

A GUIDE TO ANCILLARY STUDIES IN ADD HEALTH

Add Health will review and will approve, reject or request modification to ancillary study proposals in a timely manner (generally within 12 weeks). To allow adequate time to revise, re-submit and re-review proposals that are not approved, applicants are strongly encouraged to submit proposals **at least (6) six months** in advance of anticipated grant application deadline. An ancillary study must be approved by Add Health before a grant to support it is submitted for funding.

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. The approval notice will document Add Health's support for the project and guarantee its collaboration, and should be included in the grant application. In the event that a study is rejected, the investigator will be notified of the reason for the decision.

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 and Dissemination Cores.

General policies

A. 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.

B. General Requirements for Approval

Add Health welcomes the addition of ancillary studies that have scientific merit but will not do any of the following:

1. duplicate or interfere with existing Add Health activities (including already approved ancillary studies)
2. adversely affect respondent cooperation in Add Health
3. threaten the security of Add Health data and/or identities of Add Health respondents
4. create an unacceptable diversion of Add Health study resources, including personnel or study samples
5. jeopardize the public image of Add Health.

C. 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 (see Section D for institution requirements).

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.

D. Requirements of Institutions

The institution at which the ancillary study investigator will conduct the research must meet all of the following criteria:

1. be an institution of higher education, a research organization, or a government agency
2. have an institutional review board (IRB) that complies with applicable Federal regulations governing research involving human subjects
3. demonstrate completion of research ethics training by all research team members who will work with the Add Health data or biospecimens
4. have a demonstrated record of using sensitive data according to commonly accepted standards of research ethics.

E. Funding Requirements

Investigators proposing to conduct an ancillary study must cover all costs incurred by the study, such as selecting special samples; collecting, processing or shipping biospecimens; preparing and documenting analysis files; performing statistical analysis; integrating ancillary data into the Add Health study; and archiving excess biospecimens. Some of these activities can only be performed by the Add Health staff. In most cases, the investigator will need to budget and establish a subcontract with the Add Health project to cover such costs. Add Health staff should be contacted prior to submission of any proposal seeking these funds to provide cost estimates for budgeting these costs.

F. 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 Project; the Biology Project will recommend approval or disapproval to the Add Health PI.

All proposals will be reviewed according to the following criteria:

1. Scientific Merit

- a. Significance. Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge, clinical practice or public health policy be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?
- b. Approach. Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, well-reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?
- c. Innovation. Is the project original and innovative? For example: Does the project challenge existing paradigms, practice or policy; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?
- d. Investigators. Are the investigators appropriately trained and well-suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)?
- e. Environment. Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or respondent populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

2. Add Health Priorities and Policies

- a. Consistency with scientific objectives of Add Health
- b. Acceptable burden to Add Health respondents
- c. Parsimonious use of biospecimens (if applicable)
- d. Minimal burden to Add Health staff and biospecimen repositories (if applicable)
- e. Appropriate plan for disposition of stored samples (if applicable) (e.g., returning excess biospecimens)
- f. Draws on unique characteristics of Add Health
- g. No/minimal overlap with current portfolio of studies

G. Commercial Use of Add Health Data

Add Health will not approve ancillary studies that are subject to consulting or licensing obligations to another institution, corporation or business entity. Approval of an ancillary study shall not be deemed a grant under any patents (either existing or future) or any rights to use Add Health data for any products or processes for profit-making or commercial purposes.

H. Studies Collecting New Original Questionnaire Data on Add Health Participants or Merging Secondary Data Sources onto Add Health Data

All new questionnaire data collected from Add Health participants or secondary data appended to Add Health records become the property of the Add Health Project and will be made available to the research community according to Add Health Policies for the Cleaning and Release of Ancillary Study Data (Appendix A-1). Proposals to collect new or append extant data must include an explanation of what data will be collected and/or appended, an estimate of the number of variables to be added to the Add Health data, and a description of the data sources (if extant) and variable constructs.

I. Studies Involving New or Archived Biospecimens

Requests to collect new biospecimens or use archived biospecimens will receive especially careful consideration in light of the ongoing need to minimize burden and ensure that adequate amounts of biospecimens are reserved for current and future Add Health objectives. Proposals to collect new or use archived Add Health biospecimens must include an explanation of the type and quantity of material needed and a justification of the amount.

All biospecimens and any data resulting from their analysis become the property of Add Health and will be made available to the research community according to the terms of the Add Health Biospecimen Distribution Agreement (Appendix A-2). Proposals to collect new or use archived Add Health biospecimens must include an explanation of the assays to be performed and an estimate of the number of variables to be added to the Add Health data. After assays are complete, any unused biospecimen must be either returned or destroyed based on prior agreement with Add Health.

J. Data and Biospecimen Distribution Agreements

If the study is approved and funded, the principal investigator will be required to complete the following distribution agreements prior to the release of any data or biospecimens by the Carolina Population Center (CPC)/University of North Carolina:

1. The Agreement for the Use of Sensitive Data from the National Longitudinal Study of Adolescent to Adult Health (Appendix A-3); and
2. If applicable, the Add Health Biospecimen Distribution Agreement (Appendix A-2).

Additionally, the ancillary study PI will be required to submit:

1. Proof of completion of research ethics training by all research team members who will work with the Add Health data or biospecimens
2. If applicable, proof of completion of HIPAA training by all research team members who will work with the Add Health data or biospecimens
3. IRB approval for the ancillary study.

K. Data Security

Protecting the identity of individual Add Health respondents is a critical issue for the Add Health study. Confidentiality of individually identifiable data about Add Health respondents must be assured. For detailed ancillary study data security obligations, see Appendix A-3: Agreement for the Use of Sensitive Data from the National Longitudinal Study of Adolescent to Adult Health.

L. Annual Study Progress Reports

After an ancillary study is funded and initiated, the PI is responsible for submitting annual progress reports on the status of the study (see Appendix A-5) until Add Health has released final ancillary data. These progress reports must summarize the study's activities, including:

1. data/specimens collected to date
2. assays and analyses in progress or completed
3. for studies proposing to use DNA or other biospecimens, information on biospecimen use and storage
4. for studies proposing to use DNA, details of the polymorphisms genotyped and methods proposed to be used

To facilitate annual reporting, annual report forms will be sent by the Add Health study staff to ancillary study investigators on June 1 of every year in the study period. These forms must be completed and returned to CPC no later than July 1 of the same year. Ancillary studies that fail to comply with the annual reporting requirement may be ineligible for renewal of their Add Health restricted use data agreement and/or biospecimen distribution agreement.

M. Publication of Results

1. Results from the Collection of New Questionnaire Data or the Merging of Secondary Data onto Add Health Data

New questionnaire data collected from Add Health participants or secondary data to be merged with Add Health data must be linked to the existing Add Health longitudinal data and released by the Add Health study staff to the scientific community of Add Health users before any manuscripts, abstracts or presentations derived from the ancillary study may be submitted for review. Any such manuscript, abstract or presentation shall include appropriate attribution to Add Health, as specified in the Add Health restricted use data agreement (Appendix A-3). For detailed policies on data cleaning, variable construction and data release, see Appendix A-1: Add Health Policies on the Cleaning and Release of Ancillary Study Data.

2. Results from the Collection or Use of Add Health Biospecimens

Subject to the terms of the Add Health Biospecimen Distribution Agreement (Appendix A-2), Add Health shall not release ancillary data resulting from the collection or use of Add Health biospecimens to the scientific community of Add Health users for a period of one year beginning upon release of the final, clean data file to the ancillary study PI. During this one-year period, the ancillary study PI may create and submit manuscripts, abstracts or presentations regarding the ancillary study, with appropriate attribution to Add Health, as specified in the Add Health restricted use data agreement (Appendix A-3). For detailed policies on the cleaning and release of ancillary biological data, see Appendix A-2: Add Health Biospecimen Distribution Agreement and the exhibits referenced therein, including Exhibit A: Add Health Policies on the Cleaning and Release of New Data Resulting from the Collection or Use of Add Health Biospecimens.

N. How to Apply

1. For ancillary studies that involve collecting new questionnaire data from Add Health respondents or merging secondary data onto Add Health data, review the Add Health Policies on the Cleaning and Release of Ancillary Study Data (Appendix A-1).
2. For ancillary studies that involve the collection or use of Add Health biospecimens, review the Add Health Biospecimen Distribution Agreement (Appendix A-2) and the exhibits referenced therein.
3. Review the Agreement for the Use of Sensitive Data from the National Longitudinal Study of Adolescent to Adult Health (Appendix A-3).
4. Complete the Add Health Ancillary Study Proposal Form (Appendix A-4).
5. Submit to:

Add Health Ancillary Studies
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206 W. Franklin Street
Chapel Hill, NC 27516
addhealth_ancillary@unc.edu