

**Part I. Basic Study Information**

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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:
- Address:
- Phone:
- E-mail address:

• Brief abstract describing the study (200 words maximum):

5. Proposed start dates:

6. Proposed end dates:

7. Estimated cost (please work with the Ancillary Study Coordinator to develop this):

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

9. 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 (see Section G above)?

Yes

No

## Part II. Use of Previously-Collected Biospecimens

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1. Do you propose to use archived biospecimens?

Yes

No (**skip to Section III**)

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

Type of Biospecimen	Amount Needed	Number of Respondents
Wave V Serum		
Wave V Plasma		
Wave V DNA		

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

4. What are the respondent selection criteria?

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

6. During what study years will the biospecimens be assayed by the ancillary study?

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

Yes

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

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

9. Provide a description of your plans for the final disposition of samples after analyses are completed:

## Part III. Genomic Information

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1. Do you propose to use genomic materials (any data from Add Health respondents' DNA)?

Yes

No (**skip to Section IV**)

2. What specific gene(s), genotype(s), or SNPs will be investigated and by what methods of genotyping?

3. State the genetic hypothesis of interest:

4. What is/are the primary dependent variable(s)?

5. What is/are the primary independent variable(s)?

## Part IV. Advantages for and Burden on Add Health

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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 types of assistance will the ancillary study require from the Add Health staff? This information will be used to estimate the amount of Add Health staff time to be spent on the project.

3. What burden, if any, will this study place on Add Health sample members?

## Part V. Assurances

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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 and fax numbers, 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 VI. Description of the Proposed Ancillary Study

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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. Conceptual framework and hypotheses
5. Data and/or biological materials requested or to be collected
7. Sample size and justification (i.e., formal power calculation)
8. Analysis Plan for each aim
8. Study timeline
9. Literature references

**Please email the completed proposal to:**

Add Health Studies Coordinator, Add Health  
National Longitudinal Study of Adolescent to Adult Health  
Carolina Population Center  
UNC-Chapel Hill, CB #8120  
Carolina Square, Suite 210  
123 West Franklin Street  
Chapel Hill, NC 27516  
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