



## HCHS/SOL ANCILLARY STUDIES Submission Guidelines (Edited 24May2019)

Following are guidelines for investigators who intend to submit an ancillary study proposal to the HCHS/SOL Ancillary Studies Committee. The HCHS/SOL Ancillary Studies Policy should be consulted first; it can be found on the public portion of the HCHS/SOL website ([www.csc.unc.edu/hchs/](http://www.csc.unc.edu/hchs/) under About the Study → Ancillary Studies). Also referred to in these guidelines is the Ancillary Proposal Submission packet, found in the same section of the study website. Plan your submission timing appropriately for the study investigator monthly call schedule. Currently, the Ancillary Committee meets by telephone on the first Tuesday of each month and submissions are needed 2 weeks prior for assignment to reviewers.

### **I. Encouragement of involvement by Hispanic/Latino investigators**

The HCHS/SOL Study Investigators and NHLBI encourage ancillary study proposals by Hispanic/Latino investigators, and encourage investigators who submit ancillary study proposals to incorporate Hispanic/Latino investigators as part of the research team.

### **II. Concept Proposal Stage**

To facilitate the review process, it is recommended that investigators first submit a Letter of Intent or Concept Proposal via the HCHS/SOL web portal Ancillary Studies Proposal Submission page, the schematic for which can be found under the Ancillary Studies link on the study website. The Study's response to this Concept Proposal indicates whether submission of a full ancillary study proposal is encouraged.

### **III. Proposal Stage**

Ancillary study proposals are submitted by completing the information in the Proposal Submission Packet found on the study website under Ancillary Studies. In addition to a cover memo from the ancillary study principal investigator, these materials include a realistic estimate of the anticipated burden associated with the proposed study, a request for the use of study materials, if applicable, and the study proposal. For a successful and timely review it is important that all relevant materials in this packet be completed. The submitter if using any stored bio-specimens, should also include a bio-repository impact statement memo from the HCHS/SOL Lab as part of the full proposal packet. Please contact the lab prior to submission of the full proposal. Final Steering Committee approved submissions will be forwarded to the OSMB. The OSMB asks for a 3 week review period and that each study submission for their review adheres to a page limit of 4 pages, plus page of specific aims.

### **IV. Timeline for submission and review of applications**

The timeline for review and processing of ancillary study proposals is described here to assist investigators in planning the submission process. Because proposals for ancillary studies require review and approval by the HCHS/SOL Ancillary Studies Committee, the HCHS/SOL Steering Committee, and the Observational Studies Monitoring Board (OSMB) advising the NHLBI, in sequence, it is strongly suggested that applications be submitted to the HCHS/SOL Coordinating Center no later than **12 weeks** prior to the intended date of submission to the funding agency.

If the ancillary study requires approval by the funding agency for a budget in excess of a cap, the investigators need to consider the funding agencies' schedule for submission of such requests (at present, twice yearly in the case of most NIH institutes). Such a request to NIH for approval to exceed a funding cap can be submitted after notification of approval of the Concept Proposal.