**Warning** – Use this Word Template version of HCHS/SOL Ancillary Proposal Submission with caution. All portions must be present and accidental or purposeful deletions of required fields or portions may delay final approval. The Study and Institute expects the submitter to use care and proof their work prior to submission.

May 1, 2014

# Full Ancillary Study Proposal Form (Two Parts)

# Hispanic Community Health Study / Study of Latinos (HCHS/SOL) revised May 24, 2019

# PART I. Basic Study Information and Projected Impact on HCHS/SOL

# A. Identifying Information

#  1. Title of study:

#  Short Title of study (25 characters):

# 2. Principal investigator(s) (name, address, phone and fax numbers, e-mail address):

#  3. HCHS/SOL Sponsor:

# B. Involvement of Participants, Centers and Laboratories

# 1. Summary Table of Involvement of HCHS/SOL Centers in this ancillary study

# (Leave cell blank if Not Applicable)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Center | Enroll, examine or add questions, i.e. burden (N participants) | Number of burden minutes per participant | FTE per center | Conduct lab analysis(N participants) | Provide stored samples or other materials (N participants) | Analyze data (yes/no) |
| Bronx Field Center  |       |       |       |       |       |       |
| Chicago Field Center  |       |       |       |       |       |       |
| Miami Field Center  |       |       |       |       |       |       |
| San Diego Field Center  |       |       |       |       |       |       |
| MN Laboratory |       |       |       |       |       |       |
| Coordinating Center  |       |       |       |       |       |       |
| Other (specify) |       |       |       |       |       |       |

#  2. HCHS/SOL Participant Involvement:

# a. Describe number of subjects needed; special characteristics of study population; age and sex distribution. Will participants be contacted, interviewed, examined, or asked to provide specimens? Will the study involve an imaging component, radiation, or administration of a drug or contrast? If so, describe participant involvement and safety monitoring, whether clinical reads of images will be done, and how incidental findings will be handled. Estimate time required of each participant.

# b. Will the study provide reimbursement/compensation to participants; if so how much?

#

# c. What are the benefits to the participants for their participation?

#  3. HCHS/SOL Field Center Involvement:

#

# a. Describe effort (and estimated time) required of HCHS/SOL staff at each participating center. Include consent, collection of samples, etc.

#

#  4. HCHS/SOL Coordinating Center Involvement

#

# a. Describe specific effort and estimated time required of HCHS/SOL Coordinating Center staff.

# b. 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?

# c. 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)?

#

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

# e. What variables will be needed from the HCHS/SOL main study database to be analyzed:

# 5. Laboratory Involvement:

#

#

# a. Complete table below on analytes and study participants:

|  |  |  |  |
| --- | --- | --- | --- |
| Analyte(specify below) | Number in full cohort | Number in a subset of full cohort | Number in a case/control subset |
|  |       |       |       |
|  |       |       |       |

# b. Complete table below on volume of specimen, lab facility and analytes (maximum total request of 250 μg from blood samples) :

#

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of Specimen | N | Volume Requested | Time point (Currently only Exam 1) | Specify proposed lab and analytes to be assayed at each lab (be specific) |
| Serum |  | μl |       |       |
| EDTA plasma |  | μl |       |       |
| Citrate plasma |  | μl |       |       |
| DNA |  | μg/ng |       |       |
| Urine |  | ml |       |       |
| Other (specify) |  |  |  |  |

# c. 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 or online).

# d. Are thawed/re-frozen specimens acceptable? [ ]  Yes [ ]  No

#  If No, specify reasons for specific assays:

# e. Describe efforts to integrate sample needs with those of other studies to conserve sample and/or limit freeze-thaw cycles.

# f. Are samples required to be fasting or non-fasting?

# g. If approved, when will samples be requested for retrieval?

#

# h. If your proposal includes any genomic materials, name the gene(s), genotypes, or SNPs to be investigated:

#

# 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 to be addressed:

#

# i. Should the genetic or other laboratory results be reported to patients and/or their physicians? Base your response on your knowledge of existing literature and current practice regarding increased risk and availability of treatment. If Yes, describe your proposed plan for reporting results and alert values, if applicable.

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

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

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

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

# 9. Data collected by the Ancillary Study, will be provided to the HCHS/SOL Coordinating Center for integration into the main database. The Ancillary Study PI will be given the first and exclusive opportunity to analyze, present and publish data collected under the auspices of the Ancillary Study. One year after data cleaning is complete, ancillary Study data will be made available for additional uses by other HCHS/SOL investigators. Data will also be deposited in the NHLBI Data Repository (BioLINCC) and the NIH genetic repository (dbGaP) according to NHLBI and NIH policy as described in the Ancillary Study Policy, Section 5.8.c.

# I agree to the above description of data availability and sharing (yes or no).

# PART II. Description of the Ancillary Study

# Please provide a brief (not to exceed 5 pages, plus one page of aims) description of the proposed study. Include all of the following or write N/A if not applicable:

# Purpose/Aims:

# Background:

# Hypotheses:

# Experimental 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

#

# Part III –

1. **Lab / Biorespository**

# Please submit an electronic copy of the completed proposal through the web portal.

# The portal can be found on the investigator website at *Ancillary Studies Hub 🡪 Ancillary & Consortium Studies 🡪 Submissions.*

# For Coordinating Center Use Only

# Approved by AS Committee? [ ]  Yes [ ] No

# Date:

**Approved by Steering Committee?** [ ]  Yes [ ] No

# Date:

# If approved, ancillary study #

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