



HCHS/SOL

Implementation of Ancillary Studies

HCHS/SOL Coordinating Center

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1. Introduction

On March 3, 2018 the Hispanic Community Health Study/Study of Latinos (HCHS/SOL) Steering Committee (SC) approved guidelines for Ancillary Studies to be conducted in the setting of the 3rd clinic examination of the HCHS/SOL cohort (see Appendix 1). The aims of these guidelines are to encourage and facilitate the implementation of innovative studies as ancillary to the HCHS/SOL, and to facilitate their conduct at high levels of data quality, minimal participant burden and optimal efficiency. The following text sets out guidelines for the implementation of ancillary studies related to the 3rd examination of the HCHS/SOL cohort (HCHS/SOL V3).

1.1. Background

NHLBI plans to fund a limited clinic exam in the HCHS/SOL from approximately November 1, 2019 through October 31, 2022. This limited cohort exam (or core HCHS/SOL V3 exam) will serve as a platform for independently funded examination components via ancillary studies whose data collection will reflect additional, hypothesis-driven content. The research aims of V3 ancillary studies need not be limited to those within the mission of the NHLBI, but must be consistent with or complementary to the HCHS/SOL study objectives, and must be consistent with the informed consent provided by the HCHS/SOL cohort members.

1.2. Components of the HCHS/SOL V3

The components of the Institute-funded, core HCHS/SOL V3 exam include: anthropometry, updated participant personal information, personal medical history and focused health interviews, sitting blood pressure, phlebotomy for selected laboratory tests (total cholesterol, HDL-C, triglycerides, fasting glucose, and HbA1c), and storage of serum/plasma/whole blood and urine samples for future analyses. These data elements will be available to approved ancillary studies.

1.3. Roles of the HCHS/SOL Investigators and Staff

It is the role of the HCHS/SOL investigators, their leadership, and study personnel to facilitate the successful completion of ancillary studies approved by the SC and NHLBI, and to ensure ancillary studies are harmonized in their implementation with – if not fully integrated into – HCHS/SOL V3. In regards to recruitment, it should be noted that only HCHS/ SOL and its study personnel are eligible to make the initial recruitment contact. Activities performed by SOL personnel on behalf of an ancillary study need to be reimbursed.

1.4. Roles of the Ancillary Study Investigators

Ancillary study principal investigators and study personnel are expected to meet the scientific aims and goals of their study in ways that reduce participant and staff burden, and optimize efficiency for both HCHS/SOL and the ancillary studies.

Ancillary study principal investigators and study managers are encouraged to manage and run their studies by participating in the committees set up as joint HCHS/SOL and ancillary study committees. These functional groups are sub-committees of the HCHS/SOL SC and include Operations, Quality Assurance, Endpoints, Analysis, Publications, and possibly others. Participation by ancillary study investigators and/or managers in such committees is welcome, as deemed pertinent to individual ancillary studies. The meeting schedule of the various committees is listed on the calendar found on the HCHS/SOL website.

2. Planning Ancillary Studies

Careful planning is required to achieve harmonization between ancillary and parent study, spanning from study design to data collection and logistics. To attain each study's goals, achieve efficiency and reduce participant burden, ancillary study investigators should allocate sufficient time (3 months at a minimum) to collaborate with the HCHS/SOL in planning their study's implementation in the setting of SOL.

3. IRB Review

HCHS/SOL V3 is being conducted under a single IRB (sIRB) managed by the UNC Office of Human Research Ethics. Starting in January 2023, UNC IRB will no longer serve as the single IRB of record for ancillary studies for which UNC is not the primary awardee. At the time of planning to apply for funding, the ancillary study PI will need to contact their institution to plan serving as the single IRB. Typically, the institution provides a letter acknowledging to serve as the single IRB of record. In addition, this needs to be specified in the sIRB plan. Note that managing the single IRB has cost implications that need to be considered in the budget.

4. Implementing Ancillary Studies

4.1. Study Development

Upon receipt of a favorable score by the funding agency, the ancillary study principal investigator should send the grant application materials submitted to the funding agency to the HCHS/SOL SC, for review. The ancillary study PI should engage the HCHS/SOL CC to plan for the implementation of the ancillary study and its harmonization with HCHS/SOL V3. The SOL Coordinating Center will work with the ancillary study researcher(s) on the development of data collection instruments, staff training and certification, data management, and study implementation.

4.2. Ancillary Study Protocol

An ancillary study lead investigator is responsible for the creation of study forms, and a manual of procedures (MOP) with specific instructions for all aspects related to the conduct of the ancillary study. The ancillary study MOP is approved by the HCHS/SOL SC and the NHLBI prior to staff training and pilot studies. All forms and/or scripts administered to HCHS/SOL study participants must be in both English and Spanish language. The HCHS/SOL translation subcommittee will review translations to ensure that they are culturally sensitive for all HCHS/SOL backgrounds. Certification of the Spanish translation is required for HCHS/SOL V3 AS.

4.3. Training

Training of the ancillary study personnel should occur at least 3 weeks prior to the study startup. A central staff training, in coordination with training of the HCHS/SOL V3 staff and/or other ancillary study staff, is recommended. For ancillary studies conducted as part of HCHS/SOL V3, cross-training of parent study staff and personnel supported by ancillary studies is desirable, for efficiency and back-up. Central training by means of web meetings and videos should be considered, unless specialized in-person training is required. The training materials, certification standards, and procedures are the responsibility of the ancillary study. This information will be posted on the HCHS/SOL website for reference by staff and for re-training, as needed.

4.4. Staff Certification

Ancillary studies determine the level of certification of their study personnel. HCHS/SOL requires that staff working with SOL study participants be certified in the use of informed consent, participant safety, CDART (data management program), and General Interviewing Techniques (GIT). If ancillary study personnel collect data to be used by HCHS/SOL, the parent study staff training and certification criteria apply. Certification can be part of training, or follow it as deemed appropriate by the ancillary study investigator team. Staff certifications need to be reported to the HCHS/SOL CC, where an up-to-date list of certifications is kept for all HCHS/SOL and ancillary study staff.

5. Documentation

An ancillary study lead investigator is responsible for study documentation which includes the MOP, forms, participant study reports, recruitment call scripts, and any other study protocol documentation needed for study completion.

5.1. Standard procedure for documentation

- Final documents will be posted on the study website as PDF files for field center download. Document version and date should be part of the cover page (header) of the document.
- Documentation updates, especially for protocol changes, should be supported with a table containing changes in the document. A clean version and a tracked change document should be made available for IRB submission. Both documents should be posted in the study website for field center download.
- All forms, scripts, and reports that would be administered/shared with the participants should have an English and Spanish version. The Spanish version has to be certified by a professional; as required by one of the field center IRBs.
- All documentation should have the study logo.
- Manuals should have a table of contents and a table for changes/updates.

5.2. Protocols and Manuals

Final documents will be posted to the study website by the HCHS/SOL CC, for access by the investigators and field center personnel. This includes data collection forms, manuals, phone scripts, training information, and other documentation required for study implementation. HCHS/SOL does not distribute documentation via email or dropbox. Once the document is finalized, the word document is sent to the HCHS/SOL CC for study website upload. Once the upload is completed, a document release message is sent to field center project managers and PIs.

5.3. Study Forms

It is anticipated that most ancillary study data will be acquired by direct entry into the HCHS/SOL data management system (CDART). Some data collection forms and a number of administrative forms may be collected on paper. Ancillary study PIs and their staff should work closely with HCHS/SOL CC personnel to develop and test all study forms and their inclusion into the V3 data stream.

5.3.1. Paper forms

- Paper forms used by ancillary studies are version-controlled. They are required to have the standard format and header information: Form Code, date, version #, Logo, Participant ID, and an administrative section.
- Final paper forms, approved by the HCHS/SOL SC, are posted on the HCHS/SOL study website.
- All data capture forms require written question by question (QxQ) instructions, addressing each datum, corresponding administration scripts, and special instructions on data collection.
- Forms administered to a participant require English and Spanish versions.

5.3.2. CDART forms

CDART forms are direct-entry, screen versions of the paper forms. The development of forms in CDART begins once a paper form has been approved and deemed final. Screen development and testing takes around 3-4 weeks (depending on the complexity and number of forms) from the time of final form release.

6. Data Management and Data Flow

For optimal efficiency, ancillary studies are encouraged to integrate their data collection within the extant parent study data collection and management procedures. This is in the interest of reducing participant and staff burden and maximizing data quality. The ancillary study data flow should thus be incorporated into the HCHS/SOL stream of data for V3.

If integrated into the parent study data flow the HCHS/SOL CC will be responsible for periodically producing updated management reports that include ancillary study information, to be provided to the HCHS/SOL SC and each ancillary study lead investigator and manager, and to the HCHS/SOL OSMB (an advisory body to the NHLBI).

7. Quality Assurance/Quality Control

Integration of an ancillary study in HCHS/SOL V3 will allow for inclusion of quality assurance procedures and quality control analyses for the HCHS/SOL V3 ancillary studies to be conducted by the HCHS/SOL Coordinating Center on behalf of each ancillary study. The presence of an ancillary study representative on the Quality Control Committee is encouraged.

8. Directory information

For purposes of communication and inclusion in the study directory, ancillary study personnel are asked to create their individual account for website access. Access documentation provided by the PI is located in: [Staff Directory and Author Database Update Instructions](#). The HCHS/SOL Coordinating Center does not update contact information (each person is responsible for updated contact information).

9. Study Website for Ancillary Studies

The HCHS/SOL website has a HUB for ancillary studies, for convenient access to manuals and study information to be shared with study personnel. The following information is required to effectively

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create an Ancillary Study WebPage (URL): Brief description of the study (max of 5 lines), containing the contract dates, main PI name, and study award (contract)

10. Data Closure

To ensure high data quality the HCHS/SOL CC will provide lists of data queries, as guided by the ancillary study PI. If the data collected for the ancillary are included in the SOL V3 data flow, the ancillary study principal investigator may request incremental data closure for purposes of quality assurance/quality control. The (final) data closure process should start two months before completion of recruitment. The final queries will allow for of 2-3 weeks of data cleanup by field center staff. Once data closeout is complete HCHS/SOL CC will create the investigators' data files. This will take 4-6 weeks from the date the data have been locked. Costs accrued at the CC must be compensated by the ancillary study.

11. Data Files for Use by Ancillary Study Investigators

Please refer to the document "Policy and Agreement" for the use of datasets, located at <https://sites.csc.unc.edu/hchs/study-data-and-analytic-methods>. Document name "Steering Cmte Endorsed Distribution of Investigator Use Data Memorandum - Spring 2012"

12. Manuscripts

Ancillary studies adhere to the publication policies in place in the HCHS/SOL: manuscript proposals are submitted for review and coordination by the SOL Publication Committee, as well as manuscripts for publication prior to submitting them to a journal. Please refer to the policies and resources available in the Publications Hub on the HCHS/SOL website.