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NCANDA Data Distribution Agreement

This **Data Distribution Agreement** is entered into by and between National Institute on Alcohol Abuse and Alcoholism (NIAAA) and

(“**Recipient**”).

WHEREAS, NIAAA, pursuant to its public health mission to identify and characterize the role of alcohol abuse on the developing adolescent brain, supports research projects in which data is collected by scientific investigators;

WHEREAS, SRI, University of California – San Diego (**UCSD**), Oregon Health and Science Center, University of Pittsburgh, and Duke University (“**NCANDA Data Collection Centers**”), all collect data from participants of the National Consortium on Alcohol and Neurodevelopment in Adolescence (**NCANDA**) which is stripped of personal identifiers, i.e., name and any dates including date of birth (“**NCANDA Data**”);

WHEREAS, UCSD serves as the administrative center for the NCANDA Data (“**NCANDA Administrative Center**”), and SRI performs analysis and distribution of the NCANDA Data;

WHEREAS, NIAAA will coordinate the sharing and distribution of NCANDA Data, maintained at SRI, with qualified scientific investigators and institutions who desire to use the NCANDA Data.

NOW THEREFORE, the parties mutually agree as follows:

1. Recipient will submit a signed and dated Data Distribution Agreement to NIAAA for each project for which NCANDA Data is requested.

2. SRI, at the direction of NIAAA, agrees to provide Recipient access to NCANDA Data for the sole use by Recipient's principal investigator ("**Principal Investigator**") to conduct a specific NIAAA pre-approved research project (“**Research Project**”).

3. NCANDA Data will be used by Recipient only in connection with the Research Project. Recipient is responsible for taking all steps to ensure that NCANDA data is not used for unauthorized purposes.

4. Recipient acknowledges that possession and use of the NCANDA Data is at Recipient’s sole risk and expense.

5. This Data Distribution Agreement is not transferable to any third party, including any of Recipient’s subsidiaries or affiliates (“**Third Parties**”). Recipient shall not transfer the Research Project to any Third Party without NIAAA’s prior written consent. With respect to the Research Project, Recipient cannot appoint a new principal investigator, conduct the Research Project at a different facility under Recipient's control, or make other substantive changes, including changes in the research protocol, unless NIAAA is provided with written

notice and Recipient and NIAAA agree to an appropriate amendment of the Data Distribution Agreement.

6. Recipient agrees to retain control over NCANDA Data and further agrees not to provide the NCANDA Data, with or without charge, to any other entity or any individual other than the Principal Investigator of the Research Project and the Principal Investigator's research staff with respect to the Research Project.

7. If SRI chooses to make additional or updated NCANDA Data publicly available, SRI agrees to provide Recipient with access to such additions or updates.

8. Recipient agrees to provide NIAAA, through the NCANDA Administrative Center, with copies of any publications or presentations related to the NCANDA Data within twelve (12) months after receipt of NCANDA Data, or upon the publication of research in which such data were analyzed, whichever comes first, and annually thereafter upon the anniversary of this date. This will continue until the Research Project is completed. NIAAA and the NCANDA Administrative Center may at any time distribute these results to qualified scientific investigators, subject to any patents or pending patent applications of Recipient. Recipient shall provide NCANDA with the results of the Research Project, including but not limited to findings or measurements with respect to the participants of the Research Project, indexed by each participant's ID number, in the electronic format specified by NCANDA. **Recipient also agrees to send to NIAAA annual progress reports which summarize and document all work performed using the NCANDA Data until the conclusion of the Research Project. Such annual progress reports shall be due to NIAAA before December 31 of each respective year.**

9. The Principal Investigator will acknowledge the contributions of NCANDA, which is supported by NIH Grants AA021697, AA021697-04S1, AA021695, AA021692, AA021696, AA021681, AA021690, AA021691, in any and all publications or presentations involving the NCANDA Data. The Principal Investigator will also cite the version number, digital object identifier, and publications that the release of the NCANDA Data specifies (via, for example, the README file provided with the release). The Principal Investigator will not include "NCANDA" as an author of publications or presentations and will not include specific authors from the original publications from which these data are derived, if authorship is based solely on the use of NCANDA Data. Recipient will provide to NIAAA and the NCANDA Administrative Center a list of all such presentations, disclosures, and publications.

10. When the Research Project is completed, Recipient must provide written notification of completion to NIAAA, SRI International, and the NCANDA Administrative Center and must provide written certification of the destruction of all NCANDA data in accordance with all applicable laws and/or accepted safety procedures. The Research Project shall be deemed completed for purposes of this Distribution Agreement three (3) years after the effective date of this Distribution Agreement, unless Recipient obtains NIAAA's consent to extend the term of such Research Project. Any such extension must be in writing and in accordance with the terms and conditions of the Data Distribution Agreement under which SRI International is distributing NCANDA Data to Recipient. If Recipient receives NIAAA's consent to an extension of the Data Distribution Agreement, then Recipient must promptly notify the NCANDA Administrative Center of that extension.

11. Recipient agrees that the NCANDA Data received from SRI International will not be used, either alone or in conjunction with any other information, in any effort whatsoever to establish

the individual identities or contact any of the participants from whom data were obtained.

12. The United States Government, SRI, the NCANDA Administrative Center, NCANDA Data Collection Sites, and subcontractors of these entities are not responsible for the accuracy of data provided to Recipient.

13. THE NCANDA DATA PROVIDED HEREUNDER IS PROVIDED "AS IS" AND SRI MAKES NO REPRESENTATIONS, WARRANTIES, OR CONDITIONS (WHETHER EXPRESS OR IMPLIED, ORAL OR WRITTEN, STATUTORY, OR OTHERWISE) WITH RESPECT TO THE NCANDA DATA, OR ANY PORTION THEREOF, INCLUDING, BUT NOT LIMITED TO, ANY AND ALL IMPLIED WARRANTIES OR CONDITIONS OF TITLE, MERCHANTABILITY, LACK OF NEGLIGENCE, THE NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY, FITNESS OR SUITABILITY FOR A PARTICULAR PURPOSE (WHETHER OR NOT SRI KNOWS, HAS REASON TO KNOW, HAS BEEN ADVISED, OR IS OTHERWISE IN FACT AWARE OF SUCH PURPOSE). UNDER NO CIRCUMSTANCES WILL SRI BE LIABLE TO RECIPIENT OR ANY THIRD PARTY FOR LOST PROFITS, LOST OPPORTUNITIES, OR ANY INCIDENTAL, SPECIAL, OR CONSEQUENTIAL DAMAGES, IRRESPECTIVE OF THE THEORY UNDER WHICH SUCH ACTION IS BROUGHT, WHETHER IT WAS CAUSED OR ALLEGEDLY CAUSED BY THE NEGLIGENCE OF SRI, OR WHETHER OR NOT SRI HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

14. Recipient agrees not to claim, infer, or imply Governmental endorsement of the Research Project, the Recipient, or any 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, SRI International, the NCANDA Administrative Center, NCANDA Data Collection Sites, and subcontractors of these entities harmless and to indemnify all such parties for all liabilities, demands, damages, expenses, and losses arising out of Recipient's possession and use of NCANDA Data.

15. Recipient acknowledges that the collection of NCANDA Data were approved by the Institutional Review Board (IRB) of the local collection sites in accordance with Department of Health and Human Services regulations at 45 CFR Part 46. Recipient agrees to report any unanticipated problems or issues involving risks to subjects or others associated with the use of the NCANDA Data to NIAAA, SRI, and the NCANDA Administrative Center. Recipient remains subject to applicable state and local laws, regulations, and institutional policies that provide additional protection for human subjects.

16. NIAAA may terminate this Data Distribution Agreement if Recipient fails to fully comply with any of the terms specified herein and if the non-compliance has not been remedied within thirty (30) days after the date of written notice by NIAAA of such non-compliance. Upon termination of this Data Distribution Agreement, Recipient agrees to provide NIAAA with written certification of destruction of NCANDA Data.

17. Failure to comply with any of the terms specified herein may result in disqualification of the Recipient from receiving additional NCANDA Data from NIAAA and SRI International.

18. NIAAA reserves the right to distribute, through any mechanism, NCANDA Data to others and to use NCANDA Data for its own purposes.

19. Amendments to the Distribution Agreement must be made in writing with the consent of NIAAA.

20. Recipient expressly certifies that all information provided in connection with this Data Distribution Agreement is truthful and accurate.

21. This Data Distribution Agreement shall be construed in accordance with federal law as applied by federal courts in the District of Columbia.

Recipient's Principal Investigator

Name & Title: _____

Mailing Address: _____

Phone Number: _____

Fax Number: _____

Email: _____

Recipient's Authorized Representative

Name & Title: _____

Mailing Address: _____

Phone Number: _____

Fax Number: _____

Email: _____

SIGNATURES: Save Form

Mail to DD

_____ _____

Recipient's Principal Investigator Date

Save Form

Mail to ES

_____ _____

Recipient's Authorized Representative Date

Save Form

Mail to EPD

_____ _____

NIAAA's Authorized Representative Date