

Add Health Ancillary Study Modification Form

Please submit this form with your revised proposal and cover letter attached separately specifying the change:

Date of request:

Principal Investigator: Study #:

Study title:

Is this study already funded and underway?

No
 Yes → Please describe the status of the study?

Funding agency: Funding submission date:

Project period: From to (Month/Day/Year)

I acknowledge that 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.

REASON FOR MODIFICATIONS

Please specify any changes to the following (if there is no change, leave blank or enter "NA").

1. Proposal title:

Proposal title justification:

2. PI/Investigators:

PI/Investigators justification:

3. Funding status:

Funding status justification:

4. Funding source:

Funding source justification:

5. Project period: to (Month/Day/Year)

Project period justification:

6. Study aims:

Study aims justification:

7. Number of variables:

Number of variables justification:

8. Study population (e.g. sampling, exclusion criteria, sample size):

Study population justification:

9. Biospecimens: *specify all changes requested.*
Fill in both the current and proposed columns to clarify all requested changes.

Description	Current	Proposed
Sample Size		
Wave (I, II, III, IV or V)		
Biospecimen type		
Biospecimen volume		
Biospecimen concentration (if type = DNA or RNA)		
Biospecimen laboratory		
Biospecimen analyte(s) measured		
Biospecimen assay method		

Biospecimens justification, including but not limited to:

- Proposed change to methods
- Changes in amount of biospecimen
- Changes to number of respondents
- Changes to selection criteria
- Changes to handling and storage of samples

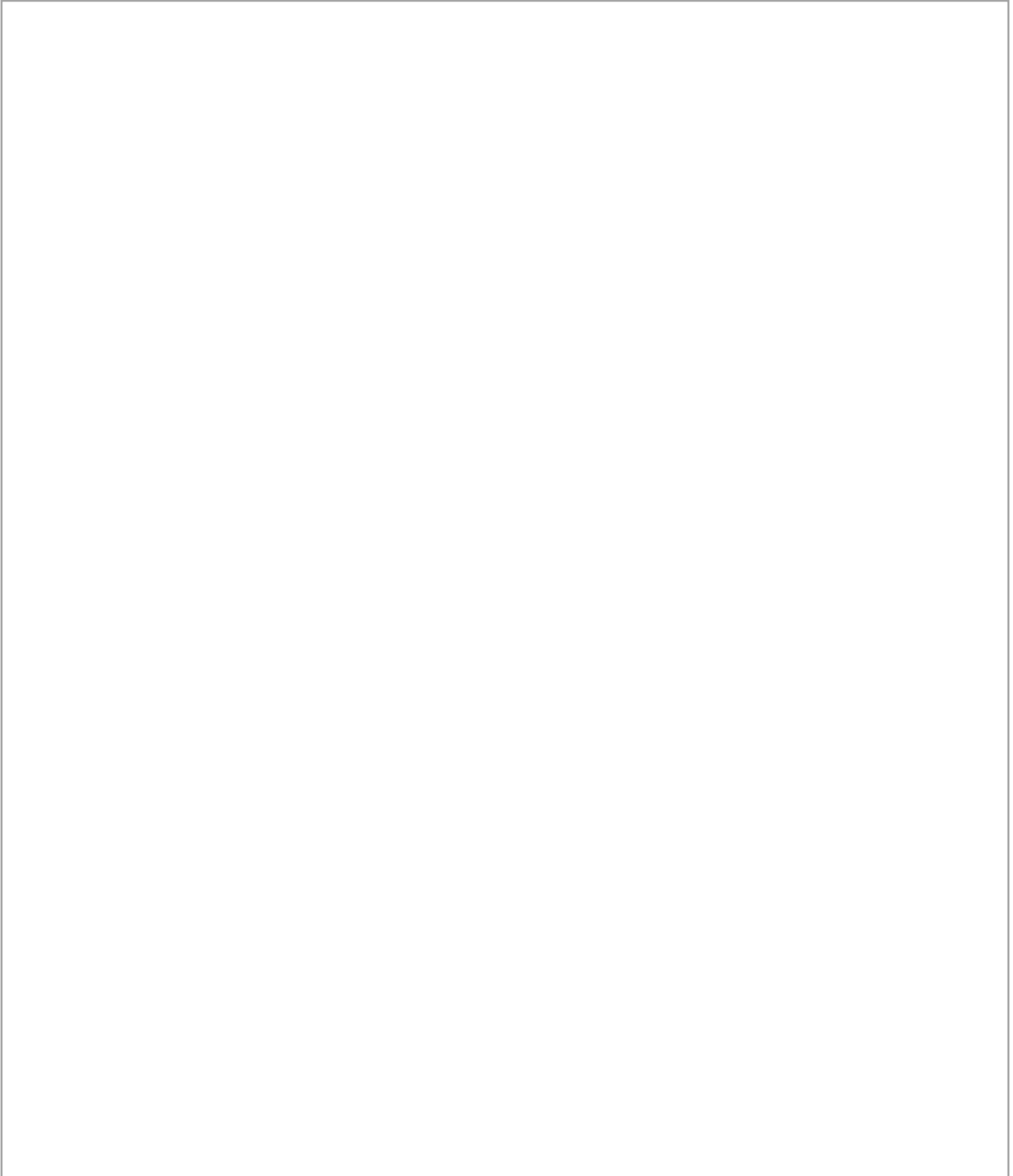
Biospecimen lab justification - If your ancillary study requires a specialized laboratory outside of the preferred Laboratory for Clinical Biochemistry Research (LCBR), Add Health's partner laboratory at the University of Vermont (UVM), please provide strong written justification for this request that includes:

- Reason LCBR cannot be used
- If the proposed lab has experience with this type of specimen
- If the proposed lab has experience with this type of method
- Plans for quality control
- Plans for final disposition of any leftover sample

10. Participant burden (including planned reporting of results):

Participant burden justification:

11. Describe rationale and specifics below or on a separate page. If there are any other changes not captured above, describe.

A large, empty rectangular box with a thin black border, intended for the user to provide a detailed description of the rationale and specifics for the changes mentioned in the text above. The box is currently blank.

APPLICATION CHECKLIST (REQUIRED)

- Completed Modification Request form
- Revised Add Health Ancillary Study proposal (submit both below):
 - With tracked changes
 - Clean proposal