



Rush University Medical Center

Data Use Agreement FOR LIMITED DATA SET RECIPIENT

THIS Data Use Agreement (“Agreement”) is effective upon execution and is entered into by and between _____ (“Recipient”) and Rush University Medical Center (“Data Provider”).

WHEREAS, Recipient and Data Provider are or may become parties to one or more agreements (collectively, the “Primary Agreement”) pertaining to certain research involving the use of the Limited Data Set (as hereinafter defined) provided by Data Provider (the “Study”); and

WHEREAS, Data Provider and Recipient mutually agree to enter into this Agreement to comply with the requirements of Provider’s institutional policies and procedures (e.g. Institutional Review Board approval) for the transfer, handling, storage and management of anything provided to Recipient from Data Provider to the extent that those policies and procedures apply and to comply with all applicable federal and state laws and regulations governing patient privacy and confidentiality of health information, including without limitation Section 514(e) of the Privacy Rule, 45 Code of Federal Regulations (“C.F.R.”) section 164.514(e), issued pursuant to the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”).

1. **Definitions.** The capitalized terms “Health Care Operations,” “Required by Law,” and “Research” have the meanings set forth in 45 C.F.R. section 164.501. The capitalized term “Public Health Activities” has the meaning set forth in 45 C.F.R. 164.512(b). For convenience of reference, the definitions of “Protected Health Information” and “Limited Data Set” as of the Effective Date are as follows:

- a) **“Limited Data Set”** means Protected Health Information (as hereinafter defined) that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual: (i) Names; (ii) Postal address information, other than town or city, State, and zip code; (iii) Telephone numbers; (iv) Fax numbers; (v) Electronic mail addresses; (vi) Social security numbers; (vii) Medical record numbers; (viii) Health plan beneficiary numbers; (ix) Account numbers; (x) Certificate/license numbers; (xi) Vehicle identifiers and serial numbers, including license plate numbers; (xii) Device identifiers and serial numbers; (xiii) Web Universal Resource Locators (URLs); (xiv) Internet Protocol (IP) address numbers; (xv) Biometric identifiers, including finger and voice prints; and (xvi) Full face photographic images and any comparable images.

- b) **“Protected Health Information”** shall have the same meaning as the term “protected health information” in 45 C.F.R. § 164.501, limited to the information created or received by Recipient from or on behalf of Data Provider.
2. **Provision of Limited Data Set.** Upon Recipient’s execution of this Agreement, Data Provider will provide Recipient a Limited Data Set: A) that contains the minimum amount of Protected Health Information reasonably necessary for the purposes as set out in Section 3 of this Agreement, for which Recipient is to receive the Limited Data Set; and B) from which all of the direct identifiers, as specified in 45 C.F.R. section 164.514(e)(2), of the individuals whose Protected Health Information is included in the Limited Data Set and of the relatives, household members and employers of those individuals have been removed.
3. **Recipient’s Permitted Uses and Disclosures.** Recipient is permitted to use and disclose the Limited Data Set for the purposes set out in the attached Exhibit(s). There is at least one Exhibit attached to this Agreement but additional Exhibits may be executed and added after this Agreement is executed if additional purposes are desired.
- Distribution of the data to any third party is prohibited except with express written approval of the Data Provider.
4. **Prohibition on Unauthorized Uses and Disclosures.** A) Recipient will neither use nor disclose the Limited Data Set for any purpose other than as permitted by Section 3 of this Agreement, as otherwise permitted in writing by Data Provider, or as Required by Law; B) Recipient is not authorized to use or disclose the Limited Data Set in a manner that would violate the Privacy Rule, 45 C.F.R. Part 164, Subpart E, if done by Data Provider; C) Recipient will not attempt to identify the information contained in the Limited Data Set or contact any individual who may be the subject of information contained in the Limited Data Set.
5. **Information Safeguards.** Recipient will adopt and use appropriate administrative, physical, and technical safeguards to preserve the integrity and confidentiality of the Limited Data Set and to prevent its use or disclosure, other than as permitted by Section 3 of this Agreement, as otherwise permitted in writing by Data Provider, or as Required by Law.
7. **Permitted Recipients, Subcontractors, and Agents.** Recipient will require any agent or subcontractor to which Recipient is permitted by this Agreement or in writing by Data Provider to disclose and let use the Limited Data Set to agree by written contract to comply with the same restrictions and conditions that apply to Recipient’s use and disclosure of the Limited Data Set pursuant to this Agreement.
8. **Reporting.**

- a) In all oral presentations or written publications concerning the Data, Recipient will acknowledge Data Provider's contribution of the Limited Data Set as scientifically appropriate unless requested otherwise by Data Provider.
- b) Before Recipient submits a paper or abstract for publication or otherwise publicly discloses information about the Limited Data Set, Recipient shall ensure that Data Provider has at least thirty (30) days to review the proposed publication or disclosure. Data Provider reserves the right to delete information that is considered Confidential Information of the Data Provider. When used in this Agreement, the term "Confidential Information" means confidential and proprietary information disclosed by the Provider that, prior to disclosure, is marked with a legend indicating its confidential status, or is disclosed orally or visually if the Data Provider identifies such information as confidential at the time of disclosure. In no event is information Confidential Information if it:
 - (A) was in Recipient's possessions before receipt from Data Provider;
 - (B) is or becomes a matter of public knowledge through no fault of Recipient;
 - (C) is received by Recipient, without restriction as to further disclosure, from a third party having an apparent bona fide right to disclose the information to Recipient;
 - (D) is independently developed by Recipient without the use of Data Provider's Confidential Information;
 - (E) is required to be disclosed by law or court order.
- c) Recipient acknowledges that information contained in the Limited Data Set was received through funding provided by a federal agency and the corresponding Federal Grant number(s), supplied to Recipient by the Data Provider, will be used by Recipient in reporting on the Limited Data Set.
- d) If any data developed by Recipient was generated from use of this Limited Data Set through the use of public funds (including but not limited to federal, state or local funds) , then this new data generated from the Limited Data Set will be provided to Data Provider at no cost to Data Provider so that it can be repurposed (including but not limited to sharing with other investigators): i) one year after data generation or ii) at the time of publication, whichever comes first; or iii) at a time mutually agreed upon by both parties.

9. **Intellectual Property.** Recipient agrees that if the Study results in an invention, a new use, or a product (collectively referred to as an "Invention") based on or relating to the Limited Data Set, Recipient will promptly disclose the Invention to Data Provider on a confidential basis. Inventorship will be determined in accordance with U.S. patent law (if patentable) or by mutual agreement between the Parties (if not patentable), taking into account the role and contributions of individuals involved in the development of the Invention.

Recipient further agrees that it shall not apply or file for any intellectual property protection, including without limitation, patent protection, in any jurisdiction, incorporating any of the Limited Data Set or resulting Invention or an application from which contains or directly incorporates use of the Limited Data Set without express prior written permission of Data Provider.

If the use of the Limited Data Set in any way results in the development of any Invention with a possible commercial value, Recipient must notify Data Provider of that development and Recipient and Data Provider will negotiate in good faith and enter into a separate agreement on commercially reasonable terms and conditions for the equitable distribution of income from any commercial use, manufacture, or sale of the new intellectual property, products or procedures, taking into consideration the contribution of the Limited Data Set to the new intellectual property, products or procedures. Recipient is expressly prohibited from making any profit-making or commercial use of the Limited Data Set, whether alone or in collaboration with any party, without express prior written permission of Data Provider. Further, if the use of the Limited Data Set results in the development of any Invention and was generated by the use of public funds (including but not limited to federal, state or local funds) , then this Invention will be provided to Data Provider at no cost to Data Provider so that it can be used for research or educational purposes.

10. **Breach of Privacy Obligations.** Recipient will report to Data Provider any use or disclosure of the Limited Data Set that is not permitted by this Agreement or in writing by Data Provider. Recipient will make the report to Data Provider's Privacy Officer within five (5) business days after Recipient learns of such non-permitted use or disclosure. Recipient's report will at least: A) identify the nature of the non-permitted use or disclosure; B) identify the Limited Data Set content used or disclosed; C) identify who made the non-permitted use or disclosure and who received the non-permitted disclosure; D) identify what corrective action Recipient took or will take to prevent further non-permitted uses or disclosures; E) identify what Recipient did or will do to mitigate any deleterious effect of the non-permitted use or disclosure; and F) provide such other information, including a written report, as Data Provider may reasonably request.
11. **Knowledge of Non-Compliance.** Any non-compliance by Recipient with this Agreement or with HIPAA or the HIPAA Regulations automatically will be considered a breach or violation of a material term of this Agreement if Recipient knew or reasonably should have known of such non-compliance and failed to immediately take reasonable steps to cure the non-compliance.
12. **Indemnification.** Recipient shall indemnify, hold harmless and defend Data Provider from and against any and all claims, losses, liabilities, costs and other expenses resulting from, or relating to, the acts or omissions of Recipient in connection with the representations, duties and obligations of Recipient under this Agreement.

13. **Termination for Breach.** Data Provider may terminate this Agreement and the Primary Agreement (if applicable) if it determines, in its sole discretion, that Recipient has breached any provision of this Agreement. Data Provider may exercise this termination right by providing Recipient written notice of termination that states the breach of this Agreement that provides the basis for the termination. Any such termination will be effective immediately or at such other date specified in Data Provider's notice of termination. The obligations of Section 3 of this Agreement will survive termination of this Agreement.
14. **Expiration.** Except with respect to any provision hereof that by its terms will survive termination or expiration of this Agreement, this Agreement will expire on the date set forth in the attached Exhibit(s). Each Exhibit shall have its own expiration date that will apply to this Agreement.
15. **Return of Limited Data Set.**
 - a) Upon termination or expiration of this Agreement, Recipient will, if feasible: A) return to Data Provider or destroy the Limited Data Set; and B) obtain from each subcontractor, agent or other recipient that received the Limited Data Set under Section 5 of this Agreement, the return or destruction of the Limited Data Set.

The return or destruction must include (X) the Limited Data Set; (Y) all copies of the Limited Data Set; and (Z) any work derived from the Limited Data Set that may allow identification of any individual whose information is contained in the Limited Data Set, in the custody or under the control of Recipient or of such subcontractor, agent or other recipient, whether in tangible or electronic medium. Recipient will complete such return or destruction as promptly as possible, but not later than ten (10) days after the effective date of the termination or expiration of this Agreement, and will within such period certify in writing to Data Provider that such return or destruction has been completed.
 - b) If return or destruction is not feasible, Recipient will within ten (10) days after the effective date of the termination or expiration of this Agreement: A) provide Data Provider with a written explanation why return or destruction is not feasible; and B) certify in writing to Data Provider that Recipient or subcontractor or agent or other recipient under Section 5 of this Agreement, will neither use nor disclose the Limited Data set for any purpose other than the purposes that make return or destruction of the Limited Data Set infeasible. In addition to the foregoing, in accordance with Section 17(b) hereof, Recipient will extend the protections set forth under the Agreements to any portion of the Limited Data Set retained by Recipient for so long as Recipient retains such Limited Data Set.
16. **Notification.** All notices pursuant to this Agreement must be given in writing and shall be effective when received if hand-delivered, or upon dispatch if sent by reputable overnight delivery service or U.S. Mail to the appropriate address as set forth on the last page of this Agreement.

17. **General Provisions.**

- a) **Amendment to Agreement.** Upon the compliance date of any final regulation or amendment to a final regulation, promulgated by the U.S. Department of Health and Human Services pursuant to the Administrative Simplification provision of HIPAA Title II, Subtitle F, that affects Limited Data Sets, this Agreement and the Primary Agreement (if applicable) of which it is a part will automatically amend such that the obligations imposed on Recipient remain in compliance with the final regulation, unless either party elects to terminate this Agreement by providing written notice of termination to the other party at least ninety (90) days before such compliance date. The obligations of Section 15 of this Agreement will apply to such termination, and the obligations of Section 3 of this Agreement will survive such termination.
- b) **Continuing Privacy Obligations.** Recipient's obligation to protect the privacy of the Limited Data Set is continuous and survives any termination, cancellation, expiration, or other conclusion of this Agreement with respect to any portion of the Limited Data Set Recipient maintains after such termination, cancellation, expiration or other conclusion of this Agreement.

18. **Conflicts.** The terms and conditions of this Agreement will override and control any conflicting term or condition of any other agreement between the parties to the extent that such conflicting term or condition affects Limited Data Sets.

[Signature page follows]

_____ **IN WITNESS WHEREOF**, Data Provider and Recipient have caused this Agreement to be executed by duly authorized officers as of the day and year first written above.

RECIPIENT INSTITUTION:

_____ Address for notices:
By: _____
Its: _____

Recipient Scientist Read & Understood:

By: _____
Its: _____

DATA PROVIDER:

_____ Address for notices:
By: Thomas Wilson
Its: Assistant Vice President
Rush Alzheimer's Disease Center
600 S Paulina St., 1022
Chicago, IL 60612

Copy to:
Rush University Medical Center
Office of Legal Affairs
1700 W. Van Buren, Suite 301
Chicago, IL 60612

Provider Scientist Read & Understood:

By: _____
Its: _____