Restricted Data Use Agreement
for Confidential Data from
the National Addiction and HIV Data Archive Program

I. Definitions

A. “Investigator” is the person primarily responsible for analysis and other use of Confidential Data obtained through this Agreement.

B. “Research Staff” are all persons at the Investigator's institution, excluding the Investigator, who will have access to Confidential Data obtained through this Agreement.

C. “Institution” is the university or research institution at which the Investigator will conduct research using Confidential Data obtained through this Agreement.

D. “Representative of the Institution” is a person authorized to enter into legal agreements on behalf of Investigator's Institution.

E. “Confidential Data” consist of identifiable private information, linkable to a specific individual either directly or indirectly, for which the individual (whether a person or organization) has the expectation that the information will not be released in a manner that allows public identification of the individual or causes some harm to the individual.

F. “Private Person” means any individual (including an individual acting in his official capacity) and any private (i.e., non-government) partnership, corporation, association, organization, or entity (or any combination thereof), including family, household, school, neighborhood, health service, or institution.

G. “ICPSR” is the Inter-university Consortium for Political and Social Research.

H. “ICPSR Data Access Request System” is the web-based application system for data use agreements at ICPSR.

I. “Data Security Plan” is a component of the Agreement which specifies permissible computer configurations for use of Confidential Data through Investigator responses to a series of questions, and records what the Investigator commits to do in order to keep Confidential Data secure.

J. “Deductive Disclosure” is the discerning of an individual's identity or confidential information through the use of known characteristics of that individual. Disclosure risk is present if an unacceptably narrow estimation of an individual’s confidential information is possible or if determining the exact attributes of the individual is possible with a high level of confidence.

K. “Derivative” is a file or statistic derived from the Confidential Data that poses disclosure risk to any Private Person in the Confidential Data obtained through this Agreement. Derivatives include copies of the Confidential Data received from NAHDAP/ICPSR, subsets of the Confidential Data, and analysis results that do not conform to the guidelines in Section VI.G.
II. Description of Disclosure Risk Section

Deductive disclosure of an individual's identity from research data is a major concern of federal agencies, researchers, and Institutional Review Boards. If a person is known to have participated in ANY survey or study or whose information is known to be included in a database from which the Confidential Data were obtained, then a combination of his or her personal characteristics may allow someone to determine which record corresponds to that individual. Investigators and Institutions who receive any portion of Confidential Data are obligated to protect the individual’s confidential information from deductive disclosure risk by strictly adhering to the obligations set forth in this Agreement and otherwise taking precautions to protect the Confidential Data from non-authorized use.

III. Requirements of Investigator

A. The Investigator assumes the responsibility of completing the online restricted data access request and required documents, reports, and amendments.

B. The Investigator agrees to manage and use Confidential Data and implement all Confidential Data security procedures per the Data Security Plan.

IV. Requirements of Institution

The Institution must meet the following criteria:

A. Be an institution of higher education, a research organization, a research arm of a government agency, or a nongovernmental, not for profit, agency.

B. Have a demonstrated record of using Confidential Data according to commonly accepted standards of research ethics and applicable statutory requirements.

V. Obligations of NAHDAP/ICPSR

In consideration of the promises made in Section VI of this Agreement, NAHDAP/ICPSR agrees to:

A. Provide the Confidential Data requested by the Investigator in the Confidential Data Order Summary within a reasonable time of execution of this Agreement by appropriate NAHDAP/ICPSR officials and to make the Confidential Data available to Investigator via download or removable media.

B. Provide electronic documentation of the origins, form, and general content of the Confidential Data sent to the Investigator, in the same time period and manner as the Confidential Data.

C. Provide telephone and/or email consultation to the Investigator and/or Research Staff, to the extent that NAHDAP/ICPSR is able to respond to such inquiries.
VI. Obligations of the Investigator, Research Staff, and Institution

Confidential Data provided under this Agreement shall be held by the Investigator, Research Staff, and Institution in strictest confidence and can be disclosed only in compliance with the terms of this Agreement. In consideration of the promises in Section V of this Agreement, and for use of Confidential Data from NAHDAP/ICPSR, the Investigator, Research Staff, and Institution agree:

A. That the Confidential Data will be used solely for research or statistical purposes relative to the research project identified in the request to obtain confidential data accompanying this Agreement, and for no other purpose whatsoever without the prior consent of NAHDAP/ICPSR. Further, no attempt will be made to identify private persons, no Confidential Data of private person(s) will be published or otherwise distributed, and Confidential Data will be protected against deductive disclosure risk by strictly adhering to the obligations set forth in this Agreement and otherwise taking precautions to protect the Confidential Data from non-authorized use.

B. To supply NAHDAP/ICPSR with a completed online request to obtain confidential data that will include the following:
   1. Signed Agreement
   2. Data Security Plan
   3. Confidential Data Order Summary specifying which files and documentation are requested
   4. Supplemental Agreement with Research Staff signed by each Research Staff member
   5. Pledges of Confidentiality for each Research Staff member
   6. Curriculum Vitae (CV) or resume for the Investigator and each Research Staff member
   7. A copy of a document signed by the Institution's Institutional Review Board (IRB) approving or exempting the research project.

C. To comply fully with the approved Data Security Plan at all times relevant to this Agreement.

D. That no persons other than those identified in this Agreement or in subsequent amendments to this Agreement, as Investigator or Research Staff and who have executed this Agreement, be permitted access to the contents of Confidential Data files or any files derived from Confidential Data files.
E. That within one (1) business day of becoming aware of any unauthorized access, use, or disclosure of Confidential Data, or access, use, or disclosure of Confidential Data that is inconsistent with the terms and conditions of this Agreement, the unauthorized or inconsistent access, use, or disclosure of Confidential Data will be reported in writing to NAHDAP/ICPSR.

F. That, unless prior specific approval is received from NAHDAP/ICPSR, no attempt under any circumstances will be made to link the data to any individual, whether living or deceased, or with any other dataset, including other datasets provided by NAHDAP/ICPSR.

G. To avoid inadvertent disclosure of private persons by being knowledgeable about what factors constitute disclosure risk and by using disclosure risk guidelines, such as but not limited to, the following guidelines¹ in the release of statistics or other content derived from the Confidential Data.²

1. No release of a sample unique for which only one record in the Confidential Data obtained through sampling (e.g., not a census) provides a certain combination of values from key variables. For example, in no table should all cases in any row or column be found in a single cell.

2. No release of a sample rare for which only a small number of records (e.g., 3, 5, or 10 depending on sample characteristics) in the Confidential Data provide a certain combination of values from key variables. For example, in no instance should the cell frequency of a cross-tabulation, a total for a row or column of a cross-tabulation, or a quantity figure be fewer than the appropriate threshold as determined from the sample characteristics. In general, assess empty cells and full cells for disclosure risk stemming from sampled records of a defined group reporting the same characteristics.

3. No release of a population unique for which only one record in the Confidential Data that represents the entire population (e.g., from a census) provides a certain combination of values from key variables. For example, in no table should all cases in any row or column be found in a single cell.

4. No release of the statistic if the total, mean, or average is based on fewer cases than the appropriate threshold as determined from the sample characteristics.

5. No release of the statistic if the contribution of a few observations dominates the estimate of a particular cell. For example, in no instance should the quantity figures be released if one case contributes more than 60 percent of the quantity amount.

6. No release of data that permits disclosure when used in combination with other known data. For example, unique values or counts below the appropriate threshold for key variables in the Confidential Data that are continuous and link to other data from NAHDAP/ICPSR or elsewhere.


² VI.G. can be customized with disclosure rules specific to the restricted-use dataset covered by the RDUA.
7. No release of minimum and maximum values of identifiable characteristics (e.g., income, age, household size, etc.) or reporting of values in the “tails,” e.g., the 5th or 95th percentile, from a variable(s) representing highly skewed populations.

8. Release only weighted results if specified in the data documentation.

9. No release of ANOVAs and regression equations when the analytic model that includes categorical covariates is saturated or nearly saturated. In general, variables in analytic models should conform to disclosure rules for descriptive statistics (e.g., see #7 above) and appropriate weights should be applied.

10. In no instance should data on an identifiable case, or any of the kinds of data listed in preceding items 1-9, be derivable through subtraction or other calculation from the combination of tables released.

11. No release of sample population information or characteristics in greater detail than released or published by the researchers who collected the Confidential Data. This includes but is not limited to publication of maps.

12. No release of anecdotal information about a specific private person(s) or case study without prior approval.

13. The above guidelines also apply to charts as they are graphical representations of cross-tabulations. In addition, graphical outputs (e.g., scatterplots, box plots, plots of residuals) should adhere to the above guidelines.

H. That if the identity of any private person should be discovered, then:

1. No use will be made of this knowledge;

2. NAHDAP/ICPSR will be advised of the incident within five (5) business days of discovery of the incident;

3. The information that would identify the private person will be safeguarded or destroyed as requested by NAHDAP/ICPSR; and

4. No one else will be informed of the discovered identity.

I. Unless other provisions have been made with NAHDAP/ICPSR, all originals and copies of the Confidential Data, on whatever media, shall be destroyed on or before completion of this Agreement or within 5 days of written request from NAHDAP/ICPSR. Investigator will complete and notarize an Affidavit of Destruction, attesting to the destruction of the Confidential Data. Investigators requiring the Confidential Data beyond the completion of this Agreement should submit a request for continuation three months prior to the end date of the project. This obligation of destruction shall not apply to Investigator’s scholarly work based upon or that incorporates the Confidential Data.

J. To ensure that the Confidential Data are managed and used only in compliance with the terms and conditions of this Agreement and with all applicable statutes and regulations. Noncompliance with this Agreement by any Research Staff hereto shall be deemed noncompliance and a breach by Investigator and Institution for purposes of Section VII below.
K. To include in each written report or other publication based on analysis of Confidential Data obtained from this Agreement, the following statement: Data used for this project were supported by the National Institute on Drug Abuse through a cooperative agreement that calls for scientific collaboration between the grantees and the National Institute on Drug Abuse staff.

L. That any books, articles, conference papers, theses, dissertations, reports, or other publications that employed the Confidential Data or other resources provided by NAHDAP/ICPSR reference the bibliographic citation provided by NAHDAP/ICPSR.

M. To provide annual reports to NAHDAP/ICPSR staff (through ICPSR’s online data access request system), 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 the Confidential Data or derivatives or analyses thereof;
   3. A listing of papers accepted for publication using the Confidential Data, or derivatives or analyses thereof, with complete citations;
   4. A listing of research staff or graduate students using the Confidential Data, or derivatives or analyses thereof, for dissertations or theses, the titles of these papers, and the date of completion; and
   5. A description in any change in scope of the Research Project being undertaken with the Confidential Data.

N. To notify NAHDAP/ICPSR of a change in institutional affiliation of the Investigator. Notification must be in writing and must be received by NAHDAP/ICPSR at least six (6) weeks prior to Investigator’s last day of employment with Institution. Investigator’s separation from Institution terminates this Agreement. Investigator may reapply for access to Confidential Data as an employee of the new institution. Re-application requires:
   1. Execution of a new Agreement for the Use of Confidential Data by both the Investigator and the proposed new institution;
   2. Execution of any Supplemental Agreement(s) with Research Staff and Pledges of Confidentiality by Research Staff at the proposed new institution;
   3. Preparation and approval of a new Data Security Plan; and
   4. Evidence of approval or exemption by the proposed new Institution's IRB.

   These materials must be approved by NAHDAP/ICPSR before Confidential Data or any derivatives or analyses may be stored or accessed at the new institution. Investigator must also, prior to the date of relocation, destroy all electronic and paper files containing Confidential Data or derivatives or analyses thereof at the original Institution. This obligation of destruction shall not apply to Investigator’s scholarly work based upon or that incorporates the Confidential Data.

O. If the Investigator is unable to establish and gain approval for the new location, all electronic and paper Confidential Data, will be returned to NAHDAP/ICPSR for storage. Upon approval of the new Confidential Data 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 Confidential Data as associated files. Although the Confidential Data will be stored in a secure location, NAHDAP/ICPSR staff assumes no responsibility for the Confidential Data or associated files.

P. That use of the data will be consistent with the Institution’s policies regarding scientific integrity and human subject’s research.

Q. To respond fully and in writing within ten (10) working days after receipt of any written inquiry from NAHDAP/ICPSR regarding compliance with this Agreement.

VII. Violations of this Agreement

A. The Institution will treat allegations by NAHDAP/ICPSR or other parties of violations of this Agreement as allegations of violations of its policies and procedures on scientific integrity and misconduct. If the allegations are confirmed, the Institution will treat the violations as it would violations of the explicit terms of its policies on scientific integrity and misconduct.

B. In the event Investigator or Institution breaches any provision of this Agreement, they shall be jointly and severally responsible to promptly cure the breach and mitigate any damages. The Investigator and Institution hereby acknowledge that any breach of the confidentiality provisions herein may result in irreparable harm to NAHDAP/ICPSR and the National Institute on Drug Abuse not adequately compensable by money damages. Investigator and Institution hereby acknowledge the possibility of injunctive relief in the event of breach, in addition to money damages. In addition, NAHDAP/ICPSR may:

1. Terminate this Agreement upon notice and require return of the Confidential Data and any derivatives thereof;

2. Deny Investigator future access to Confidential Data; and/or

3. Report the inappropriate use or disclosure to the Secretary of Health and Human Services.

C. Institution agrees, to the extent permitted under the law, to indemnify, defend, and hold harmless The University of Michigan, NAHDAP/ICPSR, and the sources of Confidential Data from any or all claims and losses accruing to any person, organization, or other legal entity as a result of Investigator’s, Research Staff’s, and/or Institution’s acts, omissions, or breaches of this Agreement.

VIII. Confidentiality

The Institution is considered to be a contractor or cooperating agency of NAHDAP/ICPSR; as such, the Institution, the Investigator, and Research Staff are authorized to protect the privacy of the individuals who are the subjects of the Confidential Data by withholding their identifying characteristics from all persons not connected with the conduct of the Investigator’s research project. “Identifying characteristics” are considered to include those data defined as confidential under the terms of this Agreement.
IX. Incorporation by Reference

All parties agree that the following documents are incorporated into this Agreement by reference:

A. The application information entered in the online data access request system.
B. A copy of the Institution’s IRB approval or exemption of the research project.
C. The Data Security Plan proposed by the Investigator and approved by NAHDAP/ICPSR.

X. Miscellaneous

A. All notices, contractual correspondence, and return of Confidential Data under this Agreement on behalf of the Investigator shall be made in writing and delivered to the address below:

National Addiction and HIV Data Archive Program
ICPSR
P.O. Box 1248
Ann Arbor, MI 48106-1248
nahdap@icpsr.umich.edu

B. This agreement shall be effective for ≤24 months from execution.
C. The respective rights and obligations of NAHDAP/ICPSR and Investigator, Research Staff, and Institution pursuant to this Agreement shall survive termination of the Agreement.
D. This Agreement, the Investigator’s research project, Data Security Plan, or Supplemental Agreement with Research Staff may be amended or modified only by the mutual written consent of the authorized representatives of NAHDAP/ICPSR and Investigator and Institution. Both parties agree to amend this Agreement to the extent necessary to comply with the requirements of any applicable regulatory authority.
E. The persons signing this Agreement have the right and authority to execute this Agreement, and no further approvals are necessary to create a binding agreement.
F. 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 NAHDAP/ICPSR.
### Investigator and Institutional Signatures

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