Buenas tardes/Buenas noches, mi nombre es (interviewer name), y estoy llamando para hablar

con (participant name) acerca del Estudio sobre la Salud de la Comunidad Hispana /

Estudio de Latinos (SOL), un estudio sobre la salud en el cual él/ella está registrado(a) actualmente. ¿Puedo hablar con él/ella?

N0 *¿Cuándo sería conveniente llamarlo(a) nuevamente? Gracias. Volveré a llamar.*

Sí *Buenos días/Buenas tardes/Buenas noches, (participant name), mi nombre es (interviewer name) y trabajo para el Estudio sobre la Salud de la Comunidad Hispana / Estudio de Latinos (SOL).*

Estamos llamando para saber cómo se encuentra. También queremos saber si nos puede ayudar a entender como la pandemia del COVID-19 (coronavirus) está afectando a nuestros participantes y sus familias. Nos gustaría hacerle algunas preguntas. Esto tomará algunos 15 minutos.

Esta información será manejada de la misma forma en que hemos manejado otras entrevistas telefónicas. Su participación es voluntaria. Puede negarse a participar o decidir no continuar participando en cualquier momento, por cualquier razón sin poner en riesgo su participación futura en el estudio, su relación con esta institución y/o el investigador principal del estudio.

APPENDIX 6. ADDITIONAL INCENTIVES TO PARTICIPANTS FOR REPORTING HOSPITALIZATION INFORMATION BETWEEN AFU CALLS

One key element of the medical records acquisition process is obtaining accurate information from participants on hospitalization & emergency room visits, particularly on the date of the event and the name of the hospital. Field centers may choose to offer additional incentives to participants who call to report hospitalizations between scheduled AFU calls. By encouraging participants to inform field centers as soon as possible about hospitalizations and ER visits, field centers will be able to collect more thorough and accurate information.

If a participant calls in between scheduled AFU calls to report a hospitalization or ER visit, follow these procedures:

- **If a participant calls to report events information within AFU window and AFU interview has already been completed:** Update HOE(S) form. Participants will receive an Endpoints incentive as a token of appreciation for their call to provide the hospitalization information and their commitment to the study.
- **If a participant calls within AFU window and AFU interview has not been completed yet:** Attempt to complete the full AFU interview. Participants will receive both the incentive for AFU completion and the additional Endpoints incentive.
- **If a participant calls to report a hospitalization and their AFU window is not open:** Complete the HOE(S) form, provide an Endpoints incentive, and inform participant that we will be contacting them as soon as the AFU window opens to complete their full annual interview.

Participants will be informed about the additional Endpoints incentive after their AFU interview (see below) and at other study contacts for ancillary studies.

Script to inform ppts after AFU interview completion – English

Thank you for completing your annual follow up interview. We are grateful for your continued contribution to the SOL study and will provide you with a reimbursement of $xx for the time you devoted to answering these questions about your health.

[Field center specific info on how the incentive will be delivered to participant]

I'd like to remind you that we will call again next year for your next annual follow up interview. Meanwhile, please make sure you keep a record of your hospital visits including emergency rooms and hospitalizations.

We wish you a happy and healthy year ahead, but if you have any health problems that require you to be admitted in the hospital for more than 24 hours, please call us back at [Field Center phone number] as soon as you feel better so we can keep your information updated. If you call us and give us the

name of the hospital and the date of your visit, we will give you $5 as a token of appreciation for your commitment to the study.

Script to inform ppts after AFU interview completion – Spanish

Gracias por completar su entrevista de seguimiento anual. Le agradecemos por su participación continua en el estudio SOL. Usted recibirá un reembolso de $xx por el tiempo que dedicó a responder estas preguntas sobre su salud.

[Field center specific info on how the incentive will be delivered to participant]

Recuerde que le volveremos a llamar el año que viene para su próxima entrevista de seguimiento anual. Mientras tanto, por favor asegúrese de mantener un registro de sus visitas al hospital incluyendo hospitalizaciones y visitas a la sala de emergencia.

Le deseamos un año feliz y saludable por delante, pero si tiene algún problema de salud que requiera admisión al hospital por más de 24 horas, por favor llámenos al número [Field Center phone number] tan pronto como se sienta mejor para que podamos mantener su información actualizada. Si nos llama y nos cuenta el nombre del hospital y la fecha de su visita, le daremos $5 como muestra de agradecimiento por su dedicación al estudio.