

SAMPLE

DATA USE AGREEMENT BETWEEN THE FACILITY AND [Insert Name of Data Set Recipient/Researcher]

This Data Use Agreement is made and entered into on [Insert Date] by and between [insert Holder name], hereafter "Holder" and [insert Recipient name], hereafter "Recipient."

This agreement sets forth the terms and conditions pursuant to which Holder will disclose certain protected health information, (PHI) in the form of a Limited Data Set to the Recipient.

Terms used, but not otherwise defined, in this Agreement shall have the meaning given the terms in the HIPAA Regulations at 45 CFR Part 160-164.

1. Permitted Uses and Disclosures

- 1.1 Except as otherwise specified herein, Recipient may make all uses and disclosures of the Limited Data Set necessary for (choose one):
 - Research _____
 - Public Health _____
 - Health Care Operations _____
- 1.2 In addition to the Recipient, the following individuals, or classes or individuals, are permitted to use or receive the Limited Data Set for purposes stated above: [insert names or classes of persons who may use or receive the limited data set, e.g. the researcher's staff, any collaborators, other clinical sites involved in the research, sponsors if applicable, outside laboratories].
- 1.3 To the extent that the classes of persons are not part of the Recipient's workforce who are directly involved in using the Limited Data Set, the Recipient shall enter into a Data Use Agreement with the other classes of persons before such release of the Limited Data Sets.

2. Recipient Responsibilities

- 2.1 Recipient will not use or further disclose the Limited Data Set for any purpose other than permitted by this Agreement pertaining to the use stated above, or as required by law;
- 2.2 Recipient will use appropriate administrative, physical, and technical safeguards to prevent use or disclosure of the Limited Data Set other than as provided for by this Agreement;
- 2.3 Recipient will report to the Holder any use or disclosure of the Limited Data Set not provided for by this Agreement of which the Recipient becomes aware as soon as Recipient becomes aware of such use or disclosure;
- 2.4 Recipient will ensure that any agent, including a subcontractor, to whom it provides the Limited Data Set, agrees to the same restrictions and

conditions that apply through this Agreement to the Recipient with respect to the Limited Data Set;

2.5 Recipient will not identify the information contained in the Limited Data Set; and

2.6 Recipient will not contact the individuals who are the subject of the PHI contained in the Limited Data Set.

3. Term and Termination

3.1 The terms of this Agreement shall be effective as of [insert effective date], and shall remain in effect until all PHI in the Limited Data Set provided to the Recipient is destroyed or returned to the Holder.

3.2 Upon the Holder's knowledge of a material breach of this Agreement by the Recipient, the Holder shall provide an opportunity for Recipient to cure the breach or end the violation. If efforts to cure the breach or end the violation are not successful within the reasonable time period specified by the Holder, the Holder shall discontinue disclosure of PHI to the Recipient and report the problem to the Secretary of the Department of Health and Human Services or its designee. The Holder shall immediately discontinue disclosure of the Limited Data Set to the Recipient if the Holder determines cure of the breach is not possible.

4. General Provisions

4.1 Recipient and Holder understand and agree that individuals who are the subject of Protected Health Information are not intended to be third party beneficiaries of this Agreement.

4.2 This Agreement shall not be assigned by Recipient without the prior written consent of the Holder.

4.3 Each party agrees that it will be responsible for its own acts and the results thereof to the extent authorized by law and shall not be responsible for the acts of the other party or the results thereof.

IN WITNESS WHEREOF, the parties hereto execute this agreement as follows:

The Facility

Date: _____

By: _____
(Title person with authority to sign agreement for the holder of the data)

RECIPIENT

Date: _____

By: _____
(Title of recipient or person with authority to sign agreement for the recipient)