

DATA USE AGREEMENT

This **Data Use Agreement** (the "Agreement") is by and between Johns Hopkins University ("JHU") on behalf of the Johns Hopkins Center for Clinical Trials and Evidence Synthesis and the Citalopram for Agitation in Alzheimer's Disease study ("CitAD") with its principal place of business in Baltimore, Maryland, and

_____ /
(name of entity receiving data) ("User")

with its principal place of business in

_____ /
(location of entity receiving data)

and is effective as of _____, 20____ (the "Effective Date").

RECITALS

Congress enacted the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), and subsequently the Health Information Technology for Economic and Clinical Health Act ("HITECH Act"), which provide protections for individually identifiable health information.

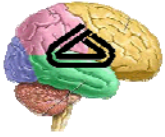
The United States Department of Health and Human Services ("DHHS") promulgated, pursuant to HIPAA, a "Privacy Rule" governing confidential health information; "Privacy Rule" means the regulations promulgated by DHHS to implement the portions of HIPAA that concern the confidentiality of health information, as amended by the HITECH Act and related regulations, and as may be further amended or otherwise changed from time to time. References to 45 CFR in this Agreement refer to sections within the Privacy Rule. At the date of this Agreement, these include 45 CFR §160 and §164, Subparts A, D & E.

JHU maintains certain information that User wishes to use for research, public health, or health care operations purposes permitted under 45 C.F.R. §164.514(e) of the Privacy Rule.

Prior to releasing any confidential health information to User, the Privacy Rule requires JHU to enter into an agreement under which User agrees to certain restrictions on the use and disclosure of the information, and which User agrees to comply with the Privacy Rule.

NOW, THEREFORE, the parties, in consideration of the premises and the mutual promises and obligations set forth herein, the sufficiency of which is hereby acknowledged, and intending to be legally bound, agree as follows:

1. **Access to Data.** JHU shall provide User with access to certain data that must constitute a "limited data set" as defined by the Privacy Rule (see Attachment A) (the "Limited Data Set") in accordance with the terms and conditions of this Agreement. Under no circumstances shall JHU be required under this Agreement to provide the User with any information that does not qualify as part of a "limited data set" under 45 C.F.R. §164.514(e).



2. **Authorized Parties.** The below named individual Principal User, Principal Investigator or Primary Responsible Person, and persons under his/her direct supervision (collectively the “Authorized Parties”), are authorized to use the Limited Data Set or any part of it on behalf of User and agree to abide by the terms of this Agreement:

 Name of Principal User, Principal Investigator or Primary Responsible Person

 Signature of Principal User

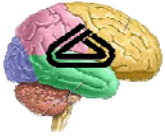
(If there is more than one Principal User, Principal Investigator or Primary Responsible Person, use an attachment to identify that person and obtain his/her signature. The attachment also must be signed by authorized representatives of User and JHU.)

The Principal User, Principal Investigator or Primary Responsible Person is responsible for seeing that those persons under his/her supervision comply with the terms of this Agreement.

3. **Permitted Use.** User, and any Authorized Party on User's behalf, may use the Limited Data Set only for the following purposes (which shall be limited to research, public health activities, and health care operations as defined in the Privacy Rule) and for no other purpose:

Use an attachment to list any additional purposes. The attachment must be signed by authorized representatives of User and JHU.

4. **Conditions of Use.** User and each Authorized Party agree as follows:
- a. Not to use or further disclose the Limited Data Set or any information contained therein other than as permitted by this Agreement or required by applicable law.
 - b. To use appropriate safeguards to prevent use or disclosure of the Limited Data Set or any information contained therein other than as provided for by this Agreement.
 - c. To report promptly to JHU, through the JHU Coordinating Center or through the Johns Hopkins Privacy Office, any access, use or disclosure of the Limited Data Set or any part of it not provided for by this Agreement of which User or any Authorized Party becomes aware.
 - d. To ensure that any agents, including subcontractors, to whom User or an Authorized Party provides the Limited Data Set or any part of it agree to the same restrictions and conditions that apply to the User and Authorized Parties under this Agreement.
 - e. Not to use the information contained in the Limited Data Set to identify the individuals whose information is contained in the Limited Data Set, nor to contact them under any circumstances.



- f. Promptly following the end of the permitted use (as defined in Section 3 above), to return all copies of the Limited Data Set to JHU or destroy them and certify to the destruction; or, if User represents and JHU agrees that neither return nor destruction is feasible, to continue to extend the protections of this Agreement to the Limited Data Set.

5. **Attribution.** User and each Authorized Party agree that any publication or presentation – including grant applications – of analyses or conclusions derived in whole or in part from the Limited Data Set shall be subject to the following:

- a. Prior review: The proposed publication or presentation shall be submitted to the JHU Coordinating Center by email at citad@citadtrial.org no later than fourteen days prior to submission to a journal, society, funding agency, or other entity.
- b. Attribution: Any publication, presentation, or other dissemination shall include the following statement:

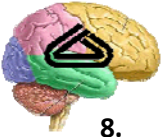
Data used in preparation of this _____ (manuscript, presentation, etc.) were obtained from the Citalopram for Agitation in Alzheimer's Disease (CitAD) study. As such, the CitAD study investigators provided data but did not participate in analysis or writing of this report. The CitAD study was supported by NIA and NIMH, (NIH: R01 AG031348-01; clinicaltrials.gov: NCT00898807).

Publications should normally reference the following two published articles:

1. Porsteinsson AP, Drye LT, Pollock BG, Devanand DP, Frangakis CF, Ismail Z, Marano C, Meinert CL, Mintzer JE, Munro CA, Pelton D, Rabins PV, Rosenberg PB, Schneider LS, Shade DM, Weintraub W, Yesavage J, Lyketsos CG; the CitAD Research Group. Effect of citalopram on agitation in Alzheimer's disease - The JHU randomized controlled trial. *JAMA*. 2014 Feb 19;311(7):682-9.
2. Drye LT, Ismail Z, Porsteinsson AP, Rosenberg PB, Weintraub D, Marano C, Pelton G, Frangakis C, Rabins PV, Munro CA, Meinert CL, Devanand DP, Yesavage J, Mintzer JE, Schneider LS, Pollock BG, Lyketsos CG; CitAD Research Group (includes Shade D). Citalopram for agitation in Alzheimer's disease: design and methods. *Alzheimers Dement*. 2012;8(2):121-30.

6. **Reliance.** User and each Authorized Party acknowledge and agree that JHU has relied upon the promises and covenants made in this Agreement and in disclosing the Limited Data Set hereunder.

7. **Relief.** User and each Authorized Party agree that the breach or threatened breach of this Agreement may cause irreparable harm to JHU and/or individuals, that JHU may not have an adequate remedy at law, and that JHU shall therefore be entitled to injunctive or other equitable relief to enforce this Agreement without obligation to post a bond. In the event JHU becomes aware of any use of the Limited Data Set or any part of it that is not authorized under this Agreement or required by applicable law, JHU may (i) terminate this Agreement upon notice; (ii) disqualify (in whole or in part) the User and/or any Authorized Parties from receiving protected health information in the future; and/or (iii) report the inappropriate use or disclosure to the Secretary of the Department of Health and Human Services. Further sanctions may apply to the User and/or Authorized Parties under 45 C.F.R. parts 160 and 164.

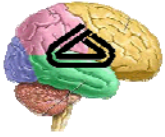


8. **Obligations Following Termination.** Upon expiration or termination of this Agreement for any reason, User and all Authorized Parties shall no longer be entitled to receive or use information contained in the Limited Data Set.
9. **Expiration of Agreement.** Except as otherwise provided in Section 4.f. above, this Agreement shall expire thirty days following satisfaction of the requirements of Section 4.f. above.
10. **Construction and Jurisdiction.** This Agreement shall be governed by and construed in accordance with the laws of the State of Maryland (excepting any conflict of laws provisions which would serve to defeat application of Maryland substantive law).

Each of the parties hereto submits to the exclusive jurisdiction of the state and/or federal courts located within the State of Maryland for any suit, hearing or other legal proceeding of every nature, kind and description whatsoever in the event of any dispute or controversy arising hereunder or relating hereto, or in the event any ruling, finding or other legal determination is required or desired hereunder.

11. **No Assignment.** This Agreement may not be assigned by User or any Authorized Party without the prior written consent of JHU.
12. **Inspection.** Within ten (10) business days of a written request by JHU, User shall allow JHU to conduct a reasonable inspection of User's facilities, systems, books, records, agreements, and policies and procedures relating to the use or disclosure of the Limited Data Set for the purpose of determining User's compliance with this Agreement. Any failure of JHU to inspect or to detect or notify User of an unsatisfactory practice does not constitute acceptance of the practice by JHU or a waiver of any remedy or right JHU has under the Agreement or applicable law.

WHEREFORE, the parties, through their authorized representatives, hereby accept and agree to the terms and conditions of this Agreement.



JOHNS HOPKINS UNIVERSITY

User

By: _____

Name (Printed): _____

Title: _____

Address: _____

Date: _____

(Name of User)

By: _____

Name (Printed): _____

Title: _____

Address: _____

Date: _____

Center for Clinical Trials and Evidence Synthesis

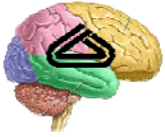
By: _____

Name (Printed): _____

Title: _____

Address: _____

Date: _____



ATTACHMENT A

DEFINITION OF "LIMITED DATA SET"

Limited data set means Protected Health Information that excludes the following direct identifiers of the patient or of relatives, employers, or household members of the patient:

1. Names;
2. Postal address information, other than town or city, State, and zip code;
3. Telephone numbers;
4. Fax numbers;
5. Electronic mail addresses;
6. Social security numbers;
7. Medical record numbers;
8. Health plan beneficiary numbers;
9. Account numbers;
10. Certificate/license numbers;
11. Vehicle identifiers and serial numbers, including license plate numbers;
12. Device identifiers and serial numbers;
13. Web Universal Resource Locators (URLs);
14. Internet Protocol (IP) address numbers;
15. Biometric identifiers, including finger and voice prints;
16. Full face photographic images and any comparable images; and
17. Any other unique identifying number, characteristic, or code except as specifically permitted by HIPAA.