Part I. Basic Study Information

1. Today's date: Click or tap to enter a date.

2. Full study title:

3. Principal investigator:
   - Name:
   - Institution:
   - Address:
   - Phone:
   - E-mail address:

4. Collaborator(s):
   - Name:
   - Institution:
   - E-mail address:

5. Brief abstract describing the study (200 words maximum):

6. Proposed start date:

7. Proposed end date:

8. Estimated cost provided by Ancillary Studies Coordinator (please attach estimate):

9. Proposed funding source and planned date of submission to external funding agency:

10. Does this study involve the support or collaboration of a for-profit corporation, or do you intend to patent any process or product of the analysis?

☐ Yes
☐ No

Part II. Use of Previously Collected Biospecimens

1. Please indicate in the table below the type and amount of biospecimen needed and the number of respondents for whom biospecimens are requested.

Wave	Serum (250 uL)	Plasma (250 uL)	DNA (1 ug)	RNA (0.5 ug)	Dried Blood spots	Stool Microbiome	Oral Microbiome
Wave IV					☐		
Wave V	☐	☐	☐			☐	☐
Wave VI	☐	☐	☐	☐		☐	

2. Provide a justification for the amount of biospecimen and number of respondents needed.

3. What are the respondent selection criteria for inclusion?

4. What assay(s) will be performed by the ancillary study?

5. When will the biospecimens be assayed by the ancillary study?

6. Can previously thawed and refrozen biospecimens be used for the assay?

☐ Yes
☐ No *(If no, provide references to supporting studies)*

7. Can the assays be completed at the Laboratory for Clinical Biochemistry Research (LCBR), Add Health's partner laboratory at the University of Vermont (UVM)?

☐ Yes (*skip to Section III*)
☐ No

8. If your ancillary study requires a specialized laboratory outside of LCBR, please provide justification for this request.

9. Point of contact for specialized laboratory who is responsible for communicating with AH and LCBR.

- Name:
- Institution:
- Address:
- Phone:
- E-mail address:

10. Provide a description of your plans for handling and storage of samples.

11. Provide a description of your plans for the final disposition of leftover biospecimens after analyses are completed.

Part III. Advantages to and Burden on Add Health

1. What is the advantage, both to you and Add Health, of conducting the study within the Add Health population as opposed to another population?

2. What burden, if any, will this study place on Add Health respondents?

Part IV. Assurances

1. What new ancillary study data will be integrated into the Add Health database? Please **specify the number and type(s) of variables that will become available to Add Health users**. (E.g., adding 2 variables for each of 10 years means that you are adding 20 new variables). Any request to later amend this information must be communicated formally to the Add Health PI.

2. In what month and year should the Add Health project staff expect to receive the ancillary study data?

3. What constructs, if any, will be used to create the ancillary study data (e.g., if a standardized scale will be used, what is the reference for that scale)?

4. Provide investigator qualifications and prior involvement in Add Health, if any.

5. Provide the name, position, and contact information (address, phone number, and e-mail address) of individual who will receive, complete, and submit annual progress report form.

6. ☐ 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.

Part V. Description of the Proposed Ancillary Study

Please provide a narrative description of the proposed study. Do not exceed 12 single-spaced pages in length, excluding references (please use Arial 11-pt font). Include the following:

1. Why Add Health?
2. Specific aims
3. Brief background and significance
4. Research questions and/or hypotheses
5. Data and/or biospecimens requested or to be collected
6. Laboratory plan for assay
7. Sample size and justification (i.e., formal power calculation)
8. Analysis plan for each aim
9. Study timeline
10. Literature references

Please email the completed proposal to:

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Chapel Hill, NC 27516
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