

EXTERNAL USE ONLY

DATA USE AGREEMENT

This Data Use Agreement (“Agreement”) is made and entered into as of this _____ day of _____, 20____ by and between _____ (“Covered Entity”), and _____ (“Data Recipient”).

WITNESSETH

WHEREAS, Covered Entity may Disclose or make available to Data Recipient, and Data Recipient may Use, Disclose, receive, transmit, maintain or create from, certain information in conjunction with research; and

WHEREAS, covered Entity and Data Recipient are committed to compliance with the health Insurance Portability and Accountability act of 1996 (“HIPAA”) and regulations promulgated thereunder; and

WHEREAS, the purpose of this Agreement is to satisfy the obligations of Covered Entity under HIPAA and to ensure the integrity and confidentiality of certain information Disclosed or make available to Data Recipient and certain information that Data Recipient Uses, Discloses, receives, transmits, maintains or creates from Covered Entity.

NOW, THEREFORE, in consideration of the foregoing recitals and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

A. DEFINITIONS

Terms used but not otherwise defined in this Agreement shall have the same meaning as those terms in the Privacy Rule.

1. Individual shall have the same meaning as the term “individual” in 45 CFR Sect. 164.501 of the Privacy Rule and shall include a person who qualifies as a personal representative in accordance with 45 CFR Sect. 164.502(g) of the Privacy Rule.
2. Limited Data Set shall have the same meaning as the term “limited data set” in 45 CFR 164.514(e) of the Privacy Rule.
3. Privacy Rule shall mean the Standards for Privacy of Individually Identifiable Information at 45 CFR Part 160 and Part 164, Subparts A and E, as amended from time to time.

4. Protected Health Information or PHI shall have the same meaning as the term “protected health information” in 45 CFR Sect. 164.501 of the Privacy Rule, to the extent such information is created or received by Data Recipient from Covered Entity.
5. Required by Law shall have the same meaning as the term “required by law” in 45 CFR Sect. 164.501 of the Privacy Rule.

B. SCOPE AND PURPOSE

1. This Agreement sets forth the terms and conditions pursuant to which Covered Entity will Disclose certain PHI to the Data Recipient.
2. Except as otherwise specified herein, Data Recipient may make all Uses and Disclosure of the Limited Data Set necessary to conduct the research described herein: _____ (include a brief description of the research and/or protocol number) _____ (“Research Project”).
3. In addition to the Data Recipient, the individuals, or classes of individuals, who are permitted to use or receive the Limited Data Set for purposes of the Research Project, include:

C. OBLIGATIONS AND ACTIVITIES OF DATA RECIPIENT

1. Data Recipient agrees to not Use or Disclose the Limited Data Set for any purpose other than the Research Project or as Required by Law.
2. Data Recipient agrees to use appropriate safeguards to prevent Use or Disclosure of the Limited Data Set other than as provided for by this Agreement.
3. Data Recipient agrees to report to the Covered Entity any Use or Disclosure of the Limited Data Set not provided for by this Agreement of which it becomes aware, including without limitation, any Disclosure of PHI to an unauthorized subcontractor, within ten (10) days of its discovery.
4. Data Recipient agrees to 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 Data Recipient with respect to such information.
5. Data Recipient agrees not to identify the information contained in the Limited Data Set or contact the individual.
6. **{To be used when UCHC is the Covered Entity only}** Data Recipient will indemnify, defend and hold harmless Covered Entity and any of Covered Entity's affiliates, and their respective trustees, officers, directors, employees and agents (“Indemnitees”) from and against any claim, cause of action, liability, damaged, cost or expense (including, without limitations, reasonably attorney's fees and court costs) arising out of or in connection with any

unauthorized or prohibited Use or Disclosure of the Limited Data Set or any other breach of this Agreement by Data Recipient or any subcontractor, agent or person under Data Recipient's control.

D. TERM AND TERMINATION

The provisions of this Agreement shall be effective as of the earlier of the Effective Date or April 14, 2003, and shall be terminated when all of the Limited Data Set provided by Covered Entity to Data Recipient is destroyed or returned to Covered Entity, or, if it is infeasible to return or destroy the Limited Data Set, protections are extended to such information, in accordance with the termination provision in this Section.

E. MISCELLANEOUS

1. A reference in this Agreement to a section in the Privacy Rule means the section as amended or as renumbered.
2. The parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for Covered Entity to comply with the requirements of the Privacy Rule and HIPAA.
3. The respective rights and obligations of Data Recipient under Section C of this Agreement shall survive termination of this Agreement.
4. Any ambiguity in this Agreement shall be resolved to permit Covered Entity to comply with the Privacy Rule.
5. There are no intended third party beneficiaries to this Agreement. Without in any way limiting the foregoing, it is the parties' specific intent that nothing contained in this Agreement gives rise to any right or cause of action, contractual or otherwise, in or on behalf of the individuals whose PHI is Used or Disclosed pursuant to this Agreement.
6. No provision of this Agreement may be waived except by an agreement in writing signed by the waiving party. A waiver of any term or provision shall not be construed as a waiver of any other term or provision.
7. The persons signing below the right and authority to execute this agreement and no further approvals are necessary to create a binding agreement.
8. In the event of any conflict between the terms and conditions stated within this Agreement and those contained within any other agreement or understanding between the parties, written, oral or implied, the terms of this Agreement shall govern. Without limiting the foregoing, no provision of any other agreement or understanding between the parties limiting the liability of Data recipient to Covered entity shall apply to the breach of any covenant in this Agreement by Data Recipient.
9. This Agreement shall be construed in accordance with and governed by the laws of the State of Connecticut.

IN WITNESS WHEREOF, the parties have executed this Agreement effective upon the Effective Date set forth above.

CONTINGENT APPROVAL FROM COVERED ENTITY (UCHC):

For IRB Project Number and Title:

1. Printed Name of Principal Investigator

Signature of Principal Investigator

2. Printed Name of IRB Chairperson

Signature of IRB Chairperson

DATA RECIPIENT(S) AT (NAME OF INSTITUTION)

3. Printed Name Title

Signature of Recipient

3.1. Printed Name Title

Signature of Recipient

3.2. Printed Name Title

Signature of Recipient

3.3. Printed Name Title

Signature of Recipient

FINAL APPROVAL FROM COVERED ENTITY (UCHC):

4. Printed Name of IRB Chairperson

Signature of IRB Chairperson

Only after final approval has been given can the limited data set be released to the data recipients.