

ATTACHMENT 15
NIAAA DRAFT DATA USER CERTIFICATION (DUC)

DRAFT

**National Institute on Alcohol Abuse and Alcoholism
Data User Agreement**

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) and (Name of Recipient Institution) hereby enter into this Distribution Agreement 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 hereafter referred to as "Study". 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 as rapid scientific progress as 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.

Although data collected by the Study have been stripped of all personal identifiers, the wealth of data available on individual participants might make possible their identification. To protect the confidentiality of study participants, Recipients who are granted access to Study data must adhere to the requirements of this Distribution Agreement and obtain IRB approval for their project. IRB approval may be from an expedited or convened review, but a simple IRB letter granting an exemption is not sufficient. Failure to comply with this Distribution Agreement 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 on the part of Study participants, their families, or the U.S. Government.

DEFINITIONS

Data: For purposes of this agreement, "Data" refers to the following information that has been collected from study participants conducted by the Laboratory of Epidemiology and Biometry.

RECIPIENT: Recipient is (check one):

- a non-profit organization organized under the laws of the State of _____ OR
- a for-profit corporation organized under the laws of the State of _____ OR
- a government agency organized under the laws of the _____ .

Principle Investigator:

_____, with a principal address at _____
requests access to Study data at his/her sole risk and at no expense to the NIAAA.

AGREED TERMS AND CONDITIONS

It is mutually agreed as follows:

1. Research Project.

1.1. These Data will be used by the PI in connection with the following research project ("Research Project"), specifically described in an attached Exhibit A. The Project description should include: project title, a 1-2 paragraph description of the objectives and design, and a brief description of the analysis plan.

1.2. The Research Project (check one) (does) (does not) involve NIAAA/DICBR/LEB study investigator(s) as co-investigator(s). If the Project does involve NIAAA/DICBR/LEB Study Investigator(s), their names are: _____

and the work they will perform is described below or in an attached Exhibit B:
(Describe briefly the work of the Co-Investigator(s) from the Study or attach an exhibit B)

1.3. Recipient will promptly notify the NIAAA of any substantive changes to the proposed Research Project or of any new projects to be initiated from the requested Data. Such notification will consist of a new project description as described in paragraph 1.1. Data will be used solely for Research Projects disclosed to the NIAAA.

1.4. This Agreement will terminate three (3) years from the effective date of this agreement. Continued use of the Data will require execution of a new Distribution Agreement as specified in paragraph 6.

2. Non-transferability. This Distribution Agreement is not transferable. Recipient agrees that appointment by Recipient of another Principal Investigator to complete the Research Project will require execution of a new Distribution Agreement in which the new Principal Investigator is designated. Recipient also agrees that it will recover from the PI all Data received under this agreement should the PI's employee relationship with the Recipient terminate for any reason.

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 thirty (30) 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, NIH 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 NNIAAA 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 Three (3) Years. Recipient agrees that Data will be removed or destroyed when three (3) years have elapsed from the effective date of this Agreement. Further use of the Data beyond that time requires completion of a new Distribution Agreement along with a current IRB approval resulting from either IRB review of a new research protocol or continuing review of the existing research protocol.

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-Endorsement, Indemnification. Recipient agrees not to claim, infer, or imply endorsement by the United States government or any of its agencies of the Research Project, the entity, or personnel conducting the Research Project or any resulting commercial product(s) except as described in paragraph 4. 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.

9. Recipient's Compliance with IRB Requirements. Recipient acknowledges that the conditions for use of Data are not exempt from review and have been approved by the Recipient's Institutional Review Board (IRB) operating under an Office of Human Research Protections (OHRP) - approved Assurance and in accordance with Department of Health and Human Services regulations at 45 CFR Part 46. Recipient agrees to comply fully with all such conditions. Recipient agrees to report promptly to the NIAAA any proposed change in the research project and any unanticipated problems involving risks to subjects or others. This Agreement is made in addition to, and does not supercede, any of Recipient's institutional policies or any local, State, and/or Federal laws and regulations that provide additional protections for human subjects.

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

11. 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.

12. Disqualification, Enforcement. Failure to comply with any of the terms specified herein may result in disqualification of Recipient from 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

this 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 this agreement. In addition, Recipient acknowledges and agrees that a breach or threatened breach of the confidentiality requirements or use limitations of this agreement may subject Recipient to legal action on the part of Study subjects, their families, or both.

13. Accurate Representations. Recipient certifies that the contents of any statements made or reflected in this document are truthful and accurate.

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

Signatures begin on the next page.

This Agreement is entered into as of : _____(effective date)

RECIPIENT:

Name of Recipient:

Name and Title of Recipient's Authorized Institutional Business Official:

Signature and Date of Recipient's Authorized Institutional Business Official:

PRINCIPAL INVESTIGATOR:

Principal Investigator's Name and Title:

Principal Investigator's Surface Mail Address:

Principal Investigator's E-Mail Address:

Principal Investigator's Telephone Number:

Principal Investigator's Fax Number:

Principal Investigator Signature and Date: _____

NIAAA:

NIAAA Authorized Representative -- Name and Title: _____

NIAAA Authorized Representative -- Signature and Date:

ATTACHMENT 1: Guidelines for Manuscripts and Abstracts from Investigators Who Use Limited Access Datasets

Manuscript Review Policy

The NIAAA reviews manuscripts from PIs who use limited access datasets only for compliance with the terms of this Data Distribution agreement. The PI must be a coauthor on all manuscripts and abstracts, and the acknowledgment as set forth in section 4 must accompany all manuscripts. Manuscripts and abstracts should be submitted to the NIAAA authorized representative prior to the end of the three (3) year limit on use of the data.

Abstracts, in general, can not use the acknowledgment as described in section 4; therefore, abstracts should clearly indicate within the text that the source of the data was a limited access dataset obtained from the NIAAA.

In addition to a review for compliance with the terms of this Data Distribution Agreement by NIAAA's authorized representative, manuscripts and abstracts may be forwarded to NIAAA staff familiar with the Study or to Study investigators for comment. If NIAAA staff or Study investigators choose to offer additional comments, these are provided to the Principal Investigator only as a courtesy. Limited access investigators are not obligated to incorporate additional comments from other NIAAA staff or Study investigators; however, these comments may provide the investigator with additional insights towards improving the manuscript.

Additional Guidelines for Manuscripts/Abstracts using Limited Access Data

Manuscripts submitted to the NIAAA by investigators using limited access datasets are reviewed within 10-14 days and abstracts are reviewed within 3-7 days. Expedited reviews can be requested. Additional comments from NIAAA staff or Study investigators, if any, are forwarded to the limited access investigator once they are received by the NIAAA authorized representative. Additional comments from NIAAA staff or Study investigators may be forwarded to the Principal Investigator prior to or after the review by the NIAAA authorized representative.