INTRODUCTION TO ANCILLARY STUDIES IN ADD HEALTH

Add Health has established a set of requirements for investigators seeking to add supplemental data to Add Health, either through separately funded data or specimen collection or use of archived biospecimens for additional assays or genotyping.

The following presents a brief introduction to the Ancillary Study proposal process. Please email Add Health at addhealth_ancillary@unc.edu with questions and to request the requisite proposal application forms and policies. Familiarize yourself with available Add Health datasets by viewing the dataset descriptions and codebooks. Add Health datasets should be reviewed thoroughly prior to the submission of an ancillary study proposal.

Add Health will review ancillary study proposals in a timely manner (generally within 12 weeks). To allow time for revision and second round review, applicants are strongly encouraged to submit proposals at least six months in advance of any anticipated grant application deadline.

All policies governing the application approval process are described in the document, A Guide to Ancillary Studies in Add Health. Detailed ancillary study data security obligations are described in Appendix A-3: Agreement for the Use of Sensitive Data. Both policy and security documents are included with the proposal application forms.

Upon completion of the review process, Add Health will send the investigator formal written notice of its decision to approve or reject the proposed study. Once an ancillary study is approved, changes in the scope or procedures of the study must be approved by the Add Health PI in consultation with the Administrative, Dissemination and Biology Cores.

Definition of an Ancillary Study

An ancillary study is any study that derives support from independent funds outside the Add Health Program Project, and does one or more of the following:

1. Collects new, original questionnaire data on Add Health respondents
2. Merges secondary data sources onto Add Health respondent or school records and Requires personal identifiers (e.g., geocodes) to perform these linkages
3. Collects new biospecimens from Add Health respondents
4. Uses archived biospecimens collected by the Add Health study.

Requirements of Investigators

Ancillary study investigators must meet the following criteria:

1. have a PhD, MD, or other terminal degree, and
2. hold a faculty appointment or research position at his/her institution

Although ancillary study investigators are not required to have previous experience with the Add Health Study, demonstrated familiarity with Add Health data and study design will significantly
enhance review of ancillary study proposals, within both Add Health and independent funding agencies. Investigators with no prior Add Health experience are therefore encouraged to develop some expertise in the use of existing Add Health data and/or establish a collaborative relationship with a past or current Add Health investigator.

**Review and Approval Process**

An ancillary study must be approved by Add Health before a grant to support it is submitted for funding. All ancillary study proposals will be reviewed by the Add Health Principal Investigator (PI) in consultation with the Add Health Administrative and Dissemination Cores. Requests to collect new biospecimens or use archived biospecimens or biological data must also be reviewed by the Add Health Biology Core; the Biology Core will recommend approval or disapproval to the Add Health PI.

**Scientific Merit**

All proposed studies will be reviewed using these criteria: Significance, Approach, Innovation, Investigators, and Environment. A detailed explanation of these criteria is included in the document, A Guide to Ancillary Studies in Add Health. Further evaluation will be predicated upon the extent to which the propose study addresses Add Health’s priorities and policies.

**Costs**

Briefly, there are two options for completing the work to link the Ancillary Study variables with the Add Health dataset, and each has different costs. Cost estimates can be provided once Add Health receives and reviews the ancillary study proposal.

**Option I: Add Health links the variables.**

**Option II: Researcher/Secure Data Facility.** The researcher must complete linking work at CPC’s Secure Data Facility (SDF) at UNC-CH. After the researcher links the variables, Add Health performs the following work: cleaning, checking variable construction, and evaluating deductive disclosure risks.