

National Institute on Alcohol Abuse and Alcoholism Data Use Agreement

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) and (Name of Recipient Institution) hereby enter into this Data Use Agreement (DUA) as of the date specified on the final page hereof.

PRELIMINARY STATEMENT

The National Institute on Alcohol Abuse and Alcoholism has supported collection of data from participants in the National Epidemiologic Survey on Alcohol and Related Conditions-III (NESARC-III). This well-characterized population provides a unique scientific resource. Promoting optimal use of it on a national scale will require a large and concerted effort that may exceed the research capacity of currently available Study Investigators. The NIAAA has a responsibility to the public in general, and to the scientific community in particular, to encourage the most rapid scientific progress possible using this resource, subject to appropriate terms and conditions. In order to take full advantage of the resource and maximize its research value, it is important that the data, collected with public funds, be made available on appropriate terms and conditions to the largest possible number of qualified investigators in a timely manner.

Recipients who are granted access to Study data must adhere to the requirements of this DUA and obtain an IRB exemption or approval for their project that may be from an expedited or convened review. Failure to comply with this DUA could result in denial of further access to study data. Violation of the confidentiality requirements of this agreement is considered a breach of confidentiality and may leave requesting investigators liable to legal action.

DEFINITIONS

Data: For purposes of this agreement, "Data" refers to the following phenotypic information that has been collected from study participants conducted by the Laboratory of Epidemiology and Biometry: **National Epidemiologic Survey on Alcohol and Related Conditions-III (NESARC III)**.

TERMS AND CONDITIONS

I request approval to access phenotypic data from the National Epidemiologic Survey on Alcohol Related Conditions-III (NESARC-III). I agree to the following:

1. Research Project.

1.1. These Data will be used by the recipient Principal Investigator and collaborators in connection with the research project specifically described in an attached Exhibit A. The Project description should include: project title, a 2-4 paragraph description of the objectives and design, and a brief description of the analysis plan.

1.2. All senior/key personnel working on this Research Project that will have access to the NESARC-III Data will also be listed on the DUA.

1.3. The DUA covers only the Research Project contemplated in the Research Use Statement section. Recipient agrees that Data will not be used in any research that is not disclosed and approved as part of the Research Project. Recipient will submit a completed DUA (this document) for each research project for which Data are requested.

1.4. This Agreement will terminate two (2) years from the effective date of this agreement. Continued use of the Data will require execution of a new DUA as specified in paragraph 6.

2. Non-transferability Agreement. This DUA is not transferable. Recipient agrees that appointment by Recipient of another Principal Investigator to complete the Research Project will require execution of a new Data Use Agreement in which the new Principal Investigator is designated. If the Recipient changes institutions and wishes to retain access to the NESARC-III Data, a new DUA in which the new institution acknowledges and agrees to the provisions of the DUA is necessary. If the Recipient adds new NESARC-III data users to their project, their name and contact information will be provided to the NESARC-III DAC.

3. Publication. Prompt publication or other public disclosure of the results of the Research Project is encouraged. Recipient agrees to provide to the NIAAA a copy of any manuscript or other disclosure document ten (10) business days in advance of submission for publication, in order to ensure compliance with the confidentiality requirements set forth in paragraphs 4,5,6,7, and 8 of this Agreement.

4. Acknowledgments. Recipient agrees to acknowledge the contribution of NIAAA-Funding support and support of the intramural program, NIAAA, National Institutes of Health, in any and all oral and written presentations, disclosures, or publications resulting from any and all analyses of Data. The Recipient will acknowledge the source of the Data by including language similar to the following either in the acknowledgment or in the text of the manuscript: 'This manuscript was prepared using a limited access dataset obtained from the National Institute on Alcohol Abuse and Alcoholism and does not reflect the opinions or views of NIAAA or the U.S. Government'.

5. Non-Identification. Recipient agrees that Data will not be used, either alone or in conjunction with any other information, in any effort whatsoever to establish the individual identities of any of the subjects from whom Data were obtained.

6. Use Limited to Two (2) Years. Recipient agrees that Data will be destroyed when two (2) years have elapsed from the effective date of this Agreement. A data destruction certificate will be provided to NIAAA. Further use of the Data beyond that time requires completion of a new DUA along with a current IRB exemption letter or approval resulting from either IRB review of a new research protocol or continuing review of the existing research protocol. Note that projects receiving initial IRB approval through expedited or convened review must submit an IRB approval letter for continuing review each year.

7. No Distribution. Recipient agrees to retain control over Data, and further agrees not to transfer Data, with or without charge, to any other entity or any individual.

8. Non-Data. Notwithstanding the definition of “Data” or the agreed Terms and Conditions of this Distribution Agreement, Recipient’s obligations under this Distribution Agreement shall not extend to any information:

- (a) that can be demonstrated to have been publicly known at the time of disclosure; or
- (b) that can be demonstrated to have been in the possession of or that can be demonstrated to have been readily available to Recipient from another source prior to the disclosure; or
- (c) that becomes part of the public domain or publicly known by publication or otherwise, not due to any unauthorized act by Recipient; or
- (d) that can be demonstrated as independently developed or acquired by Recipient without reference to or reliance upon Data provided under this Agreement.

9. Non-Endorsement, Liability. Recipient agrees not to claim, infer, or imply endorsement by the United States government, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, Department of Health and Human Services or any of its agencies of the Research Project, the entity, or personnel conducting the Research Project or any resulting commercial product(s). To the extent permitted by law, Recipient agrees to hold the United States Government, Study Investigators, and all other investigator(s) who generated Data and the agents and employees of each of them, harmless and to defend and indemnify all such parties for all liabilities, demands, damages, expenses, and losses arising out of Recipient's use of Data for any purpose.

10. Recipient's Compliance with IRB Requirements. Recipient acknowledges that the conditions for use of Data may be exempt from review or may be approved by the Recipient's Institutional Review Board (IRB) through expedited or convened review which must be operating under an Office of Human Research Protections (OHRP) - approved Assurance. Furthermore, Recipient agrees to comply with all applicable rules for the protection of human subjects, which may include Department of Health and Human Services regulations at 45 CFR Part 46 and other Federal and State laws for the use of these Data. Recipient agrees to comply fully with all such conditions. Recipient agrees to report promptly to the NIAAA any proposed change in the research project. This DUA is made in addition to, and does not supersede, any of Recipient’s institutional policies or any local, State, and/or Federal laws and regulations that provide additional protections for human subjects.

11. Recipient’s Permission to Post Information Publicly. Recipient agrees to permit the NIAAA to summarize on the NESARC-III Web site the Recipient’s research use of NESARC-III along with the Recipient’s name and organizational/institutional affiliation.

12. Privacy Act Notification. In order to access the NESARC-III, the Recipient agrees to provide the information requested below.

The Recipient agrees that information collected from the Recipient, as part of the Data Access Request, may be made public in part or in whole for tracking and reporting purposes. This

Privacy Act Notification is provided pursuant to Public Law 93-579, Privacy Act of 1974, 5 U.S.C. Section 552a. Authority for the collection of the information requested below from the recipient comes from the authorities regarding the establishment of the National Institutes of Health, its general authority to conduct and fund research and to provide training assistance, and its general authority to maintain records in connection with these and its other functions (42 U.S.C. 203, 241, 2891-1 and 44 U.S.C. 3101), and Section 301 and 493 of the Public Health Service Act. These records will be maintained in accordance with the Privacy Act System of Record Notice 09-25-200 covering “Clinical Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD”. Primary uses of this information are to document, track, and monitor and evaluate the use of the NIAAA NESARC-III datasets, as well as notify interested recipients of updates, corrections, or other changes to the database.

13. Security. Recipient acknowledges the expectations set forth by the “NESARC-III Information Security Best Practices” (see below) for the use and security of Data.

14. Annual Update. When requested, Recipient will provide to NIAAA-NESARC-III@mail.nih.gov, within four (4) weeks, an annual summary of research accomplishments form using NESARC-III Data, including copies of any presentations/publications/reports.

15. Amendments. Amendments to this Agreement must be made in writing and signed by authorized representatives of all parties.

16. Termination. The NIAAA may terminate this Agreement if Recipient is in default of any of its conditions and such default has not been remedied within 30 days after the date of written notice of such default by an authorized representative of the NIAAA. Otherwise, either party may terminate this Agreement after providing 30 days written notice to the other party. Recipients agree to immediately report violations of NESARC-III Policy to the NESARC-III Data Access Committee (DAC).

17. Disqualification, Enforcement. Failure to comply with any of the terms specified herein may result in disqualification of Recipient from further use of the NESARC-III Data and receiving additional Data. The United States Government shall have the right to institute and prosecute any proceeding at law or in equity against the Recipient for violating or threatening to violate the confidentiality requirements of the Agreement, the limitations on the use of the Data provided, or both. Proceedings may be initiated against the violating party, legal representatives, and assigns, for a restraining injunction, compensatory and punitive damages, mandamus, and/or any other proceeding in law or equity, including obtaining the proceeds from any intellectual property or other rights that are derived in whole or in part from the breach of the confidentiality requirements or use limitations of the Agreement.

18. Accurate Representations. Recipient certifies that the contents of any statements made or reflected in the DUA are truthful and accurate.

19. Duplication of Research. Recipient acknowledges that other researchers are entitled to access the Data on the same terms as Recipient so the duplication of PI’s research may occur.

NESARC-III Information Security Best Practices

The purpose of these Security Best Practices, which are subject to applicable law, is to provide minimum security standards and best practices for individuals who use NESARC-III to submit, access, and analyze Data. Keeping NESARC-III information secure through these best practices is important. Subject to applicable law, Recipients agree to immediately report breaches of Data confidentiality to the NESARC-III DAC.

Best Practices

We suggest that you:

- Do not attempt to override technical or management controls to access Data for which you have not been expressly authorized.
- Do not use your trusted position and access right to exploit system controls or access Data for any reason other than in the performance of the proposed research.
- Ensure that everyone directed to use the system has access to, and is aware of, NESARC-III information Security Best Practices and all existing policies and procedures relevant to the use of NESARC-III, including but not limited to 45 C.F.R. Part 46.
- Follow the NESARC-III password policy which includes:
 - Choose passwords of at least seven characters including at least three of the following types of characters: capital letters, lower case letters, numeric characters and other special characters.
 - Change your passwords every six months.
 - Protect your NESARC-III password from access by other individuals—for example, store it electronically in a secure location.
- Notify NESARC-III staff, as permitted by law, at NIAAA-NESARC-III@mail.nih.gov of security incidents or when access to NESARC-III is no longer required.

Security Standards

- Protect the Data, providing access solely to authorized researchers permitted access to such Data by your institution or to others as required by law.
- When you download NESARC-III Data, download the Data to a secure computer or server with strong password protection.
- Ensure that the computers hosting NESARC-III Data have the latest security patches and are running virus protection software.
- Make sure the Data are not exposed to the Internet or posted to a website that may be discovered by Internet search engines such as Google or Bing.
- If you leave your office, close out of data files or lock your computer. Consider the installation of a timed screen saver with password protection.
- Avoid storing Data on a laptop or other portable medium. If storing Data on such a device, encrypt the Data. Most operating systems have the ability to natively run an encrypted file system or encrypt portions of the file system.

- When finished using the Data, destroy the Data or otherwise dispose of them properly, as permitted by law.

NIAAA NESARC – III Data Use Agreement

Date _____

Type of Application: ____ New ____ Renewal

Date Requested: ____ National Epidemiologic Survey on Alcohol and Related Conditions – III
(NESARC- III)

Project Director/Principal Investigator

First Name: _____ Last Name: _____

Degree: _____ Academic Position (or Title) _____

Institution: _____ Department: _____

Street Address:

City: _____ State/Province: _____

Zip/Postal Code: _____ County: _____

Telephone: _____ Fax: _____

E-mail Address: _____

Research Project (title):

By signing and dating this DUA as part of requesting access to NESARC –III data, my Institutional Officials and I certify that we will abide by the DUA and the NIH and NIAAA principles, policies and procedures for the use of the NIAAA NESARC-III. I further acknowledge that I have shared this document and the NIH and NIAAA policies and procedures with all research staff who will participate in the use of the NIAAA NESARC-III.

Signature: _____ Date: _____

Authorized Institutional Business Official (as registered in the NIH eRA Commons:
<https://commons.era.nih.gov/commons/>)

Name: _____

FWA#: _____

Title: _____

Signature: _____ Date: _____

Inquiries about NESARC-III Data should be sent to:

NESARC – III Data Access Committee

Laboratory of Epidemiology and Biometry

National Institute on Alcohol Abuse and Alcoholism

National Institutes of Health

5635 Fishers Ln., Room 3080,

Rockville, MD 20852

E-mail: NIAAA-NESARC-III@mail.nih.gov

Project Director/Principal Investigator Contact Information (if different from above)

First Name: _____ Last Name: _____

Degree: _____ Academic Position (or Title) _____

Institution: _____ Department: _____

Street Address: _____

City: _____ State/Province: _____

Zip/Postal Code: _____ County: _____

Telephone: _____ Fax: _____

E-mail Address: _____

Authorized Representative (Institutional Official)

First Name: _____ Last Name: _____

Degree: _____ Academic Position (or Title) _____

Institution: _____ Department: _____

Street Address: _____

City: _____ State/Province: _____

Zip/Postal Code: _____ County: _____

Telephone: _____ Fax: _____

E-mail Address: _____

Specify All Data Users with Access to NESARC-III data below:

Senior/Key Person Profile (Collaborating Investigator)

First Name: _____ Last Name: _____

Degree: _____ Academic Position (or Title) _____

Institution: _____ Department: _____

Street Address: _____

City: _____ State/Province: _____

Zip/Postal Code: _____ County: _____

Telephone: _____ Fax: _____

E-mail Address: _____

Project Role _____ Other Project Role Category _____

Senior/Key Person Profile (Collaborating Investigator)

First Name: _____ Last Name: _____

Degree: _____ Academic Position (or Title) _____

Institution: _____ Department: _____

Street Address: _____

City: _____ State/Province: _____

Zip/Postal Code: _____ County: _____

Telephone: _____ Fax: _____

E-mail Address: _____

Project Role _____ Other Project Role Category _____

Senior/Key Person Profile (Collaborating Investigator)

First Name: _____ Last Name: _____

Degree: _____ Academic Position (or Title) _____

Institution: _____ Department: _____

Street Address: _____

City: _____ State/Province: _____

Zip/Postal Code: _____ County: _____

Telephone: _____ Fax: _____

E-mail Address: _____

Project Role _____ Other Project Role Category _____

(Add pages if needed)

Exhibit A
Research Project Description

NIAAA:

NIAAA Authorized Representative -- Name and Title

NIAAA Authorized Representative -- Signature and Date
