## Tracking of Revisions to HCHS/SOL Protocol Manuals

<table>
<thead>
<tr>
<th>Previous Manual, Date, Version</th>
<th>Date(s) of Revisions; source</th>
<th>Approved by, Date</th>
<th>Revisions</th>
<th>Previous Page #s section changed etc.</th>
<th>Distribution Date</th>
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<tr>
<td>Manual 3, Ver 1.0 dated January 8, 2008</td>
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<td>MOP 3, ver 2.0 Jan, 2011</td>
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<td>Typo corrections administrative change at CC</td>
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<td>Feb 18, 2011</td>
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<td>MOP 3, ver 2.0 Fall of 2011, Jan, 2011</td>
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<td>Retention &amp; Steering Cmtes, Jan '11</td>
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Updated 02.18.2011 _JJO and MdIA_
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**APPENDIX 1. INFORMANT / ALTERNATE RESPONDENTS FOR HCHS/SOL COHORT MEMBERS** ................................................................................................. 9
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. Quarterly Newsletter

A newsletter will be produced and distributed to respondents quarterly (Spring, Summer, Fall, 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 at least 3 articles: (1) feature article (1-page), (2) site article (1/2 page), (3) information for all study participants (1/2 page). Therefore, each site will have responsibility to prepare one article per year. The dissemination schedule will be as follows.

- Summer – June 1 (San Diego)
- Fall – September 1 (New York)
- Winter – December 1 (Chicago)
- Spring – March 1 (Miami)

The first newsletter to HCHS/SOL participants will be planned for June 1, 2008.

The Coordinating Center will post newsletters on the HCHS/SOL website. Each site will then be responsible for downloading and distributing the newsletter to respondents. Please note that this newsletter is intended for HCHS/SOL respondents and NOT the community. The field centers may choose to send the newsletter to other interested parties and stakeholders. However, the content of the newsletter 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 Years Greeting Card

Field Centers will send a New Years 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.

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 have 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.

2.7. 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, (3) 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.

<table>
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<th>ITEM (timing of item)</th>
<th>MAILINGS</th>
<th>CALLS</th>
<th>IN-PERSON</th>
<th>ALL SUBJECTS</th>
<th>SUBSET OF SUBJECTS</th>
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<td>ITEM (timing of item)</td>
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**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 participants’ consent forms.

To help promote standardization of the HCHS/SOL retention letters and cards, English and Spanish version 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 quarterly 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, art work 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) child care services, (3) educational resources, and (4) other services that respondents might need assistance with 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 respondents at the time of their initial visit. If this is not possible, field centers will ensure that monetary incentive are given to respondents within 3 weeks of their initial visit. Timely payment of incentives will help promote a positive experience and relationship between participants and field center staff.

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 for face-to-face meetings 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.

4. TRAINING AND SUPERVISION OF STAFF
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 a medical or social services consultation, 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 as well as maintain a culturally appropriate examination environment (calor/warmth). Training and supervision of staff is discussed in more detail in the Recruiter’s Manual.

4.1. 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.

4.2. Supervision

Throughout the entire process from initial interview to final examination or refusal, close supervision helps maximize recruitment, retention, and the 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. INFORMANT / ALTERNATE RESPONDENTS FOR HCHS/SOL COHORT MEMBERS

For purposes of the HCHS/SOL annual follow-up call (AFU) an alternate respondent is defined as a well-informed, mature individual who can answer health related questions on behalf of an HCHS/SOL cohort member if the latter is not available, or is unable to provide the information. A family member or other person who shares the participant’s household or knows him/her well may qualify as an alternate respondent, if sufficiently well informed about the participant’s health and use of health care. The circumstances in which an alternate respondent is needed are outlined in this document. Although technically often called an “informant,” this term should not be used in communication with the HCHS/SOL participant or the potential informants. Instead, terms such as stand-in may be used, or even “substitute respondent,” or “alternate 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 alternate respondent 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, photocopy of the documentation is necessary for a medical records department to release records in the event the participant becomes cognitively impaired and the alternate respondent signs a release form.

When is an Alternate Respondent Needed? If the interviewer has indications that the participant has difficulty answering the interviewer or may have cognitive problems the interviewer may use his/her judgment to determine if the participant is cognitively impaired and unable to answer questions reliably. If the interviewer is unsure or unable to make this determination, the supervisor should be contacted before proceeding with the interview. If the participant appears to be cognitively impaired, an alternate respondent should be utilized. Additionally, an alternate respondent may be utilized if the participant will be institutionalized long-term for medical reasons.

The HCHS/SOL study does not track mental status in its cohort participants with a screener because, among other reasons, brief screening questionnaires are not always accurate (in either direction). Moreover, since a screening questionnaire does not substitute for an interviewer’s educated judgment the HCHS/SOL study does not rely on a screening tool as the criterion for activation of an alternate respondent. Instead, through their interaction with the participants (or based on the use of an alternate respondent in a previous AFU interview) the HCHS/SOL interviewer determines whether the participant has the ability to respond. Because the criteria that trigger the use of an alternate respondent are subjective the AFU interviewers are offered additional training to assist in making this decision.

Before scheduling an AFU interview, HCHS/SOL personnel should review records from the initial interview or, in the case of a 2nd annual follow-up, the previous AFU interview. If the previous interview was conducted with an alternate respondent, the alternate respondent should again be contacted to schedule the follow-up interview.
Alternate respondent interviews should not be utilized when the HCHS/SOL cohort member is temporarily unavailable due to a short-term illness, travel or incarceration. In these cases, the interviewer should call back the HCHS/SOL cohort member when s/he is expected to return home. If the HCHS/SOL cohort member will be unavailable throughout their AFU window, the interviewer should report the cohort member as alive but not contactable.

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

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

Some designated components of the AFU are skipped when an alternate respondent is utilized. Once an interview is designated as an alternate respondent interview, these skips should occur automatically in the data entry system. If an alternate respondent is fully responsible for preparing a HCHS/SOL cohort member’s food, the alternate respondent may be asked to respond to questions on the 24-hour dietary recall. *When an alternate respondent is utilized for the 24-hour recall, a note MUST be entered in the log to indicate that an alternate respondent’s responses were utilized and that the alternate respondent was fully responsible for preparing the alternate respondent’s food.* An alternate respondent should not be asked to provide answers for the FPQ.

**Identification and Tracking of the Alternate Respondent.** *The alternate respondent may be one of the persons initially named by the study participant as a contact.* During the initial interview, 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 respondent 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 alternate respondent. This information should also be recorded and updated as needed on the Informant Tracking Form.

**Designating an Alternate Respondent.** Prior to the AFU anniversary date participants are sent a letter entitled “Follow-up by Alternate Respondent” and they are asked to complete the designation form and return it to the HCHS/SOL field center. Participants who are unwilling to
designate an alternate respondent are asked to return a portion of the letter that identifies their wish not to designate an alternate respondent. Two copies of the alternate respondent packet are sent to the participant, one for them to keep, the other for the participant to give to the “alternate respondent”. If these materials are not returned, during the annual follow-up participants will be asked to designate an alternate respondent for the HCHS/SOL Study.

To ensure that an alternate respondent has been identified for all study participants eligible for the second annual follow-up, a pre-paid envelope and letter asking participants to designate an alternate respondent should be mailed to participants together with the letter notifying participants of their upcoming second annual follow-up. A sample letter is provided below in English.

It may also be the case that HCHS/SOL field center staff already have recorded an alternate respondent and his/her contact information for a cohort participant. At this point a more formal process is introduced to help HCHS/SOL cohort members to identify an alternate respondent (see section on designating an Alternate Respondent). This information is recorded and updated as needed on the Contact Tracking Form which is completed at the time of an alternate respondent designation, and updated at subsequent contacts as needed. If at any time the alternate respondent has changed, the Contact Tracking Form is updated with the correct name and contact information for the new alternate respondent.

If no alternate respondent has been previously designated and the interviewer determines that an alternate respondent 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. The HCHS/SOL stand-in interview should take only 10 minutes to complete and contains a small number of questions on General Health (such as death and hospitalizations; GHEA Q1 Q1a-C), Contact Information (CIEA questionnaire). In addition a brief Informant Interview (IIEA) is completed at the interviewer’s discretion and a physician questionnaire (PQEA) is sent to a practitioner if physician contact information is provided by the alternate respondent.
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 respondent, designated 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 Respondent’s First Name ___________________ Alternate Respondent’s Last Name ___________________

Alternate Respondent’s phone number

Alternate Respondent’s street address

City ___________________ State ___________________ Zip Code ___________

☐ I do not wish to provide alternate respondent information.
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(es) 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 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 ______________ Apellido del Representante Alterno ______________

Teléfono del Representante Alterno

Dirección- Calle y Número del Representante Alterno

Ciudad ______________ Estado ______________ Código Postal ______________

☐ No deseo proveer nombre para un representante alterno.