***Add Health Ancillary Study Proposal Form***

# **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:
1. Collaborator(s)
* Name:
* Institution:
* Address:
* Phone:
* E-mail address:
* Brief abstract describing the study (200 words maximum):
1. Proposed start dates:
2. Proposed end dates:
3. Estimated cost (please work with the Ancillary Study Coordinator to develop this):
4. Proposed funding source and planned date of submission to external funding agency:
5. 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 Geocodes**

1. Do you propose to use previously-collected respondent geocode data?

[ ]  Yes

[ ]  No *(****skip to Section III****)*

2. What types of geocode data do you propose to use?

*Mark all that apply.*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Geocode | Wave I | Wave II | Wave III | Wave IV | Wave V |
| State |  |  |  |  |  |
| County |  |  |  |  |  |
| Census tract |  |  |  |  |  |
| Block group |  |  |  |  |  |
| Latitude and longitude |  |  |  |  |  |

# **Part III. Use of Previously-Collected Biospecimens**

1. Do you propose to use archived biospecimens?

 [ ]  Yes

[ ]  No ***(skip to Section IV)***

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)*

1. 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 IV. Genomic Information**

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

 [ ]  Yes

[ ]  No ***(skip to Section VI)***

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 V. Advantages for 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 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 VI. 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?

1. 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)?
2. Provide investigator qualifications and prior involvement in Add Health, if any:
3. 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:

# **Part VII. Description of the Proposed Ancillary Study**

Please provide a narrative description of the proposed study. Do not exceed 5 single-spaced pages in length, excluding references (please use Arial 11-pt font). Include the following:

1. Specific Aims

2. Brief background and significance

3. Conceptual framework and hypotheses

4. Data and/or biological materials requested or to be collected

5. Sample size and justification (i.e., formal power calculation)

6. Analysis Plan for each aim

8. Study timeline

9. Literature references

**Please email the completed proposal to:**

Ancillary Studies Coordinator, Add Health

National Longitudinal Study of Adolescent to Adult Health

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Chapel Hill, NC 27516

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