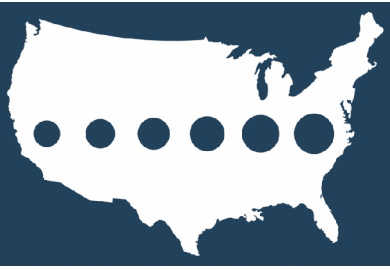


Add Health

The National Longitudinal Study of Adolescent to Adult Health

Ancillary Studies

Researcher Guidelines

Contextual Data

UNC | CAROLINA POPULATION CENTER

ADD HEALTH ANCILLARY STUDIES

Contextual Data

The development of an Add Health Ancillary Study is time-intensive and may also be costly. Please read the following guidelines carefully.

What is a Contextual Data ancillary study? An Ancillary Study is any study that adds data to Add Health that is beyond what is included in the activities of the core Add Health Study. Ancillary Study costs are supported by the investigator, and must be approved by Add Health before any grants for support are submitted for funding. and merges secondary data sources or constructed variables to Add Health respondent records that requires unique identifiers (e.g., geocodes, school identifiers) to perform these linkages.

To allow adequate time to submit revise, re-submit, and re-review proposals and applications that are not approved, applicants are strongly encouraged to submit proposals at least **six months in advance** of an anticipated grant application deadline. Investigators who conduct an Ancillary Study must cover all costs incurred by the study, such as preparing and documenting analysis files and integrating ancillary data into the Add Health Study. Most funding agencies require an approval letter included with a grant submission, therefore, **an ancillary study must be approved by Add Health before a grant to support it is submitted for funding**.

Although Ancillary Study investigators are not required to have previous experience with the Add Health Study, demonstrated familiarity with Add Health data and its study design will significantly enhance review of Ancillary Study proposals, within both Add Health and independent funding agencies.

Contextual Ancillary Studies are conducted in 5 Phases:

- **Phase 1: Getting started**
- **Phase 2: Applying for an Ancillary Study** (6 months review timeline). **This includes the initial proposal review and the full application review.**
- **Phase 3: Obtaining funding and completing require documentation**
- **Phase 4: Conducting your study**
- **Phase 5: Releasing of the data**

SECTION I

Requirements

A. Investigator Requirements

Ancillary Study investigators must meet the following criteria:

1. Have a PhD, MD, or other terminal degree.
2. Hold a faculty appointment or research position at their institution.
3. Work for an institution of higher education, a research organization, or a government agency.
4. Have an institutional review board (IRB) that complies with applicable Federal regulations governing research involving human subjects.
5. Demonstrate completion of research ethics training by all research team members who will work with the Add Health data.
6. Have a demonstrated record of using sensitive data according to commonly accepted standards of research ethics.

B. Funding Requirements

Investigators proposing to conduct an ancillary study must cover all costs incurred by the study, such as preparing and documenting analysis files and integrating ancillary data into the Add Health Study. In most cases, the investigator will need to budget and establish a subcontract with the Add Health project to cover such costs. All ancillary data are reviewed for deductive disclosure risk, cleaned, and checked by Add Health staff. All dataset documentation must also be reviewed and codebooks created by Add Health staff. Add Health staff must be contacted prior to submission of any proposal seeking funding from an external agency to provide cost estimates for budgeting these costs.

There is a minimum charge of $6,000 for Add Health staff effort and security management charges. All ancillary studies are required to also hold a restricted-use data contract. The cost estimate ranges are as follows:

1-10 variables	11-20 variables	21-30 variables	> 30 variables
$7,000-$9,000	$9,000-$12,000	$12,000-$15,000	$16,000 +

***Note** that the amounts below are estimates and study costs are subject to change. Please work with the Add Health Studies Coordinator to draft a cost estimate.*

SECTION II

Add Health Priorities and Policies

Add Health welcomes the addition of ancillary studies that have scientific merit. However, Add Health will not consider ancillary studies that:

- Duplicate or interfere with existing Add Health activities (including already approved ancillary studies).
- Adversely affect respondent cooperation in Add Health.
- Threaten the security of Add Health data and/or identities of Add Health respondents.
- Create an unacceptable diversion of Add Health study resources, including personnel or study samples.
- Jeopardize the public image of Add Health.
- Are not consistent with both Add Health scientific objectives and the priorities of our main funding agencies, the Division of Behavioral and Social Research of the National Institute on Aging and/or the Population Dynamics Branch of the Eunice Kennedy Shriver National Institute of Child Health and Human Development.

Commercial Use of Add Health

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.

Released Add Health Data

It is Add Health's expectation that ancillary studies make resulting data available to the Add Health community of data users. Ancillary study approval indicates Add Health's agreement to work with study investigators to complete the proposed project, conditional on investigators securing the necessary funding to support the work. Approval does not indicate that investigators have the exclusive right to pursue proposed activities. In some instances, ancillary studies may be proposed and approved that overlap in their planned work. In such instances, Add Health will work with investigators to facilitate collaboration.

Merging Secondary Data Sources onto Add Health Data

All 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 the Data and Material Use Agreement (DMUA). Proposals to append extant data must include an explanation of:

1. What data will be appended.
2. An estimate of the number of variables to be added to the Add Health data.
3. Description of the data sources (if extant) and variable constructs.

SECTION III

Ancillary Studies Committee Review Criteria

The review of Add Health Ancillary Study proposals is both time-consuming (on the part of Add Health) and serious. We not only consider such reviews to be similar to those of an NIH Study Section (e.g., Five Dimensions of Scientific Merit), but we also give serious consideration to both Add Health priorities and policies and to the scientific priorities of our main funding agencies over the years, particularly the Division of Behavioral and Social Research of the National Institute on Aging (NIA) and the Population Dynamics Branch of the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD).

All proposals will be reviewed according to the following criteria:

- Consistency with scientific objectives of Add Health.
- Consistent with the scientific priorities of our main funding agencies over the years, particularly the Division of Behavioral and Social Research of the National Institute on Aging (NIA) and/or the Population Dynamics Branch of the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD).
- Acceptable burden to Add Health respondents.
- Draws on unique characteristics of Add Health.
- No/minimal overlap with the current portfolio of studies.
- A minimal burden to Add Health staff

SECTION III (continued)

Ancillary Studies Committee Review Criteria

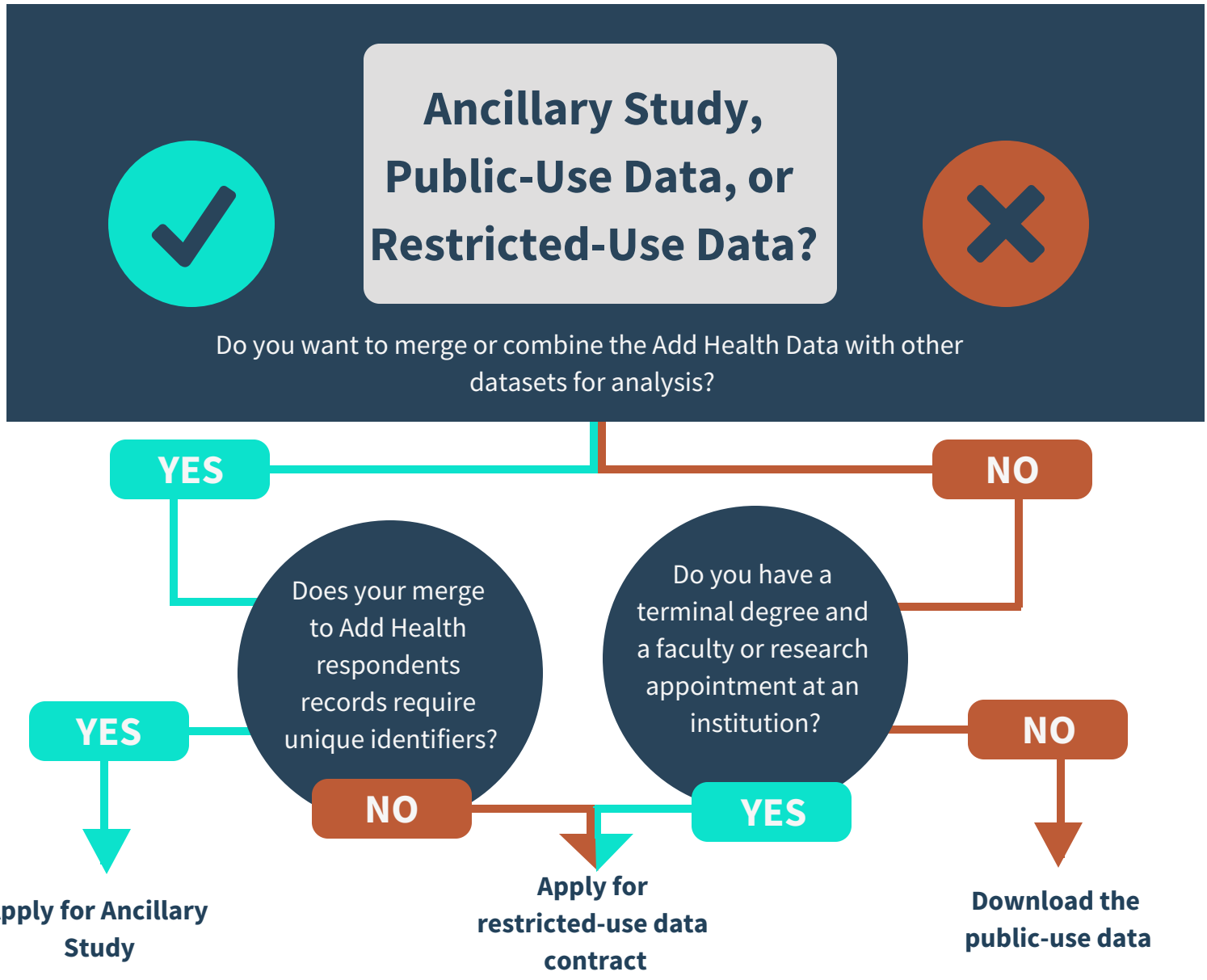
Scientific Merit

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?
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?
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?
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 principle investigator and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)?
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?

Section IV

Phase 1 - Getting Started

Step 1: Determine if you require an ancillary study or if your research can be conducted with a restricted use data contract. Please see the chart below for assistance.
Step 2: Review the Add Health codebooks for existing datasets to confirm data do not currently exist.
Step 3: Review the Add Health completed and approved Ancillary Studies table to confirm there isnt an Ancillary Study in progress that will provide the data you can use for your research plans and to ensure there is no significant overlap in concepts.
Step 4: Be sure to submit your ancillary study application well in advance of any planned grant proposals **(at least 6 months)**. Add Health Ancillary Study approval should be obtained before any grants including the planned activities are submitted.



Section V

Phase 2: Applying for a Contextual Ancillary Study

Submitting your proposal

Step 1	Submit a brief 1-page concept proposal to **AddHealth_Ancillary@unc.edu** for Add Health review. Proposals are reviewed monthly.
Step 2	Address feedback and resolve issues from the preliminary proposal review.

If your proposal is approved, you will be invited to submit a full application

Step 3	Submit an Ancillary Study application form for Add Health review, along with number of variable and a narrative description (12 pages maximum) including: Why Add Health, specific aims, brief background and significance, conceptual framework and hypotheses, data requested or to be collected, sample size and justification (i.e. formal power calculation), analysis plan for each aim, and study timeline. Applications that pass the screening are then assigned to reviewers.
Step 4	Reviewers may have questions or comments thus more than one round of reviews may be required. If revisions are requested, they should be made in a resubmitted application. Accepted applications may move on to Phase 3. Rejected applications will be provided with a final determination and reason for the decision
Step 5	Work with the Add Health Studies Coordinator to develop a cost estimate. The Ancillary Investigator must cover all costs incurred by the study such as preparing and documenting analysis files, data merge, codebook creation, and integrating ancillary data into the Add Health Study.

Because there is no guarantee your application will be approved, please **do not submit a grant application for external funding until approval is given.**

Section VI

Phase 3: Obtain funding and complete documentation

Once the Ancillary Study is approved, the investigator can submit applications to receive funding using the formal written notice documenting Add Health's support for the project and guarantee for collaboration.

After receiving funding, the Ancillary Study Investigator will be required to complete the following distribution agreements prior to the release of any data by the Carolina Population Center (CPC)/University of North Carolina

1. Review, fill and sign the Data and Material Use Agreement.
2. Go to the CPC Data Portal and apply for a Restricted-Use Contract if one is not already in place.
3. Proof of completion of research ethics training by all research team members who will work with the Add Health data.
4. Proof of completion of HIPAA training by all research team members who will work with the Add Health data
5. IRB approval for the ancillary study.

After an Ancillary Study is approved, changes in the scope or procedures of the study must be submitted via a modification form, reviewed, and approved by Add Health. A modification form can be found on the Ancillary Studies website or by contacting the Studies Coordinator at addhealth_ancillary@unc.edu.

Annual Status Reports

After an Ancillary Study is funded and initiated, the PI is responsible for submitting annual progress reports of the study's status to Add Health until Add Health has released final ancillary data. These progress reports must summarize the study's activities, including:

1. Progress of data collected to date
2. Analysis in progress or completed
3. Updates to scope, design, or methods
4. Updates to timeline

Annual report forms will be sent out 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 contract and/or their Data and Material Use Agreement.

Section VII

Phase 4: Conducting your study

Step 1: Schedule your launch meeting - Once your required documents are submitted and funding has been obtained, the Add Health Studies Coordinator will schedule a meeting with the Ancillary Study Investigator's team and Add Health to discuss your data plans and answer any questions.

Step 2: Data set preparation - After data collection is completed, it is time to assemble the planned contextual variables. Be sure to document data sources, variable construction and other relevant details. This information should include, but not be limited to:

- a detailed description of the source data.
- programming code documenting any variable construction.
- references for variable constructs (e.g., the reference for the standard scale used).
- documentation on the cleaning process to date.

Step 3: Submit clean data file for merge - Once Add Health has received the files, staff will examine the data for deductive disclosure risks and modify the data to reduce these risks. During this time, the following will be conducted:

- Ancillary data will be merged with existing Add Health data.
- Variable construction of the added data will be tested, researched, and reviewed. Consultants may be contacted, as necessary.
- Frequency distributions of the added variables will be evaluated for deductive disclosure.
- Cross tabulations of the new data with existing Add Health data will be run and reviewed.
- Logical associations among the new and existing data will be mapped out and evaluated.
- Documentation will be examined and edited.
- Decisions about modifications to the variables will be made in consultation with the Ancillary Studies Investigator. This may involve dropping variables, collapsing categories, or modifying the data in other ways to protect the identity of the study participants.
- A preliminary data file will be created.
- Codebooks following the Add Health standards will be created.

Section VII

Phase 4: Conducting your study (continued)

Step 4: Receive preliminary dataset - After the data is merged, the preliminary with masked participant IDs dataset will be placed on the secure research workspace (SRW) and the Ancillary Study Investigator will be given 30 days to review the data for errors. If an error is found, Add Health will make the necessary corrections and the Ancillary Study Investigator will be given an additional 30 days to review.

Ancillary Study Investigators are not permitted to submit any manuscripts, abstracts, or presentations derived from the Ancillary Study for review until the secondary data has been merged and released to the scientific community of Add Health users. Once the data has been approved by the Ancillary Study Investigator, the preliminary dataset will be removed from the SRW and Add Health staff will begin preparations to release the final datasets. Because the final dataset is likely to be different from this preliminary dataset, the investigator is encouraged to develop & document analysis programs so they may be re-run against the final dataset that is released to the public.

Step 5: Prepare documentation - The Add Health Studies Coordinator will provide a User Guide template for the dataset that the Ancillary Study Investigator will need to create.

Step 5: Pay invoice - After the preliminary data has been approved, Add Health will conduct a final disclosure review and prepare the data for dissemination. The Ancillary Studies Coordinator will submit an invoice at this time for payment. Payment must be received before data can be released.

Section VIII

Phase 5: Public release of the data

Once approval to disseminate is received from the Ancillary Study Investigator, a tentative release date will be set for the new data. The timeframe for release will be determined by the number of variables included in the ancillary dataset and the availability of Add Health staff to work on the final deductive disclosure risk review. The final data will be released to the entire user community at the same time. The Ancillary Study Investigator can request the data via the CPC Data Portal and begin publishing and presenting on the data.

The determination of what is included in the released file is made in collaboration with the Ancillary Study Investigator and their team. The Add Health Director/PI may assist in making decisions if needed.

Ancillary Study Investigators are not permitted to submit any manuscripts, abstracts, or presentations derived from the Ancillary Study for review before the release date of the final file. The Ancillary Study Investigator agrees to use only data from the final released file for analysis and submitted manuscripts, and any such work must include appropriate attribution to Add Health as specified in the Add Health restricted-use data agreement.

Section IX

Applying for a Restricted-Use Data Contract

In order to receive preliminary ancillary data for review, the Ancillary Study investigator will need to apply for a restricted-use data contract. This contract is an agreement signed by two parties, the Ancillary Study Institution and UNC-Chapel Hill on behalf of Add Health.

To apply for restricted-use data, please download and complete the Restricted-Use Data Contract using the CPC Data Portal at https://data.cpc.unc.edu/ and select Add Health, or contact addhealth_contracts@unc.edu.

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.
All data work will take place in the Secure Research Workspace (SRW). The SRW helps keep Add Health data more secure in our efforts to maintain the strict confidentiality of our participants. The SRW is available through remote access. All research and analysis will take place only within the SRW.

For detailed ancillary study data security obligations, see The Add Health website https://addhealth.cpc.unc.edu/.

Section X

Ancillary Study Roadmap - Contextual

Phase I

- Review Researcher Guidelines
- Review previously conducted Ancillary Studies
- Determine if you need public-use data, restricted-use data, or to apply for an Ancillary Study

8 months prior to funding submission

Phase II

- Submit one-page proposal
- Respond to reviewers feedback (resubmit if applicable)
- Submit full Ancillary Study application form
- Respond to reviewers feedback
- Receive decision

6 months prior to funding submission

Phase III

- Secure external funding
- Submit additional documentation, including DMUA, ethics training, HIPPA training, and IRB approval
- Apply for restricted-use data contract (if applicable)

Dependent on funding agency's timeline

Phase IV

- Data merge and deductive disclosure review by Add Health
- Create user guide
- Review preliminary data and codebooks
- Approve data for release
- Pay invoice

6 to 12 months

Phase V

- Final data review by Add Health
- Data released to full user community
- Request the final released file using CPC Data Portal
- Prepare publications, Manuscripts, and presentations using the final released file

6 to 8 weeks

Add Health

The National Longitudinal Study of Adolescent to Adult Health

Please contact and submit applications to:

Email:
addhealth_ancillary@unc.edu

For more information:

Website
https://addhealth.cpc.unc.edu

Address
Add Health
Carolina Population Center
University of North Carolina - Chapel Hill
CB# 8120
Chapel Hill, NC 27599-8120

UNC CAROLINA POPULATION CENTER