

**DATA USE AGREEMENT**

**THIS DATA USE AGREEMENT** is made and entered into on       by and between       (hereinafter “Holder”), the party that holds a limited data set and discloses it to a recipient, and       (hereinafter “Recipient”), the party that requests and receives a limited data set for research.

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

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

# Permitted Uses and Disclosures

* 1. Except as otherwise specified herein, Recipient may make all uses and disclosures of the Limited Data Set necessary to conduct the research described or identified by HSC protocol number as follows (“Research Project”):

* 1. In addition to the Recipient, the individuals, or classes or individuals, who are permitted to use or receive the Limited Data Set for purposes of the Research Project include the following individuals or classes of persons (such as the researcher’s staff, any collaborators, other clinical sites involved in the research, sponsors if applicable, outside laboratories):

To the extent that the classes of persons are not part of Recipient’s workforce who are directly involved in the Research Project, Recipient shall enter into a data agreement with the other classes of persons before such release of the Limited Data Sets.

# Recipient Responsibilities

# Recipient will not use or disclose the Limited Data Set for any purpose other than permitted by this Agreement pertaining to the Research Project or as required by law;

# 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;

# Recipient will report to Holder any use or disclosure of the Limited Data Set not provided for by this Agreement of which Recipient becomes aware within 15 days of becoming aware of such use or disclosure;

# 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 Recipient with respect to the Limited Data Set;

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

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

1. **Term and Termination**
	1. The terms of this Agreement shall be effective as of the date written above and shall remain in effect until all PHI in the Limited Data Set provided to Recipient is destroyed or returned to Holder.
	2. Upon Holder’s knowledge of a material breach of this Agreement by Recipient, 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 Holder, Holder shall discontinue disclosure of PHI to Recipient and report the problem to the Secretary of the Department of Health and Human Services or its designee. Holder shall immediately discontinue disclosure of the Limited Data Set to Recipient if Holder determines cure of the breach is not possible.

# General Provisions

* 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.
	2. This Agreement shall not be assigned by Recipient without the prior written consent of Holder.
	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.
	4. Additional screening, academic, or other requirements, if any, imposed by Holder for the release of a limited data set to Recipient are set forth in Appendix A and incorporated as part of this agreement.

**IN WITNESS WHEREOF**, the parties hereby execute this Agreement as of the date written above.

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| --- | --- |
| **HOLDER**By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Name:      Title:      Date: \_\_\_\_\_\_ | **RECIPIENT**By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Name:      Title:      Date: \_\_\_\_\_\_ |

**APPENDIX A**

**Additional Requirements for Release of Limited Data Set**

**THIS APPENDIX to the Data Use Agreement** entered into on the date stated above contains additional screening, academic, or other requirements, if any, imposed by Holder for the release of a limited data set to Recipient.

[ ]  **None**

[ ]  **Additional requirements as set forth below**