HCHS/SOL Ancillary Studies PROPOSING INVESTIGATOR CHECKLIST

THIS CHECKLIST DOES NOT NEED TO BE SUBMITTED TO THE ANCILLARY STUDIES COMMITTEE. IT IS A GUIDE TO BE USED WHILE PREPARING AN ANCILLARY STUDY PROPOSAL.

I. Required Application Information: *Your proposal cannot be reviewed by the Ancillary Studies (AS) Committee without the following elements:*

- ☐ Approval from sponsoring field center or Coordinating Center PI (Bronx: Kaplan, Isasi; Chicago: Daviglus, Pirzada; Miami: Penedo, Llabre, Cordero; San Diego: Talavera, Gallo; Coordinating Center: Cai, Sotres-Alvarez)
- ☐ Approval from PI of an existing Ancillary Study, if the project will use their data or materials [if applicable]
- ☐ Biorepository Impact Statement [to be included when submitting Full proposal or Amendments for Ancillary Studies requesting biospecimens]
- ☐ Response to Reviewers [if applicable, revised proposals]
- ☐ For Ancillary Studies involving a Consortium: The Consortium Proposal must be approved by the Steering Committee first. A Consortium number must be provided in the Ancillary Full Proposal form.
- ☐ For Ancillary Studies doing Secondary Data Analyses: NIH aims page (including references); Secondary Data Analyses Ancillary Study form which cites the number of an approved manuscript proposal

II. Things to consider when planning your Ancillary Study.

The AS Committee does NOT require the project budgets to be submitted with the Ancillary Study application. However, it is imperative to review whether your study will require the following activities and appropriate budget allocations:

Coordinating Center:

- ☐ Data collection, data transfer or data archiving
- ☐ Creating data files
- ☐ Generating reports such as participant enrollment reports
- ☐ Creating biosample list for the Central Lab
- ☐ Access to Secure Research Workspace (e.g., for using participant address or other identifying information)

Field Centers:

- ☐ Data collection
- ☐ Participant incentives
- ☐ Transportation services or reimbursement of travel costs
- ☐ Returning results or medical referrals to participants
- ☐ Plan for training and certification of data collection staff

Other:

- ☐ Central Lab (U Minnesota) (e.g., pull samples and ship, perform lab tests)
- ☐ Single IRB (must be managed by the Ancillary Study PI's institution, or third-party arrangements)