# HCHS SOL LogoApproved Ancillary Study Amendment Request Form

*(This form also used for expired study extensions)*

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

**A. Identifying Information**

1. Original HCHS/SOL Approval Tracking Number (from approval notification):
2. Title of study:
   * 1. Short Title of study (25 characters):
3. Principal investigator(s) (name, address, phone and fax numbers, e-mail address):
4. HCHS/SOL Sponsor:
5. This is a request for deadline extension of one year with no changes to previously proposed and approved ancillary study (rest of form can be left blank):

**Current Status of Study (e.g. submitted/outcome of review, not submitted, funded):**

**Proposed revisions to the originally approved study (**In the table below, capture side-by-side comparison of proposed changes. Work scope, aims, study design, study size, methods, measurements, assays, specimens, collaborators, time line…**)**

|  |  |
| --- | --- |
| **Original features to be modified** | **Proposed revision** |
|  |  |
| ***Expand as needed*** |  |

**Rationale of Proposed Amendment to Approved Ancillary Study** (200 word limit)**:**

## PART II. Amended Ancillary Study

Please provide a brief description of the proposed amended study. Include all of the following headings (specify N/A if not applicable). Please adhere to the following page limits: 1 page for the specific aims; 4 pages exclusive of specific aims.

**Background:**

**Specific Aims:**

**Approach (study design, measurements, analytic approach):**

**HCHS/SOL Participant involvement:**

If HCHS/SOL participants are engaged:

Data to be collected on SOL participants by the ancillary study:

Study size justification:

Participant burden and safety:

**If HCHS/SOL study participants are engaged, please complete Table 1. If biospecimen is requested, complete Table 2.**

**Table 1**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Center** | **Enroll, examine or interview (N participants)** | **Participant time (minutes)** | **Staff time (minutes)** | **Staff FTE funded by ancillary study** |
| Bronx Field Center |  |  |  |  |
| Chicago Field Center |  |  |  |  |
| Miami Field Center |  |  |  |  |
| San Diego Field Center |  |  |  |  |
| MN Laboratory |  |  |  |  |
| Coordinating Center |  |  |  |  |
| Other (specify) |  |  |  |  |

**Table 2**

**Lab / Biorepository**

**Complete the table below for biospecimen requested (maximum total request of 250 μL**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of Specimen | N requested | Volume Requested | Cohort exam time point | Specify proposed lab and analytes to be assayed at each lab |
| Serum |  | μl |  |  |
| EDTA plasma |  | μl |  |  |
| Citrate plasma |  | μl |  |  |
| DNA |  | μg/ng |  |  |
| Urine |  | ml |  |  |
| Other (specify) |  |  |  |  |

Please submit an electronic copy of the completed proposal through the HCHS/SOL investigator website at *Ancillary Studies / Consortia Hub 🡪 Ancillary & Consortium Studies 🡪 Submissions.*

……

## For NIH Project Office Use

**NIH Determination of OSMB Review**

As part of the review by the Ancillary Studies committee NIH Project Office indicates whether this study requires review by the OSMB.

**Name of NIH person:**

**OSMB Review required:**

## For Coordinating Center Use (To select a square , please double left click, select “Checked”)

Approved by AS Committee?  Yes No

Date:

**Approved by Steering Committee?  Yes No**

Date:

If approved, ancillary study #