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|  | **DEPARTMENT OF HEALTH & HUMAN SERVICES** | Public Health Service  National Institutes of Health |
|  | National Institute on Alcohol  Abuse and Alcoholism  6700B Rockledge Drive Bethesda, MD 20892-6902 |

**Data Transfer Agreement**

**for the Transfer of Clinical Data for Research Purposes**

This Clinical Data Transfer Agreement (“**Agreement**”) is by and between:

The **National Institute on Alcohol Abuse and Alcoholism ("NIAAA")**, part of the National Institutes of Health, a component of the United States Department of Health and Human Services (“**PROVIDER**”),

**AND**,

Click or tap here to enter text., an academic/non-profit organization having a place of business at *Click or tap here to enter text.* (“**RECIPIENT**”),

for the transfer of data collected from individuals who have participated in clinical research (each a “**Human Subject**”), for research purposes as further defined below. PROVIDER 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**”).

RECIPIENT and PROVIDER agree as follows:

1. The PROVIDER will transfer the following data to the RECIPIENT:

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| ***De-identified data from protocol NIAAA NCIG 002 – Levetiracetam for Alcohol Dependence*** |

which shall hereafter be referred to as the “**Clinical Data**”.

1. The RECIPIENT will only use the Clinical Data for the following internal research project described in Appendix A below, which shall hereafter be referred to as the “**Research Project**”.
2. The RECIPIENT agrees **NOT** to do any of the following:
   1. **Use the Clinical Data in humans or for any diagnostic, prognostic, or treatment purposes;**
   2. Use the Clinical Data for any commercial purposes, including selling, commercial screening, or transferring Clinical Data to a third party for commercial purposes;
   3. Transfer the Clinical 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 the PROVIDER is obtained before any transfer.
3. **If the RECIPIENT receives**:
4. Information from the PROVIDER, or information ascertained through the RECIPIENT’s use of the Clinical Data, that can be used to determine a Human Subject’s identity, either alone or when combined with other personal or identifying information; or
5. The coded Clinical Data with the key to such information in 4(A) above; or
6. Identifiable, sensitive information (“ISI”), as defined in the Public Health Service Act at 42 U.S.C 241(d)(4), regarding the Clinical Data (see <https://humansubjects.nih.gov/coc/faqs>);

**Then the RECIPIENT agrees to:**

1. Abide by all applicable human subjects and other regulations and guidance, which may include:
   1. 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
   2. 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
   3. A certificate of confidentiality issued by the NIH in accordance with 42 U.S.C 241(d) of the Public Health Service Act.
2. 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
3. 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
4. Make no further use or disclosure of the information unless approved by the PROVIDER 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, without specific written approval from the PROVIDER.
6. The RECIPIENT represents that it has obtained Institutional Review Board approval, or the necessary internal authorizations and approvals as appropriate or necessary, to use the Clinical 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 *three (3) years* 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:
   1. Has been published or is otherwise publicly available at the time of disclosure to the receiving Party or was in the possession of or readily available to the receiving Party without being subject to a confidentiality obligation from another source prior to the disclosure;
   2. Has become publicly known, by publication or otherwise, not due to any unauthorized act of the receiving Party; or
   3. The receiving Party can demonstrate it developed independently, or acquired without reference to, or reliance upon, such 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 Clinical Data.
11. 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 Clinical Data present on any physical or cloud-based computer storage device or system. RECIPIENT may retain one (1) copy of Clinical Data for archival purposes and compliance with state, local, and federal government regulations.
12. The Parties agree that this Agreement will be effective for *three (3) years* 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.
13. 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 11, above.
14. In all oral presentations or written publications concerning the use of Clinical Data, the RECIPIENT will acknowledge the PROVIDER’s contribution of Clinical Data, unless requested otherwise by PROVIDER. Specifically, all presentations, papers, published articles, theses, abstracts, dissertations and other written materials that report results based on Clinical Data must include the following acknowledgement and disclaimer, in writing, as appropriate:

*“The author(s) acknowledge(s) that the reported results are, in whole or in part, based on analyses of the Levetiracetam study data set, a multisite clinical trial of alcoholism treatment supported by the National Institute on Alcohol Abuse and Alcoholism, NIH, DHHS. The Levetiracetam study data set is a limited access data set and may be requested by application via NIAAA WEBSITE (*[*http://www.niaaa.nih.gov*](http://www.niaaa.nih.gov)*). This presentation paper/article/chapter/document) has not been reviewed or endorsed by NIAAA and does not necessarily represent the opinions of NIAAA, who are not responsible for the contents.”*

For the purposes of bibliographic citation, the recommended citation is:

* Fertig JB, Ryan ML, Falk DE, Litten RZ, Mattson ME, Ransom J, Rickman WJ, Scott C, Ciraulo D, Green AI, Tiouririne NA, Johnson B, Pettinati H, Strain EC, Devine E, Brunette MF, Kampman K, A Tompkins D, Stout R; NCIG 002 Study Group. 2012. A double-blind, placebo-controlled trial assessing the efficacy of levetiracetam extended-release in very heavy drinking alcohol-dependent patients. *Alcohol Clin Exp Res* 36(8):1421-30.

1. Any Clinical Data delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. **THE PROVIDER 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 CLINICAL DATA WILL NOT INFRINGE ANY PATENT OR OTHER PROPRIETARY RIGHTS**.
2. The PROVIDER 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 Clinical Data. No indemnification for third party claims is intended, implied, or provided by either Party.
3. This Agreement will be construed in accordance with United States Federal law as applied by the Federal courts in the District of Columbia.
4. Articles 4, 5, 7, 11, 15 and 18 shall survive the expiration or termination of this Agreement.
5. 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 PROVIDER**:

***Duly Authorized:***

**Megan Ryan, M.B.A.**

Technology Development Coordinator, NIAAA

**Date**:

**Address for Notices:**

National Institute on Alcohol Abuse and Alcoholism

**Attn**: NIAAA Technology Development Coordinator

National Institutes of Health

5635 Fishers Lane, Room 2051

Bethesda, MD 20892-9304

**Read and Understood by PROVIDER’s Investigator:**

*I represent that the Clinical Data (including any data) that I am providing under this Agreement has all the necessary approvals required (including informed consent forms, Institutional Review Board etc.) to be transferred to RECIPIENT for the uses contemplated in the Research Project.*

**Raye Z. Litten, Ph.D.**

Acting Director

Division of Medications Development

Division of Treatment and Recovery Research

National Institute on Alcohol Abuse and Alcoholism

Date:

**FOR RECIPIENT**:

***Duly Authorized:***

Signature

**Name**:

**Title**:

Date:

**Mailing Address for Notices:**

**Tel**:

**Email**:

**Read and Understood by RECIPIENT’s 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 Clinical Data.*

Signature

**Name**:

**Title**:

Date:

**Mailing Address for Delivery of Data:**

**Tel**:

**Email**:

**Appendix A**

**Data Access Policy, Application and Agreement**

**NIAAA Protocol NCIG 002:**

**A Multisite Double-Blind, Placebo-Controlled Trial of Levetiracetam Extended- Release in Very Heavy-Drinking Alcohol-Dependent Patients**

**Introduction**

This double-blind, randomized placebo-controlled trial evaluated the efficacy and safety of levetiracetam, recruiting 130 alcohol-dependent patients, 24% women and 35% ethnic minorities, from 5 sites. All subjects received either levetiracetam or placebo and Brief Behavioral Compliance Enhancement Treatment (BBCET) intervention. Patients were stratified on clinical site, and SSRI use. No significant differences were detected between the levetiracetam XR and placebo groups in either the primary outcomes (percent heavy drinking days and percent subjects with no heavy drinking days) or in other secondary drinking outcomes.

Treatment groups did not differ on a number of nondrinking outcomes, including depression, anxiety, mood, and quality of life. The only difference observed was in alcohol-related consequences. The levetiracetam XR treatment group showed significantly fewer consequences than did the placebo group during the maintenance period (p=0.02). Levetiracetam XR was well-tolerated, with fatigue being the only significantly elevated adverse event, compared with placebo (53% vs. 24%, respectively; p=0.001).

The study sponsor was the National Institute on Alcohol Abuse and Alcoholism’s (NIAAA) Clinical Investigations Group (NCIG). The data set was prepared by NIAAA and FastTrack Drugs and Biologics (the trial’s Coordinating Center), and was reviewed by CSR Incorporated.

A more detailed overview of the study and main results can be found in the primary publication:

* Fertig JB, Ryan ML, Falk DE, Litten RZ, Mattson ME, Ransom J, Rickman WJ, Scott C, Ciraulo D, Green AI, Tiouririne NA, Johnson B, Pettinati H, Strain EC, Devine E, Brunette MF, Kampman K, A Tompkins D, Stout R; NCIG 002 Study Group. 2012. A double-blind, placebo-controlled trial assessing the efficacy of levetiracetam extended-release in very heavy drinking alcohol-dependent patients. *Alcohol Clin Exp Res* 36(8):1421-30.

**Data Access Application Procedure and Access Policy**

Because the Levetiracetam Study contains individual level data, it is categorized as a controlled access data set. Access will only be provided to research investigators who, along with their institutions, have certified their agreement with the expectations and terms of access detailed in this document.

Qualified researchers should complete (1) the attached Data Access Application form and (2) sign the attached Data Transfer Agreement. This agreement is designed to protect the integrity of the data set and assure client confidentiality. Note that the signature and concurrence of your authorized institutional official is also required. This is ordinarily someone from your technology transfer office. Completed applications may be submitted by e-mail, fax, or mail to:

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| **Raye Z. Litten, Ph.D.**  Acting Director, Division of Medications Development  **National Institute on Alcohol Abuse and Alcoholism**  National Institutes of Health  5635 Fishers Lane, Room 2041  Bethesda, Maryland 20892-9304  (Rockville, Maryland 20852-1705 for Federal Express) | **Tel**: (301) 443-0636  **Fax**: (301) 443-8774  **Email**: [rlitten@mail.nih.gov](mailto:rlitten@mail.nih.gov) |

(application starts next page)

**NCIG 002 - Levetiracetam for Alcohol Dependence**

**Data Access Application**

**Date of Application**: 6/6/2019

**Applicant/Principal Investigator (P.I.):**

|  |  |
| --- | --- |
| **Name:** |  |
| **Affiliation:** |  |
| **Title** |  |
| **Address** |  |
| **Telephone:** |  |
| **Fax:** |  |
| **E-Mail:** |  |
| **Degree(s) Held:** |  |
| **Major Discipline/Field of Study:** |  |

**May we contact you in the event that updates are made to the Levetiracetam data set and/or documentation?** Yes  No

**Authorized Institutional Official**

|  |  |
| --- | --- |
| **Name:** |  |
| **Affiliation:** |  |
| **Title** |  |
| **Address** |  |
| **Telephone:** |  |
| **Fax:** |  |
| **E-Mail:** |  |

**List collaborators and data analysts (including students), if different from applicant**

**If applicant is a student who wishes to use the Levetiracetam data set in a thesis or dissertation, a faculty sponsor must submit this application and self-identify as the Applicant/P.I.**

**Information regarding the student should be provided below.**

**Collaborators, Analysts, Students and other Users**

|  |  |
| --- | --- |
| **Name:** |  |
| **Affiliation:** |  |
| **Title** |  |
| **Address** |  |
| **Telephone:** |  |
| **Fax:** |  |
| **E-Mail:** |  |
| **Degree(s) Held:** |  |
| **Major Discipline/Field of Study:** |  |

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| **Telephone:** |  |
| **Fax:** |  |
| **E-Mail:** |  |
| **Degree(s) Held:** |  |
| **Major Discipline/Field of Study:** |  |

(**Add Additional Individuals as Necessary**)

To better serve users and to learn about their interests in the Levetiracetam data, applicants are asked to briefly describe the types of questions/topics that they plan to study. Please indicate which of the following topics are of interest and briefly describe your plans for using the data set.

|  |  |
| --- | --- |
|  | **Severity of Dependence** |
|  | **Relapse** |
|  | **Treatment process/experiences** |
|  | **Psychopathology** |
|  | **Patient subtypes** |
|  | **Adverse consequences of drinking** |
|  | **Motivation** |
|  | **Compliance** |
|  | **Clinical trials methodology** |
|  | **Psychosocial functioning** |
|  | **Social support** |
|  | **Alcohol consumption patterns** |
|  | **Treatment matching** |
|  | **Treatment outcomes** |
|  | **Other** - |

Please briefly describe your research plan in the space below.

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