Data Use Agreement

Background

A data use agreement allows a researcher to share a limited data set with a colleague or another person or entity not associated with the study or the researcher's institution.

An Institutional Review Board (IRB) must be notified if a researcher or institution plans to share a limited data set with a recipient (person or entity) not named in the original IRB application. That recipient must sign a data use agreement before the limited data set is shared. A data use agreement is not required if the recipient is part of the trial and is included in the IRB Authorization or waiver of Authorization approval for the trial.

Of note:

(a) Limited data sets are not subject to the HIPAA Accounting for Disclosures provisions.

(b) Under 2013 revisions to HIPAA, unauthorized uses or disclosures of a limited data set may constitute a 'breach' for breach notification rule purposes.

If you have questions about the information above or the need for a data use agreement, please consult Notre Dame Research Compliance or the University's General Counsel.

What is a Limited Data Set?
A "limited data set" is defined as health information that excludes certain direct identifiers (listed below) but that may include city; state; zip code; elements of date; and other numbers, characteristics, or codes not listed as direct identifiers (below). The Privacy Rule's limited data set provisions requiring the removal of direct identifiers apply both to information about the individual and to information about the individual's relatives, employers, or household members.
The following identifiers **must** be removed to qualify as a limited data set:

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 fingerprints and voiceprints

16. Full-face photographic images and any comparable images

What is a Data Use Agreement?

A data use agreement is the means by which covered entities obtain satisfactory assurances that the recipient of the limited data set will use or disclose the PHI in the data set only for specified purposes. Even if the person requesting a limited data set from a covered entity is an employee or otherwise a member of the covered entity's workforce, a written data use agreement meeting the Privacy Rule's requirements must be in place between the covered entity and the limited data set recipient.

DATA USE AGREEMENT FOR LIMITED DATA SETS

This Data Use Agreement ("Agreement"), effective as of _____, 20__ ("Effective Date"), is entered into by and between _____ ("Recipient") and _____ _____ ("Covered Entity"). The purpose of this Agreement is to provide Recipient with access to a Limited Data Set ("LDS") for use in the following titled research project: _____ (Project Name) under the direct supervision of _____ (Principal Investigator) in accord with the HIPAA Regulations.

1. <u>Definitions.</u> Unless otherwise specified in this Agreement, all capitalized terms used in this Agreement not otherwise defined have the meaning established for purposes of the "HIPAA Regulations" codified at Title 45 parts 160 through 164 of the United States Code of Federal Regulations, as amended from time to time.

2. <u>Preparation of the LDS.</u> Covered Entity shall prepare and furnish to Recipient a LDS in accord with the HIPAA Regulations. **NOTICE: This agreement is valid only if the Data do not include any of the following "Prohibited Identifiers": Names; postal address information other than town, cities, states and zip codes; telephone and fax numbers; email addresses, URLs and IP addresses; social security numbers; certificate and license numbers; vehicle identification numbers; device identifiers and serial numbers; biometric identifiers (such as voice and fingerprints); and full face photographs or comparable images.**

3. <u>Minimum Necessary Data Fields in the LDS.</u> In preparing the LDS, Covered Entity or its Business Associate shall include the data fields specified by the parties from time to time, which are the minimum necessary to accomplish the purposes set forth in Section 5 of this Agreement.

4. <u>Responsibilities of Recipient.</u>

   Recipient agrees to:

   a. Use or disclose the LDS only as permitted by this Agreement or as required by law;

   b. Use appropriate safeguards to prevent use or disclosure of the LDS other than as permitted by this Agreement or required by law;

   c. Report to Covered Entity any use or disclosure of the LDS of which it becomes aware that is not permitted by this Agreement or required by law, including the presence of prohibited identifiers in the LDS;

   d. Require any of its subcontractors or agents that receive or have access to the LDS to agree to the same restrictions and conditions on the use and/or disclosure of the LDS that apply to Recipient under this Agreement; and

   e. Not use the information in the LDS, alone or in combination to identify or contact the individuals who are data subjects.

5. <u>Permitted Uses and Disclosures of the LDS.</u> Recipient may use and/or disclose the LDS only for the Research described in this Agreement or as required by law.

6. <u>Term and Termination.</u>

   a. <u>Term.</u> The term of this Agreement shall commence as of the Effective Date and terminate 5 years from Effective Date. Should the Recipient desire to keep the LDS for a longer period, a justification in writing should be made to the Covered Entity.

   b. <u>Termination by Recipient.</u> Recipient may terminate this agreement at any time by notifying the Covered Entity and returning or destroying the LDS.

   c. <u>Termination by Covered Entity.</u> Covered Entity may terminate this agreement at any time by providing thirty (30) days prior written notice to Recipient.

   d. <u>For Breach.</u> Covered Entity shall provide written notice to Recipient within ten (10) days of any determination that Recipient has breached a material term of this Agreement. Covered Entity shall afford Recipient an opportunity to cure said alleged material breach upon mutually agreeable terms. Failure to agree on mutually agreeable terms for cure within thirty (30) days shall be grounds for the immediate termination of this Agreement by Covered Entity.

   e. <u>Effect of Termination.</u> Sections 1, 4, 5, 6(e) and 7 of this Agreement shall survive any termination of this Agreement under subsections c or d.

7. <u>Miscellaneous</u>.

a. <u>Change in Law.</u> The parties agree to negotiate in good faith to amend this Agreement to comport with changes in federal law that materially alter either or both parties' obligations under this Agreement. Provided however, that if the parties are unable to agree to mutually acceptable amendment(s) by the compliance date of the change in applicable law or regulations, either Party may terminate this Agreement as provided in section 6.

b. <u>Construction of Terms.</u> The terms of this Agreement shall be construed to give effect to applicable federal interpretative guidance regarding the HIPAA Regulations.

c. <u>No Third Party Beneficiaries.</u> Nothing in this Agreement shall confer upon any person other than the parties and their respective successors or assigns, any rights, remedies, obligations, or liabilities whatsoever.

d. <u>Counterparts.</u> This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, each of the undersigned has caused this Agreement to be duly executed in its name and on its behalf.

COVERED ENTITY   **RECIPIENT**

By: _____   By: _____

Print Name: _____   Print Name: _____

Print Title: _____   Print Title: _____