

**Application for Obtaining Sensitive Data from
The NICHD Study of Early Child Care
Research Triangle Institute**

Name of Investigator: _____ Date of Application: _____

Title of Investigator: _____

Title of Research Project: _____

Street Address: _____

City/State/Zip Code: _____

Telephone Number: _____ Fax Number: _____

Email Address: _____ (Used to notify investigator of receipt of application package.)

Receiving Institution: _____

Requested Delivery Date: _____

Date Data to be Destroyed: _____ (Must be within three years of delivery date.)

Only fully completed and documented requests will be considered. Please use the following checklist to insure your application is complete.

Application check list:

- ~ This Application for Obtaining Sensitive Data
- ~ Two copies of the Agreement for the Use of Sensitive Data with original Institutional Signatures page
- ~ Sensitive Data Security Plan
- ~ Completed Data File Order
- ~ Completed Supplemental Agreement with Research Staff
- ~ Signed Security Pledge(s) by Investigator and all Research Staff
- ~ IRB approval for research project
- ~ Non-refundable fee \$250 for data sets and documentation payable to "Research Triangle Institute"
- ~ Optional non-refundable fee \$250 for supplemental documentation payable to "Research Triangle Institute"
- ~ Optional non-refundable fee, \$100 per hour, for consultation payable to "Research Triangle Institute"

Send completed applications to:

Bonnie Knoke, Project Data Coordinator
NICHD Study of Early Child Care
Research Triangle Institute
Cox Building, Room 239
P. O. Box 12194
Research Triangle Park, NC 27709

Agreement for the Use of Sensitive Data from The NICHD Study of Early Child Care

I. Definitions

- A. "The NICHD Study of Early Child Care" is the cooperative agreement undertaken by the NICHD Early Child Care Research Network under Grant No. 5 U01 HD33343-05 from the National Institute of Child Health and Human Development.
- B. "Investigator" is the person primarily responsible for analysis and other use of sensitive data obtained through this agreement.
- C. "Research staff" are all persons, excluding the investigator, who will have access to sensitive data obtained through this agreement.
- D. "Receiving institution" is the university or research institution at which the investigator will conduct research using sensitive data obtained through this agreement.
- E. "Representative of the receiving institution" is a person authorized to enter into contractual agreement on behalf of the receiving institution.
- F. "Sensitive data" includes any data from the NICHD Study of Early Child Care that might compromise the anonymity or privacy of respondents to that study. Because of the site-based, birthing-clock study design, NICHD Study of Early Child Care respondents (children, parents, and care providers) are at increased risk of deductive disclosure compared with randomly-sampled individuals. Therefore, all data collected from the NICHD Study of Early Child Care are considered to be sensitive.
- G. "Data file" includes any form of data, whether on paper or electronic media.
- H. "Funding agency" is a federal office or institute which provided funding for the NICHD Study of Early Child Care. Funding agencies are only the offices or institutes providing the funding; other divisions or institutes within the larger organization are not considered funding agencies.

II. Description of Deductive Disclosure Risk from The NICHD Study of Early Child Care

The problem of deductive disclosure of an individual respondent's identity has become a major concern of federal agencies, researchers, and Institutional Review Boards in the recent past. In essence, deductive disclosure is the discerning of an individual respondent's identity and responses through the use of known characteristics of that individual. This is not unique to The NICHD Study of Early Child Care. If a person is known to have participated in ANY survey or study, then a combination of his or her personal characteristics may allow an individual to determine which record corresponds to that individual.

The NICHD Study of Early Child Care data is more sensitive than other datasets to deductive disclosure. This is due, in part, to the site-based, birthing-clock research design. Participants in the study were recruited by ten research sites during the first eleven months of 1991 from hospitals located near the sites. During selected 24-hour intervals, all women giving birth in a hospital were screened. This screening consisted of an evaluation of eligibility with exclusions for mother less than 18 years of age, multiple births, medical complications, an expected move during the course of the study, adoption plans, a lack of English fluency of the mother, and location of the family outside the area or in an unsafe neighborhood.

During the course of the study, detailed demographic and descriptive information including ethnic and racial background, employment, income, family composition, education, and marital status was collected and updated at frequent intervals. Multiple measures of psychological well-being, adjustment, cognitive development, and social development were made at four major data collection time points. Child care histories were collected

from birth for all participants. Child care providers were observed and interviewed at four major time points as well.

Given the large number of and sensitive nature of the assessments over time, researchers who use the NICHD Study of Early Child Care Contractual Dataset are obligated to protect respondents from deductive disclosure risk by taking precautions to protect the data from non-authorized use.

III. Requirements of Investigators

Investigators must meet one of the following criteria:

A. have a PhD or other terminal degree, and hold a faculty appointment or research position at the receiving institution

or

B. be a graduate student under the direct supervision of a PhD or other terminal degree professional who holds a faculty appointment or research position at the receiving institution.

IV. Requirements of a Receiving Institution

Receiving institutions 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.

V. Obligations of the Research Triangle Institute for the NICHD Study of Early Child Care

In consideration of the promises made in Section VI of this agreement, and of receipt of the monies noted in Sections VI(I), the Research Triangle Institute agrees to:

A. Submit for review by the appropriate officials of the Research Triangle Institute the two originals of this agreement within ten working days of receipt of the two originals properly signed by the investigator and a representative of the receiving institution.

B. Return one fully-signed original to the investigator by first-class mail within ten working days of receipt of the signed originals from appropriate Research Triangle Institute officials.

C. Provide the data files requested by the investigator in the Data File Order within ten working days of execution of this contract by appropriate officials of The Research Triangle Institute and send the requested data files to the investigator on CD ROM by FED EX or UPS.

D. Provide electronic documentation of the origins, form, and general content of the data files sent to the investigator, in the same time period and manner as the data files.

E. Provide, if requested, optional hard copy documentation of the variables in the data files, the Data Dictionary, sent to the investigator, in the same time period and manner as the data files.

F. If requested, provide telephone and/or e-mail consultation to the investigator and/or research staff. Consultation and technical assistance will be provided at the rate of \$100 per hour by Dr. Cathryn L. Booth at the Seattle site of the NICHD Study of Early Child Care. It is recommended that users purchase 1-4 hours of consultation time with Dr. Booth. Rates for more extensive consultation are negotiable. Consultation will be provided for (but not limited to) the following areas:

1. General orientation to the study
2. Data collection procedures, measures, forms
3. How variables were constructed and aggregated
4. Finding variables in the raw-data and analysis data sets
5. File conversion (e.g., to SPSS)
6. Analyses that have been performed
7. Miscellaneous technical assistance.

VI. Obligations of the Investigator, Research Staff, and Receiving Institution

Data provided under this agreement shall be held by the investigator, research staff, and receiving institution in strictest confidence and can only be disclosed in compliance with the terms of this agreement.

In consideration of the promises in Section V of this agreement, and for use of data files from the NICHD Study of Early Child Care, the investigator, research staff, and receiving institution agree:

- A. That the data will be used solely for statistical analyses, and that no attempt will be made to identify specific individuals, families, households, care providers; nor will any listing of data at the individual, family, or care provider level be published or otherwise distributed.
- B. That, if the identity of any person, family, household, or care provider should be discovered inadvertently, then (1) no use will be made of this knowledge; (2) the Research Triangle Institute Principal Investigator of the NICHD Study of Early Child Care, Tyler Hartwell, will be advised immediately of the incident; (3) the information that would identify the person, family, household, or care provider will be safeguarded or destroyed as requested by the Research Triangle Institute.
- C. To avoid inadvertent disclosure of persons, families, households, or care providers by using the following guidelines in the release of statistics derived from the dataset.
 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 figure for a row or column of a cross-tabulation be fewer than three.
 3. In no case should a quantity figure be based upon fewer than three cases.
 4. In no case should a quantity figure be published if one case contributes more than 60 percent of the amount.
 5. In no case should data on an identifiable case, nor any of the kinds of data listed in preceding items 1-3, be derivable through subtraction or other calculation from the combination of tables released.
 6. Data 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 subsequent amendments to this agreement, as investigator or research staff, be permitted access to the contents of sensitive data files or any files derived from sensitive data files.
- E. To comply fully with the Sensitive Data Security Plan, which is included as part of this agreement.

- F. To respond fully and in writing within ten working days after receipt of any written inquiry from the Research Triangle Institute regarding compliance with this contract or the expected date of completion of work with the sensitive data and any data derived therefrom.
- G. To make available for inspection, at reasonable hours, by the Research Triangle Institute the physical housing and handling of all data files and any other information, written or electronic, relating to this agreement.
- H. To supply the Research Triangle Institute with:
1. a completed application form (page 1 of this document),
 2. two copies of this entire agreement with original Institutional Signatures page (pages 1-8 of this document),
 3. a Sensitive Data Security Plan (see guidelines in Attachment A),
 4. a completed Data File Order specifying which files and documentation are requested (see Attachment B),
 5. a completed and signed Supplemental Agreement with Research Staff for Use of Sensitive Data (see Attachment C),
 6. Security Pledges for the investigator and all research staff identified in the Supplemental Agreement with Research Staff for Use of Sensitive Data with original signatures (see Attachment D),
 7. a copy of the document, signed by the receiving institution's Institutional Review Board (IRB), approving the research project and acknowledging the increased risk of NICHD Study of Early Child Care respondents to deductive disclosure that require special procedures for the handling and storage of NICHD Study of Early Child Care data.
- I. To provide to The Research Triangle Institute a non-refundable fee in the amount of \$250, in the form of a check made payable to "Research Triangle Institute," to cover the expenses of producing and shipping data files and documentation, and of administering this agreement. To provide to the Research Triangle Institute, if requested, non-refundable fees for optional consultation and supplemental documentation.
- J. To include in each written report or other publication based on analysis of sensitive data from the NICHD Study of Early Child Care, the following statement:
- This study was conducted by the NICHD Early Child Care Research Network supported by NICHD through a cooperative agreement.
- K. To destroy all the electronic and paper files, at the agreed upon date specified in the Application for Obtaining Sensitive Data. Research Triangle Institute staff shall be able to visit within a year of this date, to confirm the data have been destroyed.

- L. If in the event the investigator changes institutional affiliation during the period covered by this contract, the investigator will take the following actions:
1. Inform Research Triangle Institute staff six weeks prior to the date of relocation.
 2. Resubmit a security plan for the new institution and obtain approval from Research Triangle Institute staff prior to moving any electronic or paper files, from the originally-approved site to the new location.
 3. Destroy all electronic and paper files at the originally-approved site prior to the date of relocation.
 4. If the investigator is unable to establish and gain approval for the new location, all electronic and paper files, will be returned to Research Triangle Institute for storage. Upon approval of the new security plan, these stored files will be sent to the investigator. The investigator will assume all costs associated with the shipping and storage of these files. Although the data files will be stored in a secure location, Research Triangle Institute staff assume no responsibility for the data files.
 5. Within three months of the effective date of the relocation, submit two copies of the "Institutional Signatures" page with original signatures on each and a copy of the IRB review and approval letter from the new institution.
- M. To provide annual reports to Research Triangle Institute staff which include:
1. a copy of the annual IRB approval for the research project,
 2. a listing of public presentations at professional meetings using results based on these data,
 3. a listing of papers accepted for publication using these data, with complete citations,
 4. a listing of graduate students using the NICHD Study of Early Child Care data for dissertations or theses, the titles of these papers, and the date of completion.
- N. That the investigator and the receiving institution hereby acknowledge that any breach of the confidentiality provisions herein will result in irreparable harm to Research Triangle Institute and The NICHD Study of Early Child Care, not adequately compensable by money damages. The investigator and the receiving institution hereby agree to the imposition of injunctive relief in the event of breach, in addition to money damages.

VII. Confidentiality

Research subjects who participated in the NICHD Study of Early Child Care are protected by signed informed consents stating that only project and national study staff will have access to information gained from the study. Under the terms of the consent, the receiving institution is considered to be a contractor or cooperating agency of The Research Triangle Institute as a member of the national study staff; as such, the receiving institution, the investigator, and research staff are authorized to protect the privacy of the individuals who are the subjects of the NICHD Study of Early Child Care by withholding their identifying characteristics from all persons not connected with the conduct of the study. "Identifying characteristics" are considered to include those data defined as sensitive under the terms of this contract.

VIII. 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.
- B. The Sensitive Data Security Plan proposed by the investigator and approved by the Research Triangle Institute staff.

IX. Attachments

- A. Guidelines for Sensitive Data Security Plan for the Use of Sensitive Data from The NICHD Study of Early Child Care
- B. Data File Order for the Use of Sensitive Data from The NICHD Study of Early Child Care
- C. Supplemental Agreement with Research Staff for the Use of Sensitive Data from The NICHD Study of Early Child Care
- D. Sample Security Pledge for the Use of Sensitive Data from The NICHD Study of Early Child Care

Attachment A
Guidelines for Sensitive Data Security Plan
for the Use of Sensitive Data from
The NICHD Study of Early Child Care

General Information

All requests for data must include the following information.

1. The name(s) and responsibilities of the investigator(s) and the research staff (students, research assistants, and programmers) who will have access to the data. Changes in personnel would require that this information be updated.
2. Security pledges signed by all project personnel should be included with the Application. As new personnel are added during the period of this contract, an amended Attachment C and new security pledges must be obtained and sent to the Research Triangle Institute. A sample form is attached (Attachment D).
3. A detailed description of the computer system where the data will be stored and analyzed. This description should include the type of hardware that will be used for storage and analysis; how the computer system handles backups; how long system backup copies of the data are kept; the physical location of the equipment; who has physical access to the equipment; who has permission to use the equipment; where hard copy information will be printed; how hard copy data will be handled, stored, and disposed of; the security system that would prevent unauthorized access to the data; and whether this system is used by other projects.
4. Information on the security of the backup copy of the data that will be made at the investigator's home site. Only one complete copy of the NICHD Study of Early Child Care data is permitted; however, time-delimited temporary data analysis files may be created. Temporary data analysis files should be deleted upon completion of a project. Additionally, temporary data analysis file should be deleted at the beginning of every quarter—January 1, April 1, July 1, and October 1—and recreated, as necessary, to complete analysis.
5. The time frame for analysis of the data, including the end date of the project. The time frame should not exceed three years from the original date that data files were sent to the investigator. Research projects requiring the data for more than three years should submit annual requests for continuation three months prior to the end date of the current project. Data, paper and electronic, shall be destroyed on that date unless prior arrangements have been made with the NICHD Study of Early Child Care.

Specific Guidelines—Personal Computers

Stand-alone personal computers with data and documentation stored on the hard drive.

1. The computer must be located in a locked office. Key access to the office should be restricted to project personnel only. The office must be locked at all times when not occupied by project personnel.
2. Use of the computer is restricted to project personnel only. In order to use the computer a password must be supplied before access is granted. The password should be a nonsensical combination of numbers and letters. The password should be changed on a regular schedule and never repeated. Storage of the current password should not be in close proximity to the computer.
3. The original CD ROM is the only backup copy of the data allowed and should be kept in a locked drawer or file cabinet separately from the documentation and access information. The backup copy of the data must be stored in compressed format and password protected.

4. Any hard copy printout of the data must be stored in a locked drawer or file cabinet when not being referenced by the researchers. Printed information that is no longer needed must be shredded before disposal. Printouts of data from the NICHD Study of Early Child Care are not to be distributed to anyone outside of project personnel.

Specific Guidelines—Mainframe and Network Computing

1. Access to the data is restricted to project personnel only. In order to access data files, account and file password(s) must be supplied. The password(s) should be a nonsensical combination of numbers and letters. The password(s) should be changed on a regular schedule and never repeated.
2. The original copy of the data on CD ROM should be kept in a locked drawer or file cabinet separately from the documentation and access information.
3. Any hard copy printout of the data must be stored in a locked drawer or file cabinet when not being referenced by the researchers. Printed information that is no longer needed must be shredded before disposal. Printouts of data from the NICHD Study of Early Child Care are not to be distributed to anyone outside of project personnel.

Attachment B
Data and Documentation File Order and Consultation Request
for the Use of Sensitive Data from The NICHD Study of Early Child Care

1. The data will be delivered as a SAS version 6.04 or 6.12, and as SAS export files as specified below.
2. Documentation will be sent on a CD ROM in electronic or hard copy form as specified below.
3. Data will be sent on a CD ROM via either Federal Express or UPS.

Contact person: _____ email address: _____

Investigator Name

Signature

Date

Please Check Files and Documentation Requested

~ CD ROMS (non-refundable fee \$250) Containing:

The following directories and files.

ADS	Directory containing Phase I Analysis Data Sets. Data sets are stored in two formats: 1) SAS version 6.04 (V604 subdirectory) 2) SAS transport format (XPORT subdirectory)
CCDR	Directory containing Phase I Child Care Data Reports in WordPerfect 6.1 format.
DDICT	Directory containing Phase I Data Dictionary files in Borland Paradox 7 format.
TNOTE	Directory containing Phase I Technical Notes in WordPerfect 6.1 format.
INDEX.TXT	(This file) ASCII text file describing contents of CD-ROM.
README.WPD	WordPerfect 6.1 file which provides detailed information regarding the contents and usage of the Phase I information stored on this CD-ROM.
CCDR2	Directory containing Phase II Child Care Data Reports in WordPerfect 6.1 format.
DDICT2	Directory containing Phase I Data Dictionary file in MS Access 97 format.
ADS1	Directory containing supplemental Phase I Analysis Data Sets. Data are stored as SAS version 6.12 data sets. CC_CGxx.sd2 files(where xx=01, 06, 15, 24, 36) are documented in CCDR-201 in CCDR2 folder. FC1xx.sd2 files(where xx=06, 36) are documented in CCDR-203 in CCDR2 folder. COMBINE3.sd2 is documented in COMBINE3.doc (MS-Word 97 file) in ADS1 folder.
DATA	Directory containing the raw (item level per instrument) data collected by the sites. All files are in SAS 6.04 format.
CODEBOOK	Directory containing files which describe the coding of the variables in the raw data sets. Codebooks are WordPerfect files. The WordPerfect version used varies (usually 5.1 or 6.0).

- FORMS.TXT ASCII text file listing the names and numbers of all data collection forms.
- INSTRUMT Instrument documentation - The instrument documentation is an annotated list of all research instruments used in the study with information about:
- C psychometric properties
 - C rationale for choosing the instrument
 - C modifications made by the study
 - C relevant references
 - C variables from the instrument ratified for analyses by the Steering Committee
- Word x electronic files.
- MANUALS Manuals of Operation - WordPerfect 5.1 electronic files.
- DATAFORM Data Collection Forms - WordPerfect 5.1 electronic files.

~ OPTIONAL Data Dictionary (non-refundable fee \$250)

Hard Copy – 7 bound volumes, 4564 pages, containing information from the data reduction process including:

- C instrument name
- C variables used
- C form number
- C scoring/coding instructions
- C programming (SAS) log
- C summary statistics by site
- C psychometric properties

~ OPTIONAL Consultation (non-refundable fee \$100 per hour)

Please circle number of hours requested: 1 2 3 4

Instructions for contacting Cathryn Booth, Ph.D., Principal Investigator, NICHD Study of Early Child Care, University of Washington at Seattle site will be sent with the data and documentation.

Attachment C
Supplemental Agreement with Research Staff
for the Use of Sensitive Data from
The NICHD Study of Early Child Care

- I. The undersigned research staff, in consideration of their use of sensitive data from The NICHD Study of Early Child Care, agree:
 - A. That they have read the associated Agreement for the Use of Sensitive Data from The NICHD Study of Early Child care and the Sensitive Data Security Plan incorporated by reference into it.
 - B. That they are “research staff” within the meaning of the agreement.
 - C. To comply fully with the terms of the agreement, including the Sensitive Data Security Plan.
- II. The undersigned investigator agrees that the persons designated herein are research staff within the meaning of the associated Agreement for the Use of Sensitive Data from The NICHD Study of Early Child Care.

Research Staff

_____	_____	_____
Name	Signature	Date
_____	_____	_____
Name	Signature	Date
_____	_____	_____
Name	Signature	Date
_____	_____	_____
Name	Signature	Date
_____	_____	_____
Name	Signature	Date
_____	_____	_____
Name	Signature	Date

Investigator

_____	_____	_____
Name	Signature	Date

Attachment D
Sample Security Pledge
for the Use of Sensitive Data from
The NICHD Study of Early Child Care

Pledge of Confidentiality

I, _____, through my involvement with and work on the { name of research project } will have access to data collected by The NICHD Study of Early Child Care. By virtue of my affiliation with this project, I have access to confidential information and use of data about respondents generally perceived as personal and private. I understand that access to this confidential information and data carries with it responsibility to guard against unauthorized use and to abide by the Sensitive Data Security Plan. To treat information as confidential means not to divulge it to anyone who is not a project member, or to cause it to be accessible to anyone who is not a project member. Anything not specifically named as “public information” is considered confidential.

I agree to fulfill my responsibilities on this project in accordance with the following guidelines:

1. I agree to not permit non-project personnel access to these sensitive data, either electronically or hard copy.
2. I agree to not attempt to identify individuals, families, households, or care providers.
3. I agree that in the event an identity of an individual, family, household, or care provider is discovered inadvertently, I will (a) make no use of this knowledge, (b) advise the investigator of the incident who will report it to Tyler Hartwell at Research Triangle Institute, (c) safeguard or destroy the information as directed by the investigator after consultation with Tyler Hartwell, and (d) not inform any other person of the discovered identity.

Name

Signature

Date