NIAAA DATA USE AGREEMENT

This Data Use Agreement ("**Agreement**") is by and between:

The **National Institute on Alcohol Abuse and Alcoholism**, part of the National Institutes of Health, a component of the United States Department of Health and Human Services

("**NIAAA**"),

AND,

_____

an academic/non-profit organization having a place of business at:

_____

("**RECIPIENT**"),

for the transfer of data collected from individuals who have participated in research (each a "**Human Subject**"), for research purposes as further defined below. NIAAA and RECIPIENT may each be referred to as Party or collectively as Parties. This Agreement will become effective on the date of the last signature below (the "**Effective Date**").

NIAAA and RECIPIENT agree as follows:

1. NIAAA will transfer the following data to the RECIPIENT:

   Select from Drop Down

   which shall hereafter be referred to as the "**Data**".

2. The RECIPIENT will only use the Data for the following internal research project described in the Data Access Application under title

   which shall hereafter be referred to as the "**Research Project**".

3. The RECIPIENT agrees **NOT** to do any of the following:

   (a) Use the Data for any diagnostic, prognostic, or treatment purposes;

   (b) Use the Data for any commercial purposes, including selling, commercial screening, or transferring Data to a third party for commercial purposes;

   (c) Transfer the Data to anyone who is not under the RECIPIENT Investigator's (as listed on the signature page of this Agreement) direct supervision unless advanced, written approval

of NIAAA is obtained before any transfer.

4. **If the RECIPIENT receives**:

- Information from NIAAA, or information ascertained through the RECIPIENT's use of the Data, that can be used to determine a Human Subject's identity, either alone or when combined with other personal or identifying information; or
- The coded Data with the key to such information in 4(A) above; or
- Identifiable, sensitive information ("ISI"), as defined in the Public Health Service Act at 42 U.S.C 241(d)(4), regarding the Data[1];

Then the RECIPIENT agrees to:

(a) Abide by all applicable human subjects and other regulations and guidance, which may include:

(i) The Privacy Act of 1974, as amended, at 5 U.S.C. §552a ("Privacy Act"), the Health Information Portability and Accountability Act of 1996 (HIPAA) or other equivalent privacy regulations; and

(ii) 45 C.F.R. Part 46, 21 C.F.R. Parts 50 and 56, and FDA Good Clinical Practice Guidelines (ICH E6 Good Clinical Practice: Consolidated Guidance, 62 FR 25692 (1997)); and

(iii) A certificate of confidentiality issued by the NIH in accordance with 42 U.S.C 241(d) of the Public Health Service Act.

(b) Maintain any transferred information in a secure manner that restricts access by any individual not involved in the Research Project (e.g., for paper records – locked file cabinets or continual physical presence in a room that locks, or for electronic records – encryption and password protection); and

(c) Remove or destroy any information that may be used to identify the Human Subject at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the Research Project; and

(d) Make no further use or disclosure of the information unless approved by NIAAA or required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments). Notwithstanding the foregoing, ISI is immune from the legal process, and will not, without the consent of the Human Subject, be admissible as evidence or used for any purpose in any action, suit, or other judicial, legislative, or administrative proceeding.

5. The RECIPIENT agrees not to contact or make any effort to identify Human Subjects, communities, tribes, or populations which are or may be the source of the Data.

[1] See https://humansubjects.nih.gov/coc/faqs

6. The RECIPIENT represents that it has obtained Institutional Review Board (IRB) approval or exemption or other approval or exemption from a body operating under an Office of Human Research Protections (OHRP)-approved Assurance, or the necessary internal authorizations and approvals as appropriate or necessary, to use the Data.

7. All information to be deemed confidential that is transferred between the Parties under this Agreement will be clearly marked "**CONFIDENTIAL**" by the disclosing Party ("Confidential Information") and maintained in confidence by the receiving Party for a period of *one (1) year* from the date of receipt. Any Confidential Information that is orally disclosed must be reduced to writing and marked "**CONFIDENTIAL**" by the providing Party and such notice must be provided to the receiving Party within *thirty (30) days* of the oral disclosure. Notwithstanding any other provision of this Agreement, the obligation to not disclose ISI to any other party will extend indefinitely.

8. For the purposes of this Agreement, Confidential Information will not include information that:

   (a) is within the public domain prior to the **Effective Date** of this **CDA**;

   (b) the providing **Party** has authorized public disclosure of;

   (c) is publicly disclosed by a source other than the receiving **Party**;

   (d) a **Party** obtains from a third party that has a lawful right to share the information;

   (e) is already known by a **Party**, free of any confidentiality obligations, before the **Effective Date** of this **CDA**; or,

   (f) is independently made by a **Party** without reference to the other **Party's Confidential Information**.

9. If the receiving Party becomes legally required to disclose any of the Confidential Information, the receiving Party will take all reasonable measures to disclose only that Confidential Information legally required and will notify the disclosing Party as soon as practicable. In all instances, the receiving Party will only disclose that portion of the disclosing Party's Confidential Information which is obliged to be disclosed. The disclosing Party is free to seek any remedies at law or in equity to limit or prevent the disclosure of the disclosing Party's Confidential Information.

10. The RECIPIENT will comply with all laws, rules, regulations, and policies applicable to the handling, use, and disposal of the Data.

11. 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 to connection with these and its other functions (42 U.S.C. 203, 241,

289l-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 datasets, as well as notify interested recipients of updates, corrections, or other changes to the database.

12. Upon completion of the Research Project, or upon the expiration or termination of this Agreement, whichever comes first, the RECIPIENT will immediately delete any and all Data present on any physical or cloud-based computer storage device or system and provide a certificate of data destruction to the NIAAA Data Access Committee (NIAAA DAC).

13. The Parties agree that this Agreement will be effective for *one (1) year* from the Effective Date and may be extended as mutually agreed by the Parties, in a written amendment to this Agreement that has been signed by the authorized representatives of both Parties.

14. Either Party may terminate this Agreement by providing *sixty (60) days* prior written notice to the other Party, subject to the terms of Articles 10 and 13, above.

15. In all oral presentations or written publications concerning the use of the Data, the RECIPIENT will acknowledge NIAAA's contribution of the Data, unless requested otherwise by NIAAA. Specifically, all presentations, papers, published articles, theses, abstracts, dissertations, and other written materials that report results based on the Data must include the following acknowledgement and disclaimer, in writing, as appropriate:

> *"This (**presentation paper/article/chapter/document**) was prepared using a limited access dataset obtained from the National Institute on Alcohol Abuse and Alcoholism (NIAAA). This (**presentation paper/article/chapter/document**) has not been reviewed or endorsed by NIAAA and does not necessarily represent the opinions of NIAAA, who is not responsible for the contents."*

16. The RECIPEINT will submit to the NIAAA Data Access Committee (NIAAA DAC) at NIAAA-DAC@nih.gov a progress report due upon completion of the Research Project or on the annual anniversary of the execution of this Agreement (whichever comes first). The progress report will contain the following:

- A non-confidential summary of accomplishments, including a list of any oral or written presentations, abstracts, publications, grant awards, dissertations, theses, and newly created and publicly available research resources resulting from the approved use of the Data; and
- Publication numbers of any published patent applications and issuance numbers of any patents for newly discovered or developed technologies resulting from the approved use of the Data.

To the extent the RECIPIENT is also the recipient of federal funds, reports submitted through the iEdison system are not sufficient to meet the obligation to report progress to the NIAAA DAC.

17. Any Data delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. **NIAAA MAKES NO REPRESENTATIONS AND EXTENDS NO EXPRESSED OR IMPLIED WARRANTIES OF ANY KIND, INCLUDING WARRANTIES OF MERCHANTABILITY, QUALITY, OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE DATA WILL NOT INFRINGE ANY PATENT OR OTHER PROPRIETARY RIGHTS**.

18. NIAAA will not be liable for any loss, harm, illness or other damage or injury arising from the RECIPIENT's handling, use, or disposal of the Data. No indemnification for third party claims is intended, implied, or provided by either Party.

19. This Agreement will be construed in accordance with United States Federal law as applied by the Federal courts in the District of Columbia.

20. Articles 4, 5, 7, 11, 17, and 20 shall survive the expiration or termination of this Agreement.

21. This Agreement may be executed in one or more counterparts, each of which together will be deemed original but all of which together shall constitute one and the same document. A Portable Document Format (PDF) or other common format electronic file or electronic signature will constitute valid execution and delivery of this Agreement. Any communication or notice to be given will be emailed via the contact information listed below.

SIGNATURES BEGIN ON THE NEXT PAGE

FOR NIAAA:
Duly Authorized:

Signature - Megan Ryan, M.B.A.
Technology Development Coordinator, NIAAA

Date

Signature - Aaron White, Ph.D.
Chair, NIAAA Data Access Committee

Date

Address for Notices:
National Institute on Alcohol Abuse and Alcoholism
Attn: NIAAA Technology Development Coordinator
National Institutes of Health
6700B Rockledge Drive, 1324
Bethesda, MD 20892

FOR RECIPIENT:
Duly Authorized:

Signature of the Recipient Authorized Official

Date

Name of the Recipient Authorized Official

Title of the Recipient Authorized Official

FWA #

Read and Understood by the Recipient Investigator:

I have read and understood the terms and conditions of this Agreement, and I agree to abide by them in the receipt and use of the Data.

Signature of the Recipient Investigator

Date

Recipient Investigator Name

Recipient Investigator Title

Recipient Investigator Mailing Address:

Recipient Phone number: _____