UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

Data Use Agreement

This Data Use Agreement ("Agreement"), effective as of the date of final signature, is entered into by and between the Regents of the University of California, on behalf of its San Francisco campus (hereinafter "the REGENTS") located at 3333 California Street, Suite 315, San Francisco, CA, 94143 and _____(RECIPIENT) located at _____ (RECIPIENT ADDRESS) ("the RECIPIENT"). In response to the RECIPIENT's request for the Brain Health Registry Data (hereafter "BHR DATA"), the REGENTS ask that the RECIPIENT agree to the following before the RECIPIENT receives the BHR DATA:

1. **Definitions**. The parties agree that the following terms when used in this Agreement shall have the following meanings and that the terms set forth below shall be deemed to be modified to reflect any changes made hereafter to such terms by law or regulation.

    a. "*Protected Health Information*" or "*PHI*" means individually identifiable health information, except that Protected Health Information excludes individually identifiable health information in education records covered by the Family Educational Right and Privacy Act, as amended, 20 U.S.C. §1232g, records described at 20 U.S.C. §1232g(a)(4)(B)(iv), and employment records held by a covered entity in its role as employer. PHI may include individually identifiable health information obtained or generated through research activities exclusively for research purposes only, such as health information from questionnaires, interviews, observations of behavior, and even diagnostic tests, as long as none of the information is (i) obtained or generated as part of a health care service (treatment, payment, operations, medical records), (ii) entered into a medical record, or (iii) used to make treatment decisions.

    b. *"Limited Data Set"* includes the following Protected Health Information: procedure dates and time (start, completion, technical difficulties). Such Limited Data Set shall not contain any of the following identifiers of the individual(s) who is(are) the subject(s) of the Protected Health Information, or of relatives, employers or household members of the individual(s): names; postal address information, other than town or city, state and zip code; telephone numbers; fax numbers; electronic mail addresses; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers, including license plate numbers; device identifiers and serial numbers; Web Universal Resource Locators (URLs); Internet Protocol (IP) address numbers; biometric identifiers, including finger and voice prints; and full face photographic images and any comparable images.

    c. *"BHR DATA"* means the Limited Data Set, as specified in Exhibit A. The BHR DATA shall not contain any data generated by third-party vendors unless approval to use such data is obtained by Data User from the appropriate third-party vendor. Written and signed approval from the third-party vendor is required to be submitted to the REGENTS before such data will be transferred. BHR is not responsible for data from third-party vendors.

    d. "Confidential Information" means the proprietary and confidential information communicated by one Party to the other in writing, marked as "Confidential" or, in the case of oral disclosures, identified at the time of such oral disclosure as confidential, and reduced to writing and identified as "Confidential" within thirty (30) days of disclosure.

2. **Obligations of the REGENTS**
    a. The above BHR DATA is the property of the REGENTS and is made available as a service to the research community.

b. EXCEPT AS EXPRESSLY STATED HEREIN, THE REGENTS MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE BHR DATA WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Unless prohibited by law, RECIPIENT assumes all responsibility for claims for damages against it by third parties to the extent arising from the RECIPIENT'S use of the BHR DATA. NOTWITHSTANDING ANY OTHER PROVISION OF THIS AGREEMENT, NEITHER OF THE PARTIES, OR THEIR AFFILIATES, OR ANY OF THEIR RESPECTIVE DIRECTORS, TRUSTEES, OFFICERS, EMPLOYEES, OR AGENTS SHALL HAVE ANY LIABILITY FOR ANY SPECIAL, INCIDENTAL, INDIRECT, OR CONSEQUENTIAL DAMAGES, INCLUDING BUT NOT LIMITED TO THE LOSS OF OPPORTUNITY, OR LOSS OF REVENUE OR PROFIT.

3. **Obligations of the RECIPENT**

a. The BHR DATA will be used for teaching or research activities described herein: [describe the proposed research using the dataset in detail].

b. *Use of Data from Third-Party Vendors*. To the extent the RECIPENT obtains approval to use a third-party vendor's cognitive data, the RECIPENT is prohibited from using BHR DATA for the purpose of comparing its quality or value with cognitive data provided by any other third-party vendor.

c. The RECIPIENT will use the BHR DATA in compliance with all applicable statutes and regulations.

d. The BHR DATA will not be further distributed to others without the REGENTS' written consent.

e. The RECIPIENT will refer any request for the BHR DATA to the REGENTS. The REGENTS may make the BHR DATA available under a separate Agreement to other scientists for teaching or not-for-profit research purposes only.

f. RECIPIENT agrees to use appropriate safeguards to prevent any use or disclosure of the BHR DATA other than as specified in this Agreement.

g. RECIPIENT will require that any agents, including any subcontractors, to whom it provides the BHR DATA, agrees to the same restrictions and conditions that apply to the RECIPIENT.

h. CONFIDENTIALITY. The RECIPENT shall use reasonable efforts not to disclose the REGENTS Confidential Information to anyone except those working under the supervision of the Principal Investigator for the purposes of the Research Services. The RECIPENT will use the Confidential Information only in the conduct of the Research Services and evaluation of its results. The obligations of confidentiality set forth herein shall remain in effect for a period of five (5) years from the Effective Date. The RECIPENT shall have no obligations under this paragraph with respect to information which:

i. was known to it prior to receipt hereunder, as demonstrated by written records;
ii. at the time of disclosure was generally available to public, or which after disclosure becomes generally available to the public through no fault attributable to the RECIPENT;

iii. is hereafter made available to the RECIPENT for use or disclosure by the REGENTS from any third Party having a right to do so;
iv. is required to be disclosed by law, governmental rule or regulation or order of a court with competent jurisdiction; or
v. is independently developed by the RECIPENT without reference to the Confidential Information

4. **PUBLICATION.** This section is not intended to limit any publication rights of either Party.
   a. BHR faculty and staff have invested considerable effort and already have extensive experience in creating the BHR dataset. Thus, BHR faculty and staff wish to be involved with any data analyses and publications that use BHR DATA. Therefore, it is BHR policy that all investigators who receive BHR DATA adhere to the BHR Publication Guidelines, as specified in Exhibit B, which includes Citation and Acknowledgment requirements for all abstracts, presentations, and publications using shared BHR DATA.
   b. All data recipients are asked to explicitly inform BHR faculty of the data analysis plan, as well as to discuss the BHR faculty's degree of involvement in analysis projects and authorship of any potential abstracts and papers. Each Party, consistent with academic standards, may utilize any data or information that may result from the Project in publications or presentations, provided such publication or presentation does not disclose the other Party's Confidential Information.
   c. The Parties agree that any publication or presentation of BHR DATA shall appropriately cite the contributions of both Parties, using customary standards of scientific attribution. The RECIPIENT will acknowledge The Department of Radiology and Biomedical Engineering, The Regents of the University of California, Dr. Michael Weiner, Principal Investigator, and the Brain Health Registry as the source of the BHR DATA in any publications reporting the use of the BHR DATA.
   d. Each Party shall provide the other Party with such publication or presentation thirty (30) days prior to submission for presentation or publication to permit protection of any Confidential Information and/or patent rights, if desired and applicable. Publication of results from 3rd party data must be submitted forty-five (45) days prior to allow an opportunity for the 3rd party to review. Note: although there is no guarantee of approval, Collaborator may request a shorter publication review timeline, which UCSF may grant at its own discretion.

5. **Material Breach, Enforcement and Termination.** This Agreement will terminate on the earliest of the following dates: (a) on thirty (30) days written notice by either party to the other, or (b) five (5) years from the date of the REGENTS execution of this Agreement.

6. **Miscellaneous Terms.** Neither party shall use the name, logo, symbol, or mark of the other party or any party's employee in any advertising or promotional material without the prior written approval of the other party.

The REGENTS, RECIPIENT and RECIPIENT SCIENTIST must sign this letter and return one signed copy to The REGENTS. The REGENTS will then send or allow access to the BHR DATA.

SIGNATURES ON THE NEXT PAGE

REGENTS INFORMATION and AUTHORIZED SIGNATURE

Regents Scientist: Michael Weiner

Regents Organization: University of California, San Francisco

Address: 3333 California Street, Suite 315, San Francisco, CA, 94143

Name of Authorized Official: _____

Title of Authorized Official: _____

Certification of Authorized Official:

_____ _____

Signature of Authorized Official Date

RECIPIENT INFORMATION and AUTHORIZED SIGNATURE

Recipient Scientist: _____

Recipient Organization: _____

Address: _____

Name of Authorized Official: _____

Title of Authorized Official: _____

Signature of Authorized Official/
Date Signed: _____

Date

Acknowledgement of Recipient Scientist: I have read and understood the conditions outlined in this Agreement, and I understand my obligations as an employee of the RECIPIENT regarding the receipt and use of the BHR DATA.

_____ _____

Recipient Scientist Date

EXHIBIT A
DATA SHARING SPECIFICATIONS

The following questionnaire and cognitive test data will be shared:

Participant Questionnaires

☐ ALL
☐ Baseline/Longitudinal Initial Questionnaire
☐ Caregiver Experience
☐ Combat Exposure
☐ Current Medications
☐ Demographics
☐ Depression History
☐ Diet
☐ Early History
☐ Everyday Cognition
☐ Family History
☐ Genetic Study Participation
☐ Head Injury and Concussion
☐ Hoarding and Cluttering
☐ Medical History
☐ Mood
☐ My Study Partner
☐ Profile
☐ PTSD Checklist
☐ Quality of Life
☐ Sleep

Participant Cognitive Tests
**Note- receipt and use of 3rd party cognitive tests requires preapproval from 3rd parties and acknowledgement of non-comparisons.*

☐ ALL
☐ Cogstate Brief Battery
☐ Lumos NeuroCognitive Performance Test
☐ Memtrax Brief Memory Test

Study Partner (CASPP) Questionnaires

☐ ALL
☐ Baseline/Longitudinal Initial Questionnaire
☐ Caregiver Experience
☐ Everyday Cognition
☐ Functional Activities
☐ Mild Behavioral Impairment Checklist
☐ Profile
☐ Subject Relationship

Other

☐ Subject Referral

Frequency of Data Transfer

☐ One time
☐ Annually
☐ Quarterly
☐ Monthly
☐ Other: _____

EXHIBIT B
BHR PUBLICATION GUIDELINES

A. Publication Guidelines Introduction

It is BHR policy that all investigators who receive BHR data adhere to the BHR Publication Guidelines, which includes Citation and Acknowledgment requirements for all abstracts, presentations, and publications using shared BHR data.

Additionally, all data recipients are asked to explicitly inform BHR investigators of the data analysis plan, as well as to discuss BHR investigators' degree of involvement in analysis projects and authorship of any potential abstracts and papers. BHR faculty and staff have invested considerable effort and have extensive experience in creating the BHR data set. Thus, BHR faculty and staff wish to be involved with any data analyses and publications that use BHR data.

B. Required Citation and Acknowledgment of the UCSF Brain Health Registry Project that was the Source of the Data Set

The Parties agree that any publication or presentation of BHR data shall appropriately cite contributions using customary standards of scientific attribution.

As part of the Data Use Agreement, the Recipient will agree to acknowledge The Department of Radiology and Biomedical Engineering, The Regents of the University of California, Dr. Michael Weiner, Principal Investigator, and the Brain Health Registry as the source of the BHR data in any publications reporting the use of the BHR data.

Authorship requirements for all publications are described below. Unless other agreements are made with the Brain Health Registry investigators, Brain Health Registry co-investigators should be included as authors on all publications: Michael W. Weiner, R. Scott Mackin, Rachel L. Nosheny.

1. Meeting Abstracts

a. Authorship: should include Michael W. Weiner, R. Scott Mackin, Rachel L. Nosheny unless other agreements are made with the Brain Health Registry investigators. Or, should include "Brain Health Registry" as the final author.

b.

c. Methods section: "Data for these analyses are from the UCSF Brain Health Registry."

2. Manuscripts

a. Methods section: "Data used in the preparation of this manuscript were obtained from the UCSF Brain Health Registry, an Internet based registry that facilitates clinical research."

b. Acknowledgment: "This manuscript was prepared using a data set obtained from the UCSF Brain Health Registry (The Department of Radiology and Biomedical Engineering, The Regents of the University of California, Dr. Michael Weiner, Principal Investigator) and does not necessarily reflect the opinions or views of the UCSF Brain Health Registry investigators, the NIH or the private funding partners."

c. **Authorship**: should include Michael W. Weiner, R. Scott Mackin, Rachel L. Nosheny unless other agreements are made with the Brain Health Registry investigators.

3. **Presentations**

   Methods section: “Data for these analyses are from a UCSF Brain Health Registry data set.”

   Acknowledgment: “This presentation was prepared using a data set obtained from UCSF Brain Health Registry (The Department of Radiology and Biomedical Engineering, The Regents of the University of California, Dr. Michael Weiner, Principal Investigator) and does not necessarily reflect the opinions or views of the UCSF Brain Health Registry investigators, the NIH or the private funding partners.”

C. Informing BHR about Publications Based on BHR Related Data

   All data recipients are also asked to explicitly inform BHR faculty and staff of any data analyses and publications using BHR data at least thirty (30) days prior to submission. If the analyses or publications include results from 3rd party data, it must be provided to BHR faculty and staff forty-five (45) days prior to submission to allow an opportunity for the 3rd party to review.

Contact: investigators@brainhealthregistry.org