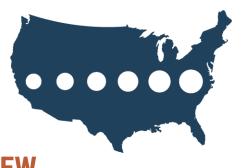


Researcher Guidelines for

ANCILLARY STUDIES

Please contact:

Add Health Ancillary Studies addhealth_ancillary@unc.edu



ADD HEALTH ANCILLARY STUDIES BASIC OVERVIEW

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

- 1. Merges secondary data sources to Add Health respondent records that require unique identifiers (e.g., geocodes) to perform these linkages.
- 2. Uses archived biospecimens collected by the Add Health Study to conduct new assays.
- 3. Adds new survey questionnaire or biological data to Add Health, either through making additions to the core instruments during a particular wave or through the use of unique identifiers to collect new survey or biological data.

The development of an Add Health Ancillary Study proposal is time-intensive. Ancillary Studies may also be costly. Please make sure to read the guidelines carefully.

Add Health will review and approve, reject or request a 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 six months in advance of an 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 the decision to approve or reject the proposed study. The approval notice will document Add Health's support for the project 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 Add Health.

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 the review of Ancillary Study proposals, within both Add Health and independent funding agencies.

Section I

General Requirements for Ancillary Studies



A. Requirements of Investigators

Ancillary study investigators must meet the following criteria:

- 1. Have a Ph.D., MD, or other terminal degrees.
- 2. Hold a faculty appointment or research position at their institution.



B. Requirements of Institution

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.



C. Funding Requirements

Investigators proposing to conduct an ancillary study must cover all costs incurred by the study, such as sample selection; collecting or pulling samples from the archive; processing and shipping biospecimens; preparing and documenting analysis files; performing statistical analysis; and integrating ancillary data into the Add Health study.

Some of these activities can only be performed by the Add Health staff and/or the Add Health archive lab, which must be paid for. 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 must be contacted prior to submission of any proposal seeking funding from an external agency to provide cost estimates for budgeting these costs.



D. Requirements for Approval

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

- 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.
- 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.

Section II

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 review committee. Please note that 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).

Requests to collect new biospecimens or use archived biospecimens or biological data will also be reviewed and approved by the Add Health Biology Team.

All proposals will be reviewed according to the following criteria:

A. Add Health Priorities and Policies

- 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.
- Parsimonious use of biospecimens (if applicable).
- A minimal burden to Add Health staff and biospecimen repositories (if applicable).
- Draws on unique characteristics of Add Health.
- No/minimal overlap with the current portfolio of studies.

Section II (continued)

B. Scientific Merit

Merit	Description
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? 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 principal 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 III

General Policies

A. 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.

B. Releasing Ancillary Study Data

It is Add Health's expectation that ancillary studies make resulting data available to the Add Health community of data users.

C. Studies Collecting 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 the **Data and Material Use Agreement**.

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.

If the proposal is approved and funded, our staff and investigators will determine the placement and format of the questions within the survey.

At this time, Add Health is not accepting applications to add questions to the Wave VI survey, the survey content has been finalized.

Section IV

Process of Linking & Cleaning Ancillary Study Data

Merging and cleaning of Ancillary Study data processes are described below, and the Ancillary Study Investigator must agree to the following prior to the approval of an Ancillary Study by the Add Health Study:

- The Ancillary Study Investigator will work with the Add Heath data staff to identify whether all Add Health respondents will be involved in the Ancillary Study or a subset. When that study population is identified, the Add Heath data staff will provide necessary information about the study participants to allow linkage of external data or specimens to the Add Health Security Management Team.
- The Security Management Team will assign a unique Ancillary Study ID that cannot be linked to the Add Health public-use data. The Ancillary Study staff will use this ID and any Add Health identifiers or data that have been provided for all work associated with collecting and processing the new data.
- Linking of the data or associated assays along with initial data cleaning (such as range checking, consistency re-coding, and construction of composite measures from newly collected data or assays), will be done by the Ancillary Study staff and will take place after the data collection/assay process using the Ancillary Study ID.
- When the initial data linking and cleaning are completed, the resulting data file will be shared with the Security Management Team. The Security Management Team will replace the Ancillary Study ID with the standard Add Health ID and provide the Ancillary Study data with the Add Health ID to the Add Health staff.
- When the Ancillary Study data are shared with the Add Health staff, the Ancillary Study Investigator must provide Add Health with the preliminary documentation for the additional variables. This information should include, but not be limited to:
 - a detailed description of the source data and/or assay procedure.
 - programming code documenting any variable construction.
 - references for variable constructs (e.g., the reference for the standard scale used).
 - for laboratory assays, the name of the assay or the protocol used for the assay, the units of the results, and quality control information.
 - documentation on the cleaning process to date.

Section IV

Process of Linking & Cleaning Ancillary Study Data (Continued)

Once Add Health staff have received the dataset from the security management team and the required documentation from the Ancillary Study Investigator, the dataset is provided to the Ancillary team for review.

- Studies utilizing biospecimens have a one-year proprietary period which restarts if/when a new dataset is provided.
- Contextual data studies do not have a proprietary period but have a 30-day review period. The Ancillary Studies Coordinator will coordinate review periods for all studies including sending reminder emails.

I. The Add Health staff begin examining the data for deductive disclosure risks and modify the data to reduce these risks. During this time, Add Health staff will perform the following checks:

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

II. While the Add Health staff are conducting this data cleaning, the Ancillary Study Investigator will be responsible for completing the following tasks:

- 1. Review ancillary data and constructed variables for errors and evaluate for performance & utility.
- 2. Submit final documentation describing the generation of the variables (User Guide) to the Ancillary Studies Coordinator.
- 3. Provide written approval of proceeding with dissemination of the data to the Ancillary Studies Coordinator.
- 4. Provide the filename and location path of the final datafile as well as any additional information requested by Add Health.
- 5. The Ancillary Study Investigator may begin analyses that would lead to presentation or publication with these data. However, no presentations or manuscript submissions may occur during this time. 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.

Section V

Add Health Policies on Data Dissemination

- 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 deductive disclosure risk review. Other projects waiting for review will also impact the scheduling of a new project. Data files will not be sent to the Security Management Team for ID transformation unless there is Add Health staff available to work on the files. The Add Health team makes the definitive decision about the final release date of the Ancillary Study datasets.
- 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.
- At the point of dissemination, the Ancillary Study Investigator returns the working data file and/or destroys all electronic copies.
- A copy of the released file is made available to the Investigator at the same time as it is made available to Add Health users. The Investigator agrees to use only data from the released file for analysis and submitted manuscripts. All presentations and submitted manuscripts must be based on the final released file. For contextual data studies, manuscripts cannot be submitted for publication before the release date of the final file while studies utilizing biospecimens are entitled to a one-year proprietary period.

Section VI

Ancillary Studies using Biospecimens

Studies Involving Archived Biospecimens

Requests to collect 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 **Data and Material Use Agreement**. Proposals to collect 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.

Requirements

If the study is approved and funded, the principal investigator will be required to submit all the requirements listed below prior to the release of any data or biospecimens by the Carolina Population Center (CPC)/University of North Carolina:

- The Add Health Data and Material Use Agreement.
- Proof of completion of research ethics training by all research team members who will work with the Add Health data or biospecimens.
- Proof of completion of HIPAA training by all research team members who will work with the Add Health data or biospecimens. If applicable.
- IRB approval for the ancillary study.
- The Data Use Contract Agreement for the Use of Restricted-Use Data.

Section VI

Steps for Add Health Ancillary Studies Involving Biospecimens

Add Health and its Biology Core review and approve the ancillary study, its biospecimen selection criteria, and volumes as well as internal quality control protocols.
The Ancillary Study PI (or designee) and the Biology Core work together to create a participant biospecimens pull list based upon approved selection criteria and Add Health standard biospecimen volumes. STEP 2b: Add Health interleaves 5% non-participant biospecimens in sets of masked duplicate pairs in the pull list. STEP 2c: Add Health interleaves 100 participant biospecimens from the second Intra-Individual Variation (IIV) visit into the pull list.
Add Health creates a pull list using a biospecimen ID and a lab/vial ID. The pull list includes all participant, non-participant, and IIV biospecimens. Add Health securely and solely maintains the crosswalk from the biospecimen and lab/vial ID to the participant and non-participant IDs.
Add Health sends the pull list to the storage lab and has the storage lab pull and assemble the masked participant, non-participant, and IIV biospecimens. The storage lab documents the box/rack locations as they prepare biospecimens for shipment.
The storage lab sends the biospecimens to the ancillary study lab and sends a manifest to both Add Health and the ancillary study lab.
The ancillary study lab performs testing. When finished, the ancillary study lab sends results to Add Health linked by a lab/vial ID. The ancillary study lab also sends QC data and internal quality documentation to Add Health for review by the Biology Core. If the lab internal quality documentation is approved, move to STEP 7.
Add Health replaces lab/vial ID in the results with a preliminary ID. Add Health also removes non-participant and IIV biospecimen data so that only participant data remain. Add Health retains the crosswalk between the preliminary ID and the AID.
Add Health makes the preliminary ID-identified participant data and internal quality control documentation available to ancillary study investigators, e.g. on Longleaf, for analysis only. Per Add Health policy, publication remains prohibited until after STEP 10.
Add Health externally assesses data quality based upon the participant, non-participant, and IIV biospecimens. If the external quality is high, move to STEP 10.
Upon satisfying the ancillary study protocols, Add Health exchanges the preliminary IDs for AIDs, then disseminates the AID-identified participant data and the internal and external quality control documentation to the ancillary study and Add Health user community at large, for analysis and publication.

Section VII

Guidelines for Add Health Biospecimens

Parsimonious use of biospecimens is an important consideration in the review of Add Health ancillary study proposals. Ancillary Study investigators should therefore:

- · consult with their proposed laboratory before submitting an Ancillary Study proposal
- determine the smallest possible biospecimen volumes needed to complete their proposed work
- only request those minimum volumes
- only run samples in singleton, when appropriate

With sufficient scientific justification, ancillary studies are limited to the following biospecimen volumes, including any necessary "dead volume", or padding: 250 µl serum, 250 µl plasma, 1 µg DNA.

**Requests for larger volumes must be accompanied by additional, compelling justification.



Selection

Ancillary study proposals must clearly specify the selection criteria and sample size to guide biospecimen sample selection. Once an ancillary study has been approved and funded, the Add Health Biology Team will work with ancillary study investigators and Add Health programmers to develop the ancillary study's sampling list, to develop its back-up sampling list, and to select the sample, all according to the approved study protocol. Any post hoc changes to approved ancillary study selection criteria, sample size, or protocol must be formally proposed and justified in an Add Health Ancillary Study Modification Request submitted to the Ancillary Studies group. Formal review and approval of such requests must precede sample selection.

Given the involvement of Add Health personnel in sample selection, associated costs must be fully anticipated and shouldered by the ancillary study. Costs must be negotiated with Add Health after ancillary study approval, but before submission for funding.



Masking

Conditional on their availability, Add Health will randomly interleave quality control (non-participant) biospecimens totaling a recommended 5% of the selected participant biospecimens into the selected sample. The quality control biospecimens will include pairs of masked duplicates, thereby totaling 2.5% of selected participant biospecimens. For example, in a study of biospecimens from n=200 participants, Add Health will randomly interleave n=10 quality control biospecimens, i.e. 2 masked duplicates from each of n=5 non-participants. Any proposed reduction in the number of quality control biospecimens designated above must be justified in detail at the time of the Ancillary Study proposal.

After including the masked duplicate pairs, Add Health will interleave n=100 Intra-Individual Variation (IIV) participant samples, depending on their availability. Costs of assaying the masked duplicate and IIV participant samples also must be fully anticipated and shouldered by the ancillary study (or selected participant sample size reduced to offset them). Add Health will replace the selected participant, non-participant masked duplicate, and IIV participant identifiers (IDs) with undifferentiated, masked ancillary study IDs before shipping samples to laboratories for assay. Add Health will control the crosswalk of participant, nonparticipant, and IIV IDs.

Add Health will not identify participant assay results to ancillary study investigators until Add Health receives the results and associated documentation of internal quality control.

Section VIII

Quality Control for Add Health Biospecimens



Internal Quality Control

Laboratories are expected to:

- 1. Follow best practices when monitoring and controlling the quality of the assay data that they generate.
- 2. Use conventional tools to do that, e.g. their own negative/positive controls, calibration standards, split samples, etc.
- 3. Immediately alert the Add Health Ancillary Studies Coordinator at addhealth_ancillary@unc.edu by email regarding any unanticipated changes in agreedupon lab protocol, reagent shortages, substituted materials, or adverse events that may affect sample integrity and/or assay quality.
- 4. Provide documentation summarizing their procedures and assay data quality (including missingness; validity; reliability) when they return data to Add Health.
- 5. Include conventional quality metrics in the documentation (including counts of missing values, differences in / correlations between known and assayed values, and within- / between-split sample coefficients of variation.
- 6. Identify masked duplicate pairs (in studies requesting DNA for large-scale genotyping).



External Quality Control

Based on the above, Add Health programmers will produce, and the Add Health Biology Team will review, an external quality control report. Costs of doing so also must be fully anticipated and shouldered by the ancillary study. The report will include standard reliability and validity measures. The report will substitute summary statistics for the above items among ancillary studies generating high dimensional (e.g. omics) data.

Ancillary study investigators can explore their assay results but cannot publish findings based on them until Add Health completes its external quality control analyses and sends the external quality control report to the ancillary study investigators.

Section IX

Applying for a Restricted-use Data Agreement

In order to receive preliminary data for review, the Ancillary Study investigator will need to apply for a restricted-use data agreement. This Agreement for the Use of Restricted-Use Data 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/.

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. Below are three different locations where you might choose to store the Add Health data.



Data Stored on an Encrypted Stand-Alone Computer

A stand-alone computer is one that is in no way connected to another computer or networked device such as a switch, hub, or router.



Data Stored on an Encrypted External Hard Drive

The external hard drive is a modified version of the stand-alone computer, in effect keeping the Add Health data off the Internet or a local area network (LAN), while using a daily-use computer.



Data Stored on a Server

There are two types of servers that can be used:

Compute Server - most secure option

- Files are stored on the server.
- All processing of the data files is done on the server.
- Data files are not shared to the user's computer over the network.

File Server - <u>least secure option</u>

- Files reside on the server.
- Files are shared to the user's computer over the network and analyzed on the local computer.

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

Section X

Annual Study Progress Report

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

- Data/specimens collected to date.
- Assays and analyses in progress or completed.
- For studies proposing to use DNA or other biospecimens, information on biospecimen use and storage.
- 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 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 contract and/or their Data and Material Use Agreement.

Section XI

Publications of Results

I. Results from the Merging of Secondary Data onto Add Health Data

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.**

II. Results from the Use of Add Health Biospecimens

Subject to the terms of the Add Health Data and Material Use Agreement, Add Health shall not release ancillary data resulting from the use of Add Health biospecimens to the scientific community of Add Health users for a **period of one year** beginning upon release of the 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**.

Section XII

Ancillary Studies Cost

All ancillary data are reviewed for deductive disclosure risk, cleaned, and checked by Add Health staff. All dataset documentation and associated codebooks must also be reviewed by Add Health staff. These tasks result in costs associated with programmer effort, data support effort, and IT consultation.

There is a minimum charge of \$6,000 for Add Health staff effort and security management charges. The cost estimate ranges are as follows::

1-10 variables	11-20 variables	21-30 variables	>30 variables
\$6,000-\$8,000	\$8,000-\$11,000	\$11,000-\$14,000	\$15,000+

Note that the amounts above are estimates and study costs are subject to change. Upon approval, the study budget will be finalized and an invoice provided.

We strongly encourage individuals interested in submitting an ancillary study proposal to contact the Ancillary Study Team at addhealth_ancillary@unc.edu well in advance of the submission of a proposal.

Section XIII

Application Process

Before considering an Ancillary Study

- 1. Review codebooks for existing Add Health datasets.
- 2. Review the Add Health Completed and Approved Ancillary Studies table and published manuscripts for potential overlap with your proposal.
- 3. Contact the Ancillary Studies Coordinator at addhealth_ancillary@unc.edu with any questions or concerns.

Applying for an Ancillary Study

- 1. Submit a brief (1-page) Concept Proposal for Add Health review. Please name file using the following nomenclature: "Lastname Firstname Filedescription"
- 2. Address feedback and resolve issues from the preliminary review.
- 3. If invited to submit a full application, submit the Add Health Ancillary Study Application Form.

 Please name file using the following nomenclature: "Lastname Firstname Filedescription"
- 4. Work with the Ancillary Studies Coordinator to develop a cost estimate.

After Approval

If the Ancillary Study is approved and funded, the principal investigator (PI) 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. Review, fill and sign the Data and Material Use Agreement.
- 2. Go to CPC Data Portal and apply for a Restricted-Use Contract.

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

- Proof of completion of research ethics training by all research team members who will work with the Add Health data or biospecimens.
- 2. Proof of completion of HIPAA training by all research team members who will work with the Add Health data or biospecimens (if applicable).
- 3. IRB approval for the ancillary study.

Upon approval, the study budget will also be finalized. A final invoice will be provided once the data is ready for dissemination. Invoices should be paid prior to the data release.

Ancillary Studies Roadmap

STAGES

Preliminary Review Application Submission Application Review & Approval

Data Cleaning Data Dissemination

STEPS

- 1. Review Ancillary Studies website.
- 2. Review Research Guidelines for Ancillary Studies pdf.
- 3. Submit Concept Proposal for review.
- 1. Address feedback from the preliminary review.
- 2. Submit the Add Health Ancillary Study Proposal Form.
- 3. Work with the Ancillary Studies Coordinator to develop a cost estimate.
- 1. Research Committee reviews proposal.
- 2. Receive approval letter.
- Submit the signed Data and Material Use Agreement.
- 4. Apply for a Restricted-use data contract.
- 5. Provide IRB approval.
- 6. Submit processing fee.

- 1. Receive Preliminary Data.
- 2. Create documentation.
- 3. Deductive Disclosure review.
- 4. Review codebooks created by Add Health.
- 5. Set a release date.

- Destroy Preliminary
 Data.
- 2. Request the final released file using CPC Data Portal.
- Prepare publications,
 Manuscripts, and presentations using the final released file.

MODE

Researchers provide a brief (1-page) Concept Proposal Researchers complete Ancillary Study Proposal Form Go to CPC Data Portal to apply for Restricteduse data contract Communication via email with the Ancillary Studies Coordinator

To request the final released file go to CPC Data Portal

TIMELINE

Eight months in advance of grant application deadline Six months in advance of grant application deadline

12 - 16 weeks

6-12 months

4 - 6 weeks

For questions email: addhealth_ancillary@unc.edu



Please contact and submit applications to:



Email:

addhealth_ancillary@unc.edu

For more information:



Website

https://addhealth.cpc.unc.edu



Twitter

@Add_Health



Address

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

