

**The University of North Carolina at Chapel Hill, Carolina Population Center
National Longitudinal Study of Adolescent to Adult Health
Data and Material Use Agreement**

This Data and Material Use Agreement (the “**Agreement**”) is made and entered into as of the date of the last signature hereto (the “**Effective Date**”) by and between:

The University of North Carolina at Chapel Hill, a non-profit, educational, research and healthcare institution with an administrative research office located 104 Airport Drive, Suite 2200, CB# 1350, Chapel Hill, NC 27599-1350, on behalf of its Carolina Population Center (“**UNC-Chapel Hill**”); AND

ENTITY NAME

A DESCRIPTION OF ENTITY

WITH ITS PRINCIPAL OFFICE AND PLACE OF BUSINESS LOCATED ADDRESS (the “**Ancillary Study Institution**”);

UNC-Chapel Hill and Ancillary Study Institution may be referred to herein individually as a “**Party**” or collectively as the “**Parties**”.

WHEREAS, the Parties desire to add supplemental data to Add Health Study through (i) externally funded data or specimen collection research and/or (ii) use of archived specimens from the Add Health Study (defined hereafter);

NOW, THEREFORE, in consideration of the mutual promises and undertakings set forth herein and intending to be legally bound, the Parties agree as follows:

I. Definitions

- A. “Add Health Data” means the data collected from Add Health Study participants.
- B. “Add Health Study” is the program project undertaken by UNC-Chapel Hill entitled, “The National Longitudinal Study of Adolescent to Adult Health” under Grant No. P01 HD31921 from the Eunice Kennedy Shriver National Institute of Child Health and Human Development.
- C. “Ancillary Study” is any study that derives support from independent funds outside of an Add Health Study.
- D. “Confidential Information” means information, Add Health Data, Materials, or any data related to or about a study participant of a proprietary nature that is directly related to an Add Health Study or necessary to disclose for the conduct of this Agreement.
- E. “Disclosing Party” means the Party providing Confidential Information to the other Party.
- F. “Investigator” is the person primarily responsible for supervision of the research project, security of the data, and use of Sensitive Data obtained through this Agreement.
- G. “IRB” is a group whose function is to review research to assure the protection of the rights and welfare of the human subjects.
- H. “HIPAA” means the Health Insurance Portability and Accountability Act, a 1996 Federal law that restricts access to individuals' private medical information.

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- I. "Receiving Party" means the Party receiving Confidential Information.
- J. "Representative of Institution" or "Institutional Representative" is a person authorized to enter into contractual agreements on behalf of Institution.
- K. "Research Staff" are all persons, excluding Investigator, who will have access to sensitive data and/or biospecimens obtained through this Agreement.
- L. "Restricted Use Data" is considered as Sensitive Data as shared by UNC-Chapel Hill under this Agreement.
- M. "Sensitive Data" includes any Data (defined hereafter) or Add Health Data that might compromise the anonymity or privacy of respondents to a study.

II. Statement of Work

A. Investigator. The Investigator is as follows:

Dr. Robert Hummer is UNC-Chapel Hill's Principal Investigator and Director for Add Health.

Dr. _____ Name of Collaborator's PI is Ancillary Study Institution's Investigator.

B. Compliance with Law. Each Party agrees to comply with all applicable United States federal, state and local laws and regulations, and IRB restrictions, including, but not limited to, those concerning the privacy and confidentiality of individually identifiable information and export control laws.

C. Requirements of Investigators. Each Party shall ensure that its Investigator meet the following criteria:

- a. Has a PhD or other terminal degree; and
- b. Has a faculty appointment or research position at Ancillary Study Institution or UNC-Chapel Hill, as applicable.

D. Requirements of the Ancillary Study Institution. The institution at which the ancillary study investigator will conduct the research must meet all the following criteria:

- a. Be an institution of higher education, a research organization, or a government agency; and
- b. Have an institutional review board IRB that complies with applicable United States Federal regulations governing research involving human subjects; and

Prior to receiving any Sensitive Data. or Materials if applicable, complete and provide proof of

- a. HIPAA training by Research Staff
- b. research ethics training by Research Staff; and
- c. give a copy of IRB approval of Ancillary Study to UNC-Chapel Hill
- d. Have a demonstrated record of using sensitive data according to commonly accepted standards of research ethics.

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III. Term

The term of this Agreement shall begin on the Effective Date and, subject to Section 7 below, shall expire on the third anniversary of the Effective Date (the "Term"). Any extension to the Term must be in writing upon terms mutually agreeable to the Parties hereto.

IV. Cost and Expenses

Ancillary Study Institution shall cover all costs and expenses incurred in connection with the activities contemplated by this Agreement.

V. Services and Payment

UNC-Chapel Hill may perform services, including, but not limited to, selecting special samples; collecting, processing, or shipping biospecimens; preparing and documenting analysis files; performing statistical analysis; integrating ancillary data into the Add Health Study; and archiving excess biospecimens.

Yes, UNC-Chapel Hill will perform services as described in Exhibit A ("Services").

In consideration of UNC-Chapel Hill's performance of the Services hereunder, Ancillary Study Institution will compensate UNC-Chapel Hill in accordance with Exhibit B attached hereto. Payments shall be made by Ancillary Study Institution within thirty (30) days of receipt of UNC-Chapel Hill's invoice.

No, UNC-Chapel Hill will not perform any services under this Agreement.

VI. Confidential Information

- A. Confidential Information shall be disclosed in writing and identified as such, or if disclosed orally, shall be identified as confidential at the time of the disclosure, and reduced to writing within thirty (30) days thereafter. Confidential Information does not include information which at the time of receipt:
1. is generally available in the public domain or thereafter becomes available to the public through no act of the receiving party; or
 2. was independently known prior to receipt thereof or was discovered independently by an employee of the receiving party who had no access to the information supplied by the disclosing party under this Agreement; or
 3. was made available to the receiving party as a matter of lawful right by a third party; or
 4. is legally required to be disclosed as per a court order.
- B. The Receiving Party's obligation of non-disclosure/non-use of the other Party's Confidential Information shall survive the expiration or earlier termination of this Agreement and shall continue for a period of five (5) years from when the Confidential Information is received hereunder.

VII. Data and Add Health Data

A. Data Provided by UNC-Chapel Hill.

1. **Definition of Data.** The data subject to this Agreement consists of {description of data} (the "Data").

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2. **License to Use Data.** UNC-Chapel Hill grants Ancillary Study Institution the right to use the Data for the purpose of analyzing the Data to add such supplemental Data to the Add Health Study (the "Purpose"). Nothing herein shall be deemed a grant of a license to any intellectual property rights of the Data except as set forth in the Purpose. It is expressly agreed that no Party shall transfer by operation of this Agreement to the other Parties hereto any patent right, copyright, or other proprietary right that any Party owns as of the commencement of this Agreement, except as specifically set forth herein.

3. Restriction on Ancillary Study Institution's Use of Data.

- a. Ancillary Study Institution acknowledges that the Data may consist of Sensitive Data that UNC-Chapel Hill is required to protect and agrees to use appropriate safeguards to protect the Data from misuse and unauthorized access or disclosure, including, without limitation, (i) maintaining adequate physical controls and password protections for any server, system, or device on which the Data may reside, and (ii) taking any other measures reasonably necessary to prevent any use or disclosure of the Data other than as provided in this Agreement.
- b. Ancillary Study Institution will report to UNC-Chapel Hill any use or disclosure of the Data not provided for by this Agreement of which Ancillary Study Institution becomes aware. Such report shall be made to the contact noted in this Agreement as soon as reasonably possible, but, in any event, no later than five (5) business days from the date on which Ancillary Study Institution becomes aware that the Data have been used or disclosed in a manner not provided for by this Agreement.
- c. Ancillary Study Institution will not attempt to identify the individuals whose information is contained in any Data transferred pursuant to this Agreement or attempt to contact those individuals.
- d. Ancillary Study Institution will hold any agent of the Ancillary Study Institution, including any permitted subcontractor, to the standards, restrictions, and conditions stated in this Agreement with respect to the Data.

B. Add Health Data.

To receive Add Health Data, Ancillary Study Institution shall execute the Agreement for the Use of Restricted-Use Data which is attached hereto in Exhibit C.

VIII. Use of New or Archived Biospecimens

The Ancillary Study Institution may request the use of either newly acquired Materials or Materials previously archived by the Add Health Study. If Ancillary Study Institution uses of any type of Materials, it shall comply with the terms and conditions in Exhibit E of this Agreement. UNC-Chapel Hill may provide Material to Ancillary Study Institution under this Agreement.

- Yes, the Ancillary Study Institution will be using either newly acquired or archived material as described in Exhibit E ("Material"). In consideration of UNC-Chapel Hill's provision of Material, Ancillary Study Institution will abide by the terms and conditions of Exhibit E attached hereto and incorporated herein.
- No, the Ancillary Study Institution will not be using any biospecimens for the Ancillary Study. UNC-Chapel Hill will not provide Material under this Agreement.

IX. Reports and Publication

A. **Reports.** Ancillary Study Institution shall submit annual progress reports on the status of the Ancillary Study by July 1st each year until UNC-Chapel Hill has released final ancillary data. Failure to comply with the obligations of this Section may result in termination of this Agreement and denial of renewal of this Agreement.

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The progress reports must include:

1. Data, Add Health Data and/or Specimens collected to date; and
2. Assays and analyses in progress or completed; and
3. Information on Specimen use and storage, as applicable; and
4. Details of polymorphisms genotype and methods proposed to be used.

B. Publication. Ancillary Study Institution shall include appropriate attribution to UNC-Chapel Hill and the Add Health Study in any publication or presentation herein.

1. Publication of Results from Data and/or Add Health Data

Ancillary Study Institution shall not publish, submit to publish, or present the results until (a) Data or Add Health Data (as applicable) is linked to the existing Add Health Study data and (b) released by UNC to the scientific community. When (a) and (b) occur, Ancillary Study Institution may then publish in accordance with this Section. For the sake of clarity, publication of Data and Add Health Data under Section 9B (1) is non-biological data.

2. Publication of Results from Collection and Use of Biospecimens

UNC-Chapel Hill must delay releasing Data resulting from the collection or use of Biospecimens for one (1) year period beginning upon the release of the final, clean data file to Ancillary Study Institution. During this one (1) year period, Ancillary Study Institution's Investigator may create and draft manuscripts, abstracts, or presentations to journals. Ancillary Study Institution and its Investigator shall not submit any manuscripts for publication before the release date of the final file.

For the sake of clarity, UNC-Chapel Hill's Investigator has the sole discretion to decide the final release date of final, clean datasets.

X. Liability

- A. To the extent permitted by law, including but not limited to the North Carolina Tort Claims Act, each Party agrees to assume all liability with respect to any expense, claim, loss, damage, or costs arising out of its own use of the Data, Add Health Data, or results from the Agreement except when such expense, claim, loss, damage, or costs are caused by the gross negligence or willful misconduct of the other Party.
- B. For the sake of clarity, the aforementioned is not intended to waive any state-mandated immunities applicable to the Parties.

XI. Disclaimer of Warranty

UNC-CHAPEL HILL, IN NO WAY, GUARANTEES THE SERVICES PERFORMED AND MAKES NO WARRANTIES, EXPRESS OR IMPLIED, REGARDING THE QUALITY OF THE RESULTS OR ADD HEALTH DATA ALTHOUGH ALL REASONABLE EFFORTS CONSISTENT WITH LABORATORY RESEARCH SERVICES WILL BE MADE. UNC-CHAPEL HILL MAKES NO REPRESENTATION OR WARRANTY REGARDING ACTUAL OR POTENTIAL INFRINGEMENT OF ANY THIRD-PARTY'S INTELLECTUAL PROPERTY. UNC-CHAPEL HILL SHALL NOT BE LIABLE TO COMPANY FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, PUNITIVE, OR EXEMPLARY DAMAGES OF ANY KIND, INCLUDING LOST PROFITS, LOSS OF BUSINESS, OR OTHER ECONOMIC DAMAGES AS A RESULT OF BREACH OF ANY TERM OF THIS AGREEMENT.

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XII. Termination

- A. Either Party may terminate this Agreement prior to the expiration of the Term by giving thirty (30) days written notice to the other Party.
- B. Upon early termination of this Agreement, the Ancillary Study Institution shall return all Confidential Information (as defined in Section 12), Materials, and any Add Health Data in its possession at the time of termination to UNC-Chapel Hill. Each Party may retain in its respective confidential files one copy of written Confidential Information of the other Party's for record purposes only.
- C. In the event of the termination, Ancillary Study Institution shall make all payments to UNC-Chapel Hill for all Services rendered in accordance with Budget, and all reasonable, non-cancellable commitments made by the UNC-Chapel Hill prior to the effective date of the termination.
- D. The following shall survive termination of this Agreement: Articles 1 - 17.

XIII. Use of Names

Neither Party shall use the name of the other Party, or the name of any of its employees, in any publicity, advertising, or news release without the prior written approval of the other Party. Notwithstanding the foregoing, UNC-Chapel Hill may, without prior consent, disclose Ancillary Study Institution's participation in the Study, including but not limited to, on UNC-Chapel Hill's website or brochures and marketing materials.

XIV. Governing Law

The Parties agree to remain silent as to governing law.

XV. Independent Contractors

It is agreed by the Parties that each Party is acting in the capacity of independent contractors hereunder. No Party shall have any authority to represent, bind or act on behalf of the other Party.

XVI. Notice.

Any notice required or permitted hereunder shall be in writing and addressed to the Party to receive such notice at the address set forth below, or such other address as is subsequently specified in writing, and shall be deemed given as of the date it is (A) delivered by hand, (B) received by Registered or Certified Mail, postage prepaid, return receipt requested, (C) delivered by electronic mail to the electronic mail address listed below, and the recipient has replied to the sender by electronic mail or other method in accordance with this Section, to acknowledge receipt of that electronic mail, or (D) received by facsimile.

To UNC-Chapel Hill:

University of North Carolina at Chapel Hill
Director, Office of Industry Contracting
104 Airport Drive, Suite 2200, CB #1350
Chapel Hill, North Carolina 27599-1350
Email: oic@unc.edu

With a required copy to UNC-Chapel Hill's Investigator:

Dr. Robert A. Hummer
Add Health Ancillary Studies
Carolina Population Center
UNC-Chapel Hill, CB #8120
Carolina Square, Suite 210
123 West Franklin Street
Chapel Hill, NC 27516

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To Ancillary Study Institution:

XVII. Miscellaneous.

- A. This Agreement constitutes the entire agreement between the Parties with respect to its subject matter and supersedes and terminates all prior agreements covenants, promises, agreements, warranties, representations, conditions, and understanding between the parties with respect to such subject matter. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the parties other than as set forth herein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by the respective authorized officers of the Parties.
- B. This Agreement is not assignable, and any attempt to do so shall be null and void.
- C. This Agreement may be executed in counterparts, and by either Party on separate counterpart, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.
- D. No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition, or of any other term, provision or condition of this Agreement.

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Investigator and Institutional Signatures

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their respective duly authorized representatives.

INSERT ANCILLARY STUDY INSTITUTION NAME

THE UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL

SIGNATURE

SIGNATURE

NAME

NAME

TITLE

TITLE

DATE

DATE

READ AND UNDERSTOOD BY INVESTIGATORS:

ROBERT A. HUMMER

ADD HEALTH PRINCIPAL INVESTIGATOR'S NAME

ANCILLARY STUDY INSTITUTION'S INVESTIGATOR NAME

SIGNATURE

SIGNATURE

DATE

DATE

Carolina Population Center
UNC-Chapel Hill Carolina Square, Suite 210
123 West Franklin Street

STREET ADDRESS

STREET ADDRESS

Chapel Hill, NC 27516

CITY, STATE, ZIP

CITY, STATE, ZIP

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Exhibit A – Services

An Ancillary Study is any study that derives support from independent funds outside the Add Health Study, the investigator proposing to conduct an Ancillary Study must cover all costs incurred by the study, such as:

- preparing and documenting analysis files;
- performing statistical analysis;
- integrating ancillary data into the Add Health study;
- selecting special samples;
- collecting, processing, or shipping biospecimens;
- and archiving excess biospecimens.

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. Some of these activities can only be performed by the Add Health staff. In most cases, the investigator will need to budget and establish a subcontract with the Add Health project to cover such costs. All 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 Exhibit D.

The 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 Exhibit C. For detailed policies on data cleaning, variable construction, and data release, see Exhibit D - Add Health Policies on the Cleaning and Release of Ancillary Study Data.

Studies Involving New or Archived Biospecimens

1. Requests to collect new biospecimens or 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.
2. 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.
3. 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 Add Health Data and Material Use Agreement.
4. Proposals to collect new or 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.
5. After assays are complete, any unused biospecimen must be either returned or destroyed based on prior agreement with Add Health.

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Exhibit B - Payment Schedule

There are two options for linking new variables to Add Health and costs vary by linkage method.

I. Linkage Options for Contextual Data

- Option I: Add Health staff links variables

If Add Health links the variables, there is a minimum charge of \$8,000 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
\$10,592-\$19,000	\$19,500-\$31,000	\$32,000-\$43,000	\$44,000-\$92,000

- Option II: Ancillary PI links variables

If the Ancillary Study PI links the variables, there is a charge for the use of the Carolina Population Center Virtual Data Enclave (CPC VDE) to do the work. The cost estimate ranges are as follows:

1-10 variables	11-20 variables	21-30 variables	>30 variables
\$6,000-\$12,050	\$12,000-\$18,800	\$19,500-\$25,500	\$26,000-\$48,000

Note that the above are current estimated costs and are subject to change. Actual costs will be determined after receipt and review of Ancillary Study proposal.

II. Linkage Options for Studies Involving New or Archived Biospecimens

- Add Health Coordinator should be contacted prior to submission of any proposal seeking these funds to provide cost estimates for budgeting these costs. Please contact the ancillary coordinator for more information at addhealth_ancillary@unc.edu

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Exhibit C - Agreement for the Use of Restricted-Use Data

This Agreement for the Use of Restricted-Use Data (hereinafter referred to as “Agreement”), is entered into by and between Institution and UNC-Chapel Hill on behalf of Add Health. Each Institution and UNC-Chapel Hill shall be considered a party to this Agreement (“Party”) and collectively the “Parties.”

I. Definitions

- A. “The National Longitudinal Study of Adolescent to Adult Health” (hereinafter referred to as “Add Health”) is the program project undertaken by the Carolina Population Center of The University of North Carolina at Chapel Hill (hereafter referred to as “UNC-Chapel Hill”) under Grant No. P01-HD31921 from the Eunice Kennedy Shriver National Institute of Child Health and Human Development.
- B. “Investigator” is the person primarily responsible for supervision of the research project, security of the data, and use of Sensitive Data obtained through this Agreement.
- C. “Research Staff” are all persons, excluding Investigator, who will have access to sensitive data obtained through this Agreement.
- D. “Institution” is the university or research institution that employs Investigator and that is the signatory to this Agreement on behalf of Investigator.
- E. “Representative of Institution” or “Institutional Representative” is a person authorized to enter into contractual agreements on behalf of Institution.
- F. “Sensitive Data” includes any data from Add Health that might compromise the anonymity or privacy of respondents to that study. Because of the school-based study design, Add Health respondents (adolescents, parents, and schools) are at higher risk of deductive disclosure than randomly sampled individuals. Therefore, all data collected from Add Health are considered to be sensitive.
- G. “Restricted-Use Data” is considered as Sensitive Data as shared under this Agreement.
- H. “Data File(s)” includes any form of data, including Sensitive Data, whether on paper or electronic media, shared under this Agreement.
- I. “Funding Agency” is a federal office or institute that provided funding for Add Health. Funding agencies are only the offices or institutes providing the funding; other divisions or institutes within the larger organization are not considered funding agencies.
- J. “Contract Period” is the three (3) year period that begins and ends on the dates specified on the Investigator and Institutional Signatures page unless this Agreement includes Romantic Pairs data, in which case the “Contract Period” is the two (2) year period that begins and ends on the dates specified on the Investigator and Institutional Signatures page.
- K. “Processing Fee” is a nonrefundable payment that covers the expenses of producing and shipping Data Files, of providing codebooks, of consulting, and of administering this Agreement.
See Attachment G: Contract Processing Fees. Note: There is no processing fee for renewals.

II. Requirements of Investigators

Investigators must meet the following criteria:

- A. Have a PhD or other terminal degree; and
- B. Hold a faculty appointment or research position at Institution

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III. Requirements of Institution

Institution must meet the following criteria:

- A. Be an institution of higher education, a research organization, or a government agency
- B. Have a demonstrated record of using sensitive data according to commonly accepted standards of research ethics

IV. Obligations of Add Health

In consideration of the promises made in Section V of this Agreement and of receipt of the monies noted in Section V. I., Add Health agrees to the following, once a copy of the completed Agreement has been received and Attachment A has been approved:

- A. To submit for review by the appropriate officials of UNC-Chapel Hill this Agreement.
- B. To provide the fully executed Agreement to the Investigator and, if requested, to the Institutional Representative.
- C. To assign the effective dates of the Contract Period on the Investigator and Institutional Signatures page. The initiation date will be within fifteen (15) working days of receipt of the executed Agreement from the Representative of UNC-Chapel Hill.
- D. To provide the Data Files requested by Investigator within a reasonable time frame following execution of this Agreement by the Representatives of the Institution and UNC-Chapel Hill. All Data Files will be compressed and encrypted.
- E. To provide codebooks which contain the origins, form, and general content of the Data Files sent to Investigator; these are available on the Add Health website.

V. Obligations of the Investigator, Research Staff, and Institution

Data Files provided under this Agreement shall be held by the Investigator, Research Staff, and Institution in confidence and can be disclosed only in compliance with the terms of this Agreement.

In consideration of the promises contained in Section IV of this agreement, and for use of Data Files from Add Health, the Investigator and Research Staff, as employees or agents of the Institution, shall abide by the terms of this Agreement, and the Institution agrees:

- A. That the Data Files will be used solely for statistical analyses: that no attempt will be made to identify specific individuals, families, households, schools, institutions, or geographic locations not provided by Add Health; and that no list of Sensitive Data at the individual or family level will be published or otherwise distributed.
- B. That if the identity of any person, family, household, school, institution or geographic location should be discovered inadvertently, then:
 - 1. No use will be made of this knowledge;
 - 2. Add Health will be advised of the incident within ten (10) business days of Investigator's, Research Staff's, or Institution's discovery of the incident;

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3. The information that would identify the person, family, household, school, or institution will be safeguarded or destroyed as requested by Add Health and a written certification of destruction provided to Add Health; and
 4. No one else will be informed of the discovered identity.
- C. To avoid inadvertent disclosure of persons, families, or households by using the following guidelines in the release of statistics derived from the Data Files.
1. In no table should all cases in any row or column be found in a single cell.
 2. In no case should the total for a row or column of a cross-tabulation be fewer than ten (10).
 3. In no case should a cell frequency of a cross-tabulation be fewer than ten (10) cases.
 4. In no case should a quantity figure be based on fewer than ten (10) cases.
 5. Data Files released should never permit disclosure when used in combination with other known data.
- D. That no persons other than those identified in this Agreement, or in amendments subsequent to this Agreement, as Investigator or Research Staff, be permitted access to the contents of Data Files or any files derived from Sensitive Data or Data Files.
1. That within ten (10) business days of becoming aware of any unauthorized access, use, or disclosure of Sensitive Data, the unauthorized access, use, or disclosure of Sensitive Data will be reported in writing to Add Health.
- E. To comply fully with the Sensitive Data Security Plan, which is included as Attachment A to this Agreement. Approval of the Sensitive Data Security Plan expires at the end of the Contract Period.
- F. To respond fully and in writing within ten (10) working days after receipt of any inquiry from Add Health regarding compliance with this Agreement or the expected date of completion of work with the Sensitive Data and any data derived therefrom.
- G. To make available for inspection by Add Health, at a mutually agreeable time during business hours, the physical housing and handling of all Data Files and any other information, written or electronic, solely relating to this Agreement and which does not constitute the confidential information of a third party.
- H. To supply Add Health with a copy of each of the following:
1. Investigator Information form
 2. Agreement for the Use of Restricted-Use Data, each with Investigator and Institutional Signatures page
 3. Sensitive Data Security Plan (Attachment A)
 4. Data Files form (Attachment B) confirming data order, and including explanatory statements for constructed datasets (if requested)
 5. Supplemental Agreement with Research Staff (Attachment C) signed by each Research Staff person and the Investigator
 6. Security Pledges (Attachment D) for the Investigator and each Research Staff person

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7. A copy of the document, originated by the Investigator and signed by Institution's Institutional Review Board (IRB), approving the research project AND the secure use, storage, and handling of the Add Health Data Files outlined in the Sensitive Data Security Plan.

- I. To provide to UNC-Chapel Hill the Processing Fee. Payment may be made by credit card or check payable to "The University of North Carolina at Chapel Hill."

An exemption to the Processing Fee may be made if the request for Data Files is from an Investigator at one of the Add Health funding agencies or institutes. To request a waiver of the Processing Fee, please include a letter from the head of the funding agency requesting that the fee be waived.

- J. To include in each written report or other publication based on analysis of Sensitive Data from Add Health, the following statement:

This research uses data from Add Health, a program project designed by J. Richard Udry, Peter S. Bearman, and Kathleen Mullan Harris, and funded by a grant P01-HD31921 from the Eunice Kennedy Shriver National Institute of Child Health and Human Development, with cooperative funding from 17 other agencies. Special acknowledgment is due Ronald R. Rindfuss and Barbara Entwisle for assistance in the original design. Persons interested in obtaining Data Files from Add Health should contact Add Health, The University of North Carolina at Chapel Hill, Carolina Population Center, Carolina Square, Suite 210, 123 W. Franklin Street, Chapel Hill, NC 27516 (addhealth_contracts@unc.edu). No direct support was received from grant P01-HD31921 for this analysis.

- K. That all journal articles based on analysis of confidential Sensitive Data from Add Health receive a PubMed Central reference number (PMCID). Journal articles must be submitted to PubMed Central to receive a PMCID. The method of PubMed Central submission and Investigator responsibility for submission depend on the journal and journal publisher.

1. Some journals automatically submit published articles to PubMed Central. For a list of journals that submit articles to PubMed Central please visit the NIH website: http://publicaccess.nih.gov/submit_process_journals.htm
2. Some journal publishers may submit the articles to PubMed Central automatically or upon request by the author. For a list of journal publishers that submit articles to PubMed Central please visit the NIH website: http://publicaccess.nih.gov/select_deposit_publishers.htm#b
3. If neither the journal nor the journal publisher will submit the article to PubMed Central, the Investigator will be responsible to submit the final peer-reviewed manuscript to PubMed Central via the NIH Manuscript Submission System (NIHMS). For detailed instructions on the process of submitting a journal article to PubMed Central, please see the NIH website: http://publicaccess.nih.gov/submit_process.htm

(If you have any problems with this process, please contact the NIHMS or PubMed help desk.)

- L. To complete the following protocol upon separation from Institution or the expiration of Investigator's contract:

1. Destroy all Data Files at the originally approved site.
2. Submit a letter stating that all Add Health Data Files have been securely erased with the secure erasure program listed in the security plan for the originally approved site.
3. Return all CDs containing Data Files, within thirty (30) days of the expiration of the Contract Period as specified on the Institutional Signatures page, or submit a renewal application.

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Add Health shall be able to visit within a year of contract termination, at a mutually-agreeable time during regular business hours, to confirm the data have been destroyed. This obligation of destruction shall not apply to Investigator's scholarly work produced during the Contract Period that is based upon or that incorporates the Restricted-Use Data.

- M. To notify Add Health in the event Investigator plans to separate from Institution during the Contract Period. Such notification must be in writing and must be received by Add Health at least six (6) weeks prior to Investigator's last day of employment with Institution. Investigator's separation from Institution will terminate this Agreement. Investigator may, however, reapply to receive Data Files from Add Health in Investigator's capacity as an employee of his or her new institution. A fee will be charged to the investigator for the administration of this process (see Attachment G: Contract Processing Fees at the end of the contract).

Concurrent with Investigator's notice to Add Health regarding a pending separation from Institution, Investigator must:

1. Return the Data File CDs to Add Health at the following address:

Add Health Contracts
Carolina Population Center
UNC-Chapel Hill
Carolina Square, Suite 210
123 West Franklin Street
Chapel Hill, NC 27516

2. Destroy all electronic and paper files at the originally approved site prior to the date of relocation and submit a letter stating that all Add Health files including Data Files have been securely erased with the secure erasure program listed in the Sensitive Data Security Plan for the originally approved site. This obligation of destruction shall not apply to Investigator's scholarly work produced during the Contract Period that is based upon or that incorporates the Sensitive Data.

- N. To obtain approval from Add Health prior to transferring this Agreement to another Investigator at the same Institution. A fee will be charged for the administration of this process (see Attachment G: Contract Processing Fees table at the end of the contract). In order to obtain such approval, Investigator must:

1. Inform Add Health in writing six (6) weeks prior to the proposed date of transfer.
2. Submit a complete copy of this Agreement in the name of the new Investigator signed by an official representative of Investigator's new institution.
3. Maintain responsibility for the security of all Data File CDs until the transfer contract has been approved.

- O. To submit annual reports to Add Health on or before each anniversary of the initial date of the Contract Period. Such reports must include:

1. A copy of the annual IRB approval for the research project
2. A list of public presentations at professional meetings using results based on the Data Files
3. A list of papers accepted for publication using these Data Files, with complete citations
4. A list of grants that have been awarded for use of the Add Health Data Files

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5. A list of graduate students using the Add Health Data Files for dissertations or theses, the titles of these papers, and the dates of completion
6. A current data user roster including the names of all Research Staff member(s) who have access to Data Files and their relationship(s) to the project
7. A list of users no longer associated with your contract since your last annual report

Such reports shall be signed by Investigator. Add Health reserves the right to terminate this Agreement in the event that the reports are not timely submitted.

- P. That Institution hereby acknowledges that any breach of the confidentiality provisions herein may result in irreparable harm to UNC-Chapel Hill that may not be adequately compensable by money damages. Institution hereby agrees that UNC-Chapel Hill may seek the imposition of injunctive relief in the event of breach, in addition to money damages to the extent allowable by applicable law. Should Investigator, Research Staff, or Institution commit a material breach of this agreement that is not cured within thirty (30) days after Investigator or Institution receives notice of such breach from Add Health, Add Health and UNC-Chapel Hill reserve the right to terminate the Agreement, in which case all electronic and paper files will be securely erased; a letter will be submitted by the Investigator, stating that all Add Health files and Data Files have been securely erased with the secure erasure program listed in the security plan; and CDs containing Data Files are to be returned. Investigator and Research Staff understands, and Institution agrees, that a violation of any of the terms and conditions of this Agreement may constitute a violation of state and federal statutes and may subject Investigator, Research Staff, and/or Institution to the criminal, civil, and administrative penalties associated with violations of those statutes, in addition to constituting a material breach of this Agreement with attendant legal liabilities.
- Q. That to the extent permitted under applicable law, both Parties agree to be responsible for the negligent acts or omissions of its employees and agents with respect to this Agreement, and nothing herein shall be considered a waiver of sovereign immunity. Sections V.P and V.Q shall survive the termination of the Agreement.
- R. Institution shall ensure that Investigator and Research Staff comply with the provisions of this Agreement. Institution shall be solely responsible for the compliance of Investigator, Research Staff and/or Institution and no legal action will be taken by Add Health against individual members of Institution staff, except in the case of willful misconduct or injunctive relief.

VI. Certificate of Confidentiality

Research subjects who participated in Add Health are protected by a certificate of confidentiality issued by the Department of Health and Human Services in accordance with the provisions of section 301(d) of the Public Health Service Act (42 U.S.C. § 241(d)) (a "Confidentiality Certificate"). Institution is considered to be a contractor or cooperating agency of UNC-Chapel Hill under the terms of the Confidentiality Certificate; as such, Institution, Investigator, and Research Staff are authorized to protect the privacy of the individuals who are the subjects of Add Health by withholding their identifying characteristics from all persons not connected with the conduct of the study. Identifying characteristics are all Add Health Data Files which are defined as sensitive under the terms of this contract.

VII. Incorporation by Reference

The Parties agree that the following documents are incorporated into this Agreement by reference:

- A. A copy of the IRB approval of the research project, taking into special consideration deductive disclosure risks.

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- B. The Sensitive Data Security Plan proposed by Investigator and approved by Add Health.
- C. The Department of Health and Human Services Confidentiality Certificate, a copy of which will be sent with the signed contract.

VIII. Attachments

- A. Security Plan for the Use of Restricted-Use Data from the National Longitudinal Study of Adolescent to Adult Health
- B. Data File Order for the Use of Restricted-Use Data from the National Longitudinal Study of Adolescent to Adult Health
- C. Supplemental Agreement with Research Staff for the Use of Restricted-Use Data from the National Longitudinal Study of Adolescent to Adult Health
- D. Security Pledge for the Use of Restricted-Use Data from the National Longitudinal Study of Adolescent to Adult Health
- E. List of Funding Agencies for the National Longitudinal Study of Adolescent to Adult Health
- F. Description of Deductive Disclosure Risk from the National Longitudinal Study of Adolescent to Adult Health
- G. Contract Processing Fees

IX. Miscellaneous

- A. The Parties agree to abide by all applicable laws and agree to remain silent on governing law and venue.
- B. All notices, contractual correspondence, and return of data under this Agreement on behalf of the Investigator shall be made in writing and delivered to the address below:

Add Health Contracts
Carolina Population Center
UNC-Chapel Hill
Carolina Square, Suite 210
123 West Franklin Street
Chapel Hill, NC 27516

- C. Provisions of Data Files, all notices, and contractual correspondence under this Agreement on behalf of Add Health shall be made in writing and delivered to Investigator at the address listed on the Institutional Signatures page. Any contractual correspondence shall be made with the Institutional Representative as listed on the Institutional Signatures page.
- D. This Agreement shall be effective for the dates indicated on the Institutional Signatures page.
- E. The respective rights and obligations of Add Health and Investigator, Research Staff, and Institution pursuant to this Agreement shall survive termination of this agreement.
- F. In the event of a material breach of this Agreement by the Investigator, Research Staff, or Institution, Add Health may terminate this Agreement by providing written notice to Investigator and Institution. In this event, Add Health will not be required to refund of any portion of the Processing Fee.

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- G. This Agreement may be amended or modified only by the mutual written consent of the authorized representatives of Add Health and Investigator and Institution. Both Parties agree to amend this Agreement to the extent amendment is necessary to comply with the requirements of any applicable regulatory authority.
- H. This Agreement contains all of the terms and conditions agreed upon by the Parties regarding the subject matter of this Agreement and supersedes any prior agreements, oral or written, and all other communications between the Parties relating to such subject matters.
- I. The Representatives of the Institution and UNC-Chapel Hill signing this Agreement have the right and authority to execute this Agreement, and no further approvals are necessary to create a binding agreement.
- J. The obligations of Investigator, Research Staff, and Institution set forth within this Agreement may not be assigned or otherwise transferred without the express written consent of Add Health.
- K. Add Health's existing ownership rights in its intellectual property, including its Sensitive Data and the Data Files, are not affected by this Agreement. Except as expressly set forth herein, no right, license, title, or interest in any of Add Health's intellectual property or in any invention, process, or product arising out of its intellectual property is granted or implied, whether or not patented or patentable.
- L. This Agreement may be executed in one or more counterparts each of which counterpart shall be deemed an original Agreement and all of which shall constitute but one Agreement.
- M. The Parties' electronic signatures shall be the legally binding equivalent of a handwritten signature.
- N. Institution agrees that Investigator can execute Attachments A, B, C, and D independent of an Institutional Representative.

X. Apply for Restricted-Use Data Contract

To find the full agreement and apply for a Restricted-use data, go to CPC Data Portal at <https://data.cpc.unc.edu/>

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Exhibit D - Add Health Policies on the Cleaning and Release of Ancillary Study Data

The conditions spell out the collaborative process and timing of data cleaning, variable construction, and release of new data. Two overarching requirements for ancillary study activities are:

- The protection of the identity of the study participants
- The provision of the data to the entire research community

Since its inception, the Add Health project has been based on creating a data resource that is widely available to the research community while protecting the privacy of the study participants. Ancillary Study Investigators get special access to any data they provide that enhances the study for a limited time while data cleaning is conducted by the Add Health staff.

The process is described below, and the Ancillary Study Investigator must agree to the following prior to approval of an Ancillary Study by the Add Health Study:

- A. The Ancillary Study Investigator will work with the Add Health 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 Health 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 SMT.
- B. 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.
- C. Linking of the data or associated assays along with initial data cleaning (such as range checking, consistency recoding 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.
- D. 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.
- E. When the Ancillary Study data are shared to 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., if a standardized scale was used, the reference for that scale)
 - for laboratory assays, the name of the assay (e.g., if a commercial kit was used) or the protocol used for the assay, the units of the results, and quality control information
 - documentation on the cleaning process to date.
 - Add Health will provide the Ancillary Study Investigator with a suggested template for providing this information.
- F. Once the Add Health staff have received the dataset from the security management team and the documentation from the Ancillary Study staff, the dataset is provided to the Ancillary Study Investigator and two things begin:
 - 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:
 - a. Ancillary data will be merged with existing Add Health data.

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- b. Variable construction of the added data will be tested, researched, and reviewed. Consultants may be contacted, as necessary.
 - c. Frequency distributions of the added variables will be evaluated for deductive disclosure.
 - d. Cross tabulations of the new data with existing Add Health data will be run and reviewed.
 - e. Logical associations among the new and existing data will be mapped out and evaluated.
 - f. Documentation will be examined and edited.
 - g. 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.
 - h. A preliminary SAS export file will be created.
 - i. Code books 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:
- a. All ancillary data and constructed variables will be reviewed for errors.
 - b. Ancillary data will be evaluated for performance and usability.
 - c. Any additional information requested by Add Health will be provided.
 - d. Final documentation describing the generation of the variables will be created and submitted to Add Health. This file will become part of the codebook created by Add Health.
 - e. 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 until all the following steps occur. Because the final dataset is likely to be different from this preliminary dataset, the investigator is encouraged to develop and document analysis programs so that they may be re-run against the final dataset that is released to the public.
- G. Add Health will set a release date for the new data in consultation with the Investigator. The period for which this cleaning will occur will be determined by how many variables are included in the Ancillary Study and Add Health staff available to work on the data cleaning and deductive disclosure risk. 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.
- H. Add Health will target a release date of six to twelve months from the receipt of the initial linked file from the security management team for datasets containing fewer than 50 variables. The release schedule and process for larger files will be negotiated with the Investigator.
- I. Once the data are completely documented and the final file is created, the data are ready to be released to all Add Health users. The determination of what is included in the released file is made by Add Health and the Investigator with the Add Health PI having the final say. At this point, the Investigator returns the working file and destroys all electronic copies.
- J. Add Health notifies the Ancillary Study Investigator of the final release date one week before the announcement is made on the Add Health list server to the users. 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.
- K. All presentations and submitted manuscripts must be based on the final released file. Manuscripts cannot be submitted for publication before the release date of the final file. The Add Health Principal Investigator makes the concluding decision about the final release date of the Ancillary Study datasets.

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Exhibit E - Material

1. Definitions.

“**Add Health Data**” includes any information and data related to Material provided by UNC-Chapel Hill to Ancillary Study Institution.

“**Material**” means the following de-identified biospecimens: saliva, urine, blood and any other biological specimen obtained from Add Health respondents that is archived in Add Health study repositories or under current Add Health-related field collection collected under Add Health Wave V UNC IRB 13-1946, the UNC IRB for a later wave of Add Health data collection (Wave VI or later) or sub-studies linked to these waves of data collection or any progeny, unmodified derivatives, or Material incorporated in substances and/or modifications created by Ancillary Study Institution.

- 2. Ownership of Biospecimens and Results.** UNC-Chapel Hill retains ownership of all Material. All biospecimens and data resulting from analysis of Material shall be the property of UNC-Chapel Hill. Ancillary Study Institution will inform UNC-Chapel Hill of research results related to Material. UNC-Chapel Hill will make such results available to the research community in accordance with the Agreement.
- 3. Cost.** The Material is provided at no cost, or with an optional transmittal fee solely to reimburse the Provider for its preparation and distribution costs. If a fee is requested, the amount will be indicated above
- 4. IRB Approval.** UNC-Chapel Hill certifies that Material was collected under appropriate Institutional Review Board approval (if required) and that the uses contemplated herein are consistent with the informed consent or other authorization (if required) signed by the individuals from whom the samples were obtained. UNC-Chapel Hill shall not supply any information that would allow determination of the identities of those individuals and Ancillary Study Institution shall not make any attempt to identify the individuals or to make any contact with them.
- 5. Use of Material.** This Material is made available for investigational use only. Ancillary Study Institution shall use Material solely for the Ancillary Study as described in Exhibit D of the Agreement. UNC-Chapel Hill shall be free, in its sole discretion, to distribute Material to others and to use it for its own purposes. Ancillary Study Institution shall not distribute or release Material to any person other than Ancillary Study Institution Investigator and laboratory personnel under Ancillary Study Institution Investigator’s direct supervision. Neither Material nor any biological materials treated therewith will be used in human beings. Ancillary Study Institution and its Investigator shall make reasonable efforts to avoid contamination or waste of Materials.
- 6. License.** This Agreement and the resulting transfer of Material constitute a license to use Material solely for not-for-profit or commercial evaluation purposes. Ancillary Study Institution agrees that nothing herein shall be deemed a grant under any UNC-Chapel Hill patents (either existing or future) or any rights to use Material for any products or processes for profit-making or commercial purposes. Material will not be used in research that is subject to consulting or licensing obligations to another party, corporation or business entity unless written permission is obtained from UNC-Chapel Hill. Ancillary Study Institution shall have no rights in Material other than as provided in this Agreement.
- 7. Publication.** Ancillary Study Institution agrees to acknowledge the source of the Material and the role of the UNC-Chapel Hill and Carolina Population Center in any publications reporting use of it. UNC-Chapel Hill must delay releasing data resulting from the collection or use of Biospecimens for one (1) year period beginning upon the release of the preliminary data file to Ancillary Study Institution. During this one (1) year period, Ancillary Study Institution’s Investigator may create and draft manuscripts, abstracts, or presentations to journals; however Ancillary Study Institution and its Investigator shall not submit any manuscripts for publication before the release date of the final file.
- 8. Disclaimer of Warranty.** Material is experimental in nature and it is provided WITHOUT WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER WARRANTY,

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EXPRESS OR IMPLIED. UNC-CHAPEL HILL MAKES NO REPRESENTATION OR WARRANTY THAT THE USE OF MATERIAL WILL NOT INFRINGE ANY PATENT OR OTHER PROPRIETARY RIGHT.

9. **Liability.** In no event shall UNC-Chapel Hill be liable for any use by Ancillary Study Institution, its employees and/or agents of Material or any loss, claim, damage or liability, of whatsoever kind or nature, which may arise from or in connection with this Agreement or the use, handling or storage of Material. Furthermore, Ancillary Study Institution agrees to indemnify UNC-Chapel Hill and any of its employees and hold it and them harmless from any action, claim, or liability, including, without limitation, liability for death, personal injury, or property damage, arising directly or indirectly from Ancillary Study Institution's possession, testing, screening, distribution or other use of Material provided under this Agreement, and/or from Ancillary Study Institution's publication or distribution of the test reports, data, and other information relating to said Material, if applicable, except in the event and to the extent such liability results from UNC-Chapel Hill's gross negligence or willful misconduct.

10. **Compliance with Law.** Each Party agrees to comply with all applicable United States federal, state, and local laws and regulations, and IRB restrictions, including, but not limited to, those concerning the privacy and confidentiality of individually identifiable information and export control laws. When the Material is used in the United States, Ancillary Study Institution shall comply with current NIH guidelines.