

# FULL Proposal Form

**Ancillary Study** **to the HCHS/SOL**

To select a square [ ] , please double left click, select “Checked”

**ADMINISTRATIVE SECTION**

**Date of Submission:**

**Title of Ancillary Study Proposal:**

**Short Title of Ancillary Study Proposal (25 characters):**

**Lead Principal Investigator** **(name / contact info)**:

Name Institution  Address

Phone e-mail address

Early-Stage Investigator:[ ]

**Other Principal Investigator(s)** (name, institution, address, phone, e-mail address)**:**

**Name of HCHS/SOL Principal Investigator sponsor**:

**Date of approval of this proposal by HCHS/SOL sponsor:**

**Administrative Supplement** [ ]

**To Parent Study:** [ ]

 **To Ancillary Study:** [ ]  **Tracking Number: *AS#***

**Consortium:** [ ]  **Tracking Number: *C#***

**Grant Renewal:** [ ]  **Original Ancillary Tracking Number: *AS#***

## Part A: Basic Study Information and Projected Impact on HCHS/SOL

1. **Funding source (institute and grant mechanism) and date of grant submission (if applicable):**

 **Proposed starting and ending dates:**

1. **Participant Burden Classification** (select one)
2. None [ ]
3. Participant contact but NO biospecimen collection [ ]
4. Participant contact and biospecimen collection [ ]
5. Will existing biospecimens be requested as part of this ancillary study?

[ ]  No0**→ Go to 4**

[ ]  Yes1

If Yes, please select all that apply:

 [ ]  DNA

 [ ]  RNA

 [ ]  Whole Blood

 [ ]  Plasma

 [ ]  Serum

 [ ]  Urine

 [ ]  Stool

 [ ]  Other. Please specify:

1. Will existing scans, tapes, digital images, tracings, etc. from the Imaging, Echo, or MRI Reading Centers be requested and analyzed as part of this ancillary study?

 [ ]  No0**→ Go to 5**

 [ ]  Yes1

If Yes, please select all that apply:

[ ]  CT

[ ]  Echo

[ ]  MRI

1. Will the analysis of previously collected data/biospecimens/materials result in new data?

 [ ]  No0

 [ ]  Yes1

1. **Brief Summary of Proposed Research and Projected Impact on the HCHS/SOL Study** (<100 words)

## B. Involvement of Participants, Centers, IRB and Laboratories

1. **Summary of HCHS/SOL centers and tasks involved** – Leave cell blank if Not Applicable

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Center** | **Enroll or examine participants (N)** | **Assay samples****(N participants)** | **FTE per Center** | **Provide samples (N participants)** | **Provide data files (yes/no)** | **Analyze data (yes/no)** |
| **Bronx** |  |  |  |  |  |  |
| **Chicago** |  |  |  |  |  |  |
| **Miami** |  |  |  |  |  |  |
| **San Diego** |  |  |  |  |  |  |
| **Central Lab (MN)** |  |  |  |  |  |  |
| **Coordinating Center (UNC)** |  |  |  |  |  |  |
| **Other (specify)** |  |  |  |  |  |  |

**8.** **HCHS/SOL participant and field centers staff involvement.**

1. **Describe staff effort (and estimated time) required.** Include consent, collection of samples, etc.
2. **Describe participant involvement.** Will participants be contacted, interviewed, examined, or asked to provide specimens? Will this contact be embedded into an existing clinic visit or involve a separate (de novo) visit? Will the study involve radiation or administration of a drug or contrast?
3. **Describe number of subjects needed and inclusion/exclusion;** special characteristics of study population; age and sex distribution.
4. **Estimate time required of each participant.**
5. **Describe any human subject protections issues including level of risk to participants and protections against risk.**
6. **If the study will have clinical implications, explain, and describe the plan for reporting results to participants and providing recommendations for follow up.**

**9.** **Coordinating Center Involvement**  [ ]  Yes [ ]  No

 **Describe HCHS/SOL Coordinating Center involvement.**

\* *Unless you provide strong justification, the Coordinating Center must be included, and its costs budgeted.*

If activities will be performed at the Coordinating Center, support for these activities should be included in the grant application. Guidelines for reimbursement are provided on the HCHS/SOL website.

Describe effort (and estimated time) required of HCHS/SOL Coordinating Center staff.

1. Will the Coordinating Center be involved in data collection, tracking, or preparation of forms or software? or will these tasks be completed locally by the Ancillary Study, and a data file sent to the Coordinating Center?
2. If a Reading Center or laboratory is involved, will data be sent directly from the Reading Center or laboratory to the Coordinating Center for processing, or will processing be done locally (either by the Ancillary Study or at the Reading Center/Laboratory)?

1. Will analyses be done locally by the Ancillary Study or by analysts at the Coordinating Center? If analyses will be done locally, should Coordinating Center verify the analyses?

**10.** **IRB**

Select the IRB plan for this ancillary study (sIRB or Local IRB) and the reason(s) for selection:

sIRB **[ ]**

a. new data collection at more than one center either directly with HCHS/SOL participants or using medical records **[ ]**

b. lab analysis of HCHS/SOL stored samples that use identifiers or require reporting data back to participants **[ ]**

c. more than one center will see PHI for the study **[ ]**

d. there eventually may be an FDA application **[ ]** (go to question 10)

or

Local IRB **[ ]**

1. proposals that only use only existing HCHS/SOL deidentified data (e.g., most student projects, career development projects) will qualify as exempt or non-human subjects research **[ ]**
2. exclusively single center proposals (this can include some investigators at other sites who are only coauthors or provide services but never see participants or PHI **[ ]**
3. lab studies where the HCHS/SOL component is already approved in the sIRB parent protocol **[ ]**

**11. HCHS/SOL stored specimens**

If stored specimens will be requested from the HCHS/SOL Central Lab, support for these activities should be included in the grant application. If the Ancillary Study is approved, please contact the Central Lab for estimates and budgeting requirements. The maximum total request from blood samples is 250 μg.

Describe materials to be used (e.g., stored plasma, urine, DNA). If blood samples are requested, please review the Criteria for Approval section of the Ancillary Study Policy (<https://sites.cscc.unc.edu/hchs/ancillary-studies-pub>) in consideration of your description of the following:

 Study participants and material requested:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Yes/No** | **Cohort** | **Total Number of Specimens** | **Full Cohort****(or )** | **Number of Cases** | **Number of Controls** |
|  | All parent study participants (or )  |  |  |  |  |
|  | Specify sample and specimens in each sample/stratum |  |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Type of Specimen** | **N** | **Volume Requested** | **Time point****(e.g. visit\*)** | **Specify proposed lab and analytes to be assayed at catch lab (be specific)** |
| Serum |  | µl |  |  |
| EDTA plasma |  | µl |  |  |
| Citrate plasma |  | µl |  |  |
| DNA |  | µg/ng |  |  |
| Urine |  | µl |  |  |
| Other (specify) |  |  |  |  |

\* Please contact HCHS/SOL Central Lab in advance and indicate here how many tubes of each visit and type you are requesting.

1. Is the proposed work consistent with the stipulations in the HCHS/SOL informed consent form? [ ]  Yes [ ]  No (The informed consent forms can be obtained from the collaborating HCHS/SOL investigator).
2. Are thawed/re-frozen acceptable? [ ]  Yes [ ]  No

If No, specify reasons for specific assays:

1. Describe efforts to integrate sample needs with those of other studies to conserve sample and/or limit freeze-thaw cycles.
2. Are samples required to be fasting or non-fasting? [ ]  Yes [ ]  No
3. If approved, when will samples be requested for retrieval?

**12. Genomic information** (defined as any data from a participant’s DNA):

1. Does your proposal include any genomic materials? (please check one)

 [ ]  No (go to question 12) [ ]  Yes

b. Name the gene(s), genotypes, SNPs to be investigated:

c. Is genetic information used to address a primary aim or secondary aim of HCHS/SOL? (please check one or both)

 [ ]  Primary aim (heart/vascular disease)

 [ ]  Secondary aim (other health conditions)

 List the conditions addressed:

d. Should DNA-based results be reported to patients’ physicians? Base your response on your knowledge of existing literature and current practice regarding increased risk and availability of treatment for adverse outcomes associated with the gene mutations to be studied.

## C. Timeline, costs, funding, data, confidentiality, data sharing

1. Proposed starting and ending dates:

2. Estimated cost by year; number of years:

a. I confirm that I have consulted with all of the participating HCHS/SOL centers and have determined reasonable costs for the required services and measurements (yes or no)

3. Source of funding; anticipated date of submission:

4. Does this study involve the support or collaboration of a for-profit corporation, or do you intend to use the data to patent any process, aspect or outcome of the analysis?

5. What is the advantage, both to HCHS/SOL and yourself, of conducting the study within the HCHS/SOL cohort versus another population?

6. Variables/measurements from the HCHS/SOL main study database to be analyzed:

7. Impact on ongoing HCHS/SOL studies (main study or other Ancillary Studies):

9. Who (name and position) will report progress of the ancillary study annually to the HCHS/SOL Coordinating Center? (Ancillary Study PI or designate preferred)

10. How will confidentiality of HCHS/SOL participants be maintained?

11. **NHLBI expects Ancillary Studies to adhere to NIH and NHLBI data-sharing policies regardless of funding source. HCHS/SOL Ancillary Studies will have to follow NIH Data Management and Sharing (DMS) policy**. The Ancillary Study PI will have exclusive opportunity to analyze, present and publish data collected under the auspices of the Ancillary Study during the funding period. Once the Ancillary Study funding ends, the data becomes part of HCHS/SOL study and will be made available to other HCHS/SOL investigators and be deposited in NIH data repositories following NIH Data Management and Sharing policy. For non-NIH funded Ancillary Studies, it is the responsibility of the Ancillary Study PI to state in writing to the HCHS/SOL Steering Committee and to NIH Project Officer any special circumstances that would warrant an exception to these guidelines.

I agree to the above description of data availability and sharing: [ ]  Yes [ ]  No

## Part D Ancillary Study Proposal

Please provide a brief (2 to 5 page) description of the proposed study. Include the following:

**Background:**

**Aims and Hypotheses:**

**Study Design (include sample size justification):**

**Methods, including:**

 **Participant involvement (if any):**

**Data to be collected by the ancillary study (attach questionnaires and forms):**

**Analysis Methods:**

**Literature References:**

**Please send form to "HCHS/SOL Ancillary Committee"** **HCHSAncillary@unc.edu** **use ‘HCHS/SOL Ancillary FULL proposal by LASTNAME’ in the subject line.**

**FILE NAME CONVENTION:**

LASTNAME\_FULL\_BriefTitle\_YYYY-MM-DD.docx (submission date)

LASTNAME\_FULL\_BriefTitle\_BIOREPOSITORY.docx (if applicable)

- Last name: use contact investigator’s last name

- Brief title: use 2 to 4 key words

- Date: use date of submission

- Make file Read Only

**Example: ISASI\_FULL\_SOLYouthCellCommunities\_2023-07-13.docx**