**DATA TRANSFER AGREEMENT**

**FOR THE TRANSFER OF CLINICAL DATA**

**FOR NON-COMMERCIAL RESEARCH PURPOSES**

This Data Transfer Agreement ("Agreement"), which is based on the NIH model Human Material Transfer agreement, has been adapted for use by National Institute on Alcohol Abuse and Alcoholism, (NIAAA), of the National Institutes of Health (NIH), an agency of the United States Department of Health and Clinical Services (“PROVIDER”). This Agreement is between NIAAA and the **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** (“RECIPIENT”), located at **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** for the transfer of clinical data for research purposes as further defined below.

PROVIDER and RECIPIENT may each be referred to as “Party” or collectively as “Parties”. This Agreement is effective as of the date of the last authorized signature below.

PROVIDER’s Investigator: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

RECIPIENT’s Investigator: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

RECIPIENT and PROVIDER agree as follows:

1. PROVIDER will transfer to RECIPIENT the following: de-identified data from protocol NIAAA NCIG 001 – Quetiapine for Alcohol Dependence (“Clinical Data”)
2. RECIPIENT will use Clinical Data only for proposed research (as described in Data Access Application and hereinafter referred to as the “Research Project”).
3. RECIPIENT agrees to use Clinical Data for non-commercial research purposes only and will not use Clinical Data for any commercial purposes, including selling, commercial screening, and manufacturing, or transfer Clinical Data to a third party for commercial purposes.
4. **RECIPIENT agrees that Clinical Data may not be used for any diagnostic, prognostic, or treatment purposes.**
5. PROVIDER will **NOT** provide RECIPIENT any associated personally identifiable information or the code to personally identifiable information.
6. RECIPIENT represents that RECIPIENT’s Investigator has obtained Institutional Review Board (IRB) approval, as appropriate, to use Clinical Data.

8. RECIPIENT will allow the use of Clinical Data only by RECIPIENT’s Investigator and RECIPIENT’s Investigator’s research team who are under the direct supervision of RECIPIENT’s Investigator and only after they have been informed of and agreed to the provisions and restrictions stated herein. Any further distribution of Clinical Data beyond RECIPIENT’s Investigator’s immediate research team requires the advance written approval of PROVIDER.

1. If any Confidential Information will be transferred between PROVIDER and RECIPIENT then that Confidential Information is subject to the following:
   1. All information to be deemed confidential under this Agreement shall be clearly marked or otherwise designated as "CONFIDENTIAL" by PROVIDER and maintained in confidence by RECIPIENT for a period of three (3) years from RECIPIENT’s receipt of the Confidential Information. Any Confidential Information that is orally disclosed by PROVIDER to RECIPIENT must be followed by written notification of the confidential nature of the information and such notice must be provided within thirty (30) days of the oral disclosure.
   2. For the purposes of this Agreement, Confidential Information includes any scientific or business information relating to Clinical Data that a Party asserts are confidential and proprietary, except for information that:
2. has been published or otherwise publicly available at the time of disclosure to RECIPIENT; or
3. was in the possession of or was readily available to RECIPIENT without being subject to a confidentiality obligation from another source prior to the disclosure; or
4. has become publicly known, by publication or otherwise, not due to any unauthorized act of RECIPIENT; or
5. RECIPIENT can demonstrate it developed independently, or acquired without reference to, or reliance upon, the Confidential Information; or
6. is required to be disclosed by law, regulation, or court order; or
7. RECIPIENT is expressly authorized by PROVIDER to disclose.
8. RECIPIENT will not contact or make any effort to identify any individual who is or may be the source of Clinical Data, without specific written approval from PROVIDER.
9. RECIPIENT will comply with all laws, rules and regulations applicable to the use of Clinical Data.
10. When the Research Project is completed, or this Agreement expires, or is terminated, whichever occurs first, any Clinical Data will both be destroyed in compliance with all applicable statutes and regulations and certified in writing to PROVIDER as being destroyed. Initiation of an additional research project using Clinical Data may be requested by RECIPIENT via email or post to PROVIDER. PROVIDER will give due consideration to such requests. RECIPIENT will be entitled to retain one (1) copy of Clinical Data for archival purposes for compliance with state, local, and government regulations.
11. In all disclosures concerning the use or analysis of Clinical Data, RECIPIENT will acknowledge 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 Quetiapine study data set, a multisite clinical trial of alcoholism treatment supported by the National Institute on Alcohol Abuse and Alcoholism, NIH, DHHS. The Quetiapine study data set is a limited access data set and may be requested by application via NIAAA WEBSITE (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:

Litten RZ, Fertig JB, Falk DE, Ryan ML, Mattson ME, Collins JF, Murtaugh C, Ciraulo D, Green AI, Johnson B, Pettinati H, Swift R, Afshar M, Brunette MF, Tiouririne NA, Kampman K, Stout R, and the NCIG 001 Study Group (2012). A double-blind, placebo-controlled trial to assess the efficacy of quetiapine fumarate XR in very heavy-drinking alcohol-dependent patients. *Alcohol Clin Exp Res* 36(3):406-16.

1. **PROVIDER makes no express or implied warranties or representations of merchantability or fitness for a particular purpose, or that the use of Clinical Data will not infringe any patent, copyright, trademark, or other proprietary rights.**
2. No indemnification for any loss, claim, damage, or liability is intended or provided by either Party under this Agreement. Each Party shall be liable for any loss, claim, damage, or liability that said Party incurs as a result of said Party’s activities under this Agreement, except that PROVIDER, as an agency of the United States Government, may be liable only to the extent as provided under the Federal Tort Claims Act (28 U.S.C. Chapter 171). No indemnification for third party claims is intended or implied by either Party.
3. Term, Termination, and Survivability
   1. 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.
   2. This Agreement will terminate immediately if the Parties agree mutually, in writing, to termination.
   3. This Agreement will terminate in sixty (60) days after either Party receives written notice of the other Party’s desire to terminate the Agreement except in the case of breach by RECIPIENT, in which case PROVIDER can terminate the Agreement immediately.
   4. Articles 5, 8, 9, 12, 14 and 16 of this Agreement will survive the expiration or termination of this Agreement.
4. This Agreement shall be construed in accordance with United States Federal law as applied by the Federal courts in the District of Columbia.
5. This Agreement may be executed in one or more counterparts, each of which together shall be deemed original but all of which together shall constitute one and the same document. An electronic (e.g. Portable Document Format or PDF) copy of the original signature of the representative of a party shall have the same validity as an original signature for the purpose of this Agreement.

*Signatures begin on next page.*

The Parties have executed this Agreement by their respective duly authorized representatives on the day and year below. Any communication or notice to be given shall be forwarded in writing to the respective addresses listed below.

**FOR PROVIDER**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Megan Ryan, MBA Date

Technology Development Coordinator

Division of Medications Development

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Raye Z. Litten, Ph.D.

Acting Director, Division of Medications Development

NIAAA

Mailing Address for Notices:

NIAAA

Megan Ryan

5635 Fishers Lane, 2051

Bethesda, MD 20892

(301) 443-4225

[mryan1@mail.nih.gov](mailto:TAO@niddk.nih.gov)

**FOR RECIPIENT:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Signature of Authorized Representative) Date

Name

Title

Mailing Address for Notices:

Email:

Phone:

**RECIPIENT’s INVESTIGATOR:**

I have read and understood the terms and conditions of this Agreement and I will abide by them in the receipt and use of this Clinical Data.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name: Date

Address:

Email:

Phone: