

**DATA USE AGREEMENT FOR DISCLOSURE OF A  
LIMITED DATA SET OUTSIDE OF THE “COVERED  
ENTITY”**

This Data Use Agreement (the “Agreement”) is entered into this [redacted] day of [redacted], 20[redacted] between the [redacted] (“Covered Entity”), and the University of Utah, on behalf of its Data Coordinating Center, Department of Pediatrics, University of Utah School of Medicine (“Data Recipient”) for purposes of compliance with the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) 45 CFR Part 160, Part 162 and Part 164 subparts A through E (“Privacy and Security Rules”).

**RECITALS**

- A. Data Recipient performs certain **[insert brief description of health care operations or public health performed by Data Recipient]** functions; and
- B. Covered Entity, through its workforce member \_\_\_\_\_, is engaged in activities involving **[insert brief description]** and possesses certain data in connection with that activity; and
- C. Covered Entity, through its workforce member, agrees to disclose a Limited Data Set (as defined below) to Data Recipient for use by Data Recipient in performing the Activities (as defined below); and
- D. Data Recipient agrees to limit its use of the Limited Data Set and protect the Limited Data Set according to the terms and conditions of this Agreement; all applicable requirements of HIPAA and the Privacy Rule (as defined below), as amended from time to time.

NOW THEREFORE, in consideration of the foregoing and other good and valuable consideration, the parties agree as follows:

**1.0 DEFINITIONS.**

Capitalized terms used but not otherwise defined in this Agreement shall have the same meaning as those terms are defined in the Standards for Privacy of Individually Identifiable Health Information, 45 CFR part 160 and part 164, subparts A and E, as amended (the “Privacy Rule”).

1.1 “Data Recipient” shall mean the University of Utah, on behalf of its Data Coordinating Center, Department of Pediatrics, University of Utah School of Medicine.

1.2 “Covered Entity” shall mean [redacted].

1.3 “Individual” shall have the same meaning as the term “individual” in 45 CFR 160.103 and shall include a person who qualifies as a personal representative in accordance with 45 CFR 164.502(g).

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1.4 “Privacy Rule” shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 CFR part 160 and part 164, subparts A and E.

1.5 “Security Rule” shall mean the Standards for Security of Individually Identifiable Health Information at 45 CFR parts 160, 162 and 164.

1.6 “Protected Health Information” shall have the same meaning as the term “protected health information” in 45 CFR 160.103, limited to the information created or received by Business Associate from or on behalf of Covered Entity.

1.7 “Electronic Protected Health Information” shall have the same meaning as the term “electronic protected health information” in 45 CFR 160.103, limited to information created, received, maintained, or transmitted by Business Associate on behalf of the Covered Entity.

1.8 “Required By Law” shall have the same meaning as the term “required by law” in 45 CFR 160.103.

1.9 “Secretary” shall mean the Secretary of the Department of Health and Human Services or designee.

1.10 “Breach” shall have the same meaning given to such term under 42 U.S.C 17921.

1.11 “Electronic Health Record” shall have the same meaning given to such term under 42 U.S.C. 17921.

1.12 “Unsecured PHI” shall have the same meaning given to such term under the HIPAA Security Rule.

**2.0 DISCLOSURE OF LIMITED DATA SET TO DATA RECIPIENT.**

2.1 Scope of Limited Data Set. For purposes of this Agreement, the Limited Data Set shall consist of the following Protected Health Information (the “Limited Data Set”):  
\_\_\_\_\_ **[Insert description of the Limited Data Set. Must not include any identifiers prohibited in the “Limited Data Set Statement and Assurance” (see, 45 CFR 164.514(e)(2)). Scope of Limited Data Set must be limited to the minimum necessary to perform the Activities.]**

2.2 Disclosure of Limited Data Set. Covered Entity agrees to disclose the Limited Data Set to Data Recipient solely for use in connection with Data Recipient’s  
\_\_\_\_\_ **[insert description of activities in sufficient detail to support the type and scope of disclosure]** and related activities (the “Activities”), and Data Recipient agrees that it shall not use the Limited Data Set for any other purpose. Data Recipient further agrees that Data Recipient shall limit access to and the use of the Limited Data Set to the following individuals or classes of individuals who need the Limited Data Set in performing the

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Activities: \_\_\_\_\_ . **[List all names of individuals or classes of individuals at Data Recipient who will have access to the Limited Data Set.]**

**3.0 OBLIGATIONS OF DATA RECIPIENT.**

3.1. Use of Limited Data Set. Data Recipient (including without limitation its employees, officers, directors, and volunteers) shall not use or disclose the Limited Data Set except as permitted under the terms of this Agreement or as required by law. Data Recipient shall not use or disclose PHI for fundraising or marketing purposes, in accordance with 42 USC 17936(a). Data Recipient shall not disclose PHI to a health plan for payment or health care operations purposes if the patient has requested this special restriction, and has paid out of pocket in full for the health care item or service to which the PHI solely relates. Data Recipient shall not directly or indirectly receive remuneration in exchange for PHI, except with the prior written consent of Covered Entity; however, this prohibition shall not affect payment by Covered Entity to Data Recipient for services provided pursuant to the Underlying Agreements.

3.2. Safeguards Against Misuse of Information. Data Recipient shall use appropriate safeguards to prevent use or disclosure of the Limited Data Set other than as permitted under this Agreement.

3.3. Reporting of Disclosures of Protected Health Information. Data Recipient shall notify Covered Entity of any use or disclosure of the Limited Data Set in violation of this Agreement by Data Recipient, its officers, directors, employees, contractors or agents, or by any third party, within one day of Data Recipient having knowledge of any such violation.

3.4. Use of Limited Data Set by Third Parties. Data Recipient shall ensure that its agents, contractors and subcontractors (collectively “Contractors”) to whom it provides any portion of the Limited Data Set shall comply with all restrictions and conditions that apply to Data Recipient with respect to the use of the Limited Data Set and that no Contractor shall use or disclose such information except as permitted under the terms of this Agreement or as required by law. Data Recipient further agrees that it shall obtain and maintain, throughout the term of this Agreement, an agreement with each Contractor that has or will have access to the Limited Data Set by or through Data Recipient, under which such Contractor agrees to be bound by the same restrictions, terms and conditions that apply to Data Recipient pursuant to this Agreement.

3.5. Identity of Individuals. Data Recipient agrees not to use the Limited Data Set in such a way as to identify any individual and further agrees not to contact any individual who may be a subject within the Limited Data Set.

3.6. Minimum Necessary Information. Data Recipient represents that Data Recipient’s request that Covered Entity disclose Protected Health Information to Data Recipient is limited in scope to the minimum Protected Health Information necessary to accomplish Data Recipient’s purpose in connection with the Activities.

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3.7 Notice of Request for Data. Data Recipient agrees to notify Covered Entity within five business days of Data Recipient’s receipt of any request or subpoena for Protected Health Information relating to this Agreement. To the extent that Covered Entity decides to assume responsibility for challenging the validity of such request, Data Recipient shall cooperate fully with Covered Entity in any such challenge.

3.8 Security Obligations. Data Recipient shall implement appropriate safeguards as are necessary to prevent the use or disclosure of PHI otherwise than as permitted by the Underlying Agreements or this Data Use Agreement including, but not limited to, administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of UUHS’ electronic PHI as required by 45 CFR 164.308, 164.310, and 164.312, as amended from time to time; and in the same manner that such provisions apply to a HIPAA covered entity. Data Recipient shall ensure that any agent, including a subcontractor, to whom it provides such electronic PHI, agrees to implement reasonable and appropriate safeguards to protect it. Data Recipient shall comply with *the provisions of 45 CFR 164.308, 164.310, 164.312 and 164.316 relating to implementation of administrative, physical and technical safeguards with respect to electronic PHI in the same manner that such provisions apply to a HIPAA covered entity.* Data Recipient agrees to report promptly to UUHS any security incident of which it becomes aware.

4.0 **OWNERSHIP OF INFORMATION.**

Data Recipient acknowledges that, as between Data Recipient and Covered Entity, all Protected Health Information received or developed by Data Recipient in connection with this Agreement shall be and remain the sole property of Covered Entity, including any and all derivatives thereof developed by Data Recipient in performing its obligations under this Agreement.

5.0 **TERM AND TERMINATION.**

5.1 Term. The term of this Agreement shall commence as of the effective date set forth above and shall terminate when all of the Protected Health Information provided by Covered Entity to Data Recipient, or created or received by Data Recipient on behalf of Covered Entity, is destroyed or returned to Covered Entity, or, if it is infeasible to return or destroy Protected Health Information, protections are extended to such information, in accordance with the termination provisions in this section.

5.2 Termination for Cause. Upon Covered Entity's knowledge of a material breach by Data Recipient, Covered Entity shall:

(a) Provide Data Recipient with written notice of the breach and an opportunity to cure the breach within 30 calendar days of receipt of such notice. Data Recipient shall immediately take steps to mitigate the breach and shall cure the breach within the 30 day notice period. If Data Recipient fails to mitigate and cure the breach within the notice period Covered Entity may immediately terminate this Agreement; or

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(b) Immediately terminate this Agreement (without opportunity to cure) if Covered Entity determines, in Covered Entity’s sole discretion, that Data Recipient has breached a material term of this Agreement; or

(c) Covered Entity shall report the violation to the Secretary.

5.3 Effect of Termination. Upon termination of this Agreement, Data Recipient shall, upon the request of Covered Entity, either return or destroy all Protected Health Information received from Covered Entity, or created or received by Data Recipient on behalf of Covered Entity, and thereafter Data Recipient shall not retain any copies of such Protected Health Information. Notwithstanding the foregoing, to the extent that Covered Entity agrees that it is not feasible to return or destroy such Protected Health Information, the terms and provisions of this Agreement shall survive termination of the Agreement and such Protected Health Information shall be used or disclosed solely for such purpose or purposes that prevented the return or destruction of such Protected Health Information.

6.0 **MISCELLANEOUS.**

6.1 Effect. The terms and provisions of this Agreement shall supercede any other conflicting or inconsistent agreements between Covered Entity and Data Recipient, including without limitation all exhibits or other attachments hereto and all documents incorporated herein by reference. Without limiting the foregoing, any limitation of liability or exclusion of damages provisions in any other agreement shall not be applicable to this Agreement.

6.2 Amendment. Data Recipient and Covered Entity agree to amend this Agreement to the extent necessary to allow either party to comply with the Privacy Rule, the Standards for Electronic Transactions (45 CFR Parts 160 and 162) and the Security Standards (45 CFR Part 142) (collectively, the “Standards”) promulgated or to be promulgated by the Secretary or other regulations or statutes. Data Recipient agrees that it will fully comply with all such Standards and that it will agree to amend this Agreement to incorporate any material changes required by the Standards.

6.3 Survival. The obligations of Data Recipient under Section 3 of this Data Use Agreement shall survive the termination of this Data Use Agreement.

6.4 Interpretation. Any ambiguity in this Data Use Agreement shall be resolved to permit Covered Entity to comply with the Privacy Rule, and state confidentiality laws.

6.5 Compliance with Laws. In performing their respective obligations under this Data Use Agreement, Covered Entity and Data Recipient shall at all times comply with all provisions of HIPAA, the Privacy and Security Rule(s), and all other relevant state and federal laws and regulations.

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6.6 No Third Party Beneficiaries. Nothing in this Data Use Agreement shall be considered or construed as conferring any right or benefit on a person not party to this Data Use Agreement nor imposing any obligations on either Party hereto to persons not a party to this Data Use Agreement.

6.7 Notices. Any notices pertaining to this Data Use Agreement shall be given in writing and shall be deemed duly given when personally delivered to a Party or a Party's authorized representative as listed below or sent by means of a reputable overnight carrier (with proof of signature), or sent by means of certified mail, return receipt requested, postage prepaid. A notice shall be deemed given on the date of receipt or refusal of receipt. All notices shall be addressed to the appropriate Party as follows:

If to Covered Entity:


If to Data Recipient:

Privacy Officer  
University of Utah Health Sciences  
650 Komas Drive, Suite102  
Salt Lake City, Utah 84108

6.8 Amendments. An amendment of the Underlying Agreements shall not alter this Data Use Agreement. This Data Use Agreement may not be changed or modified in any manner except by an instrument in writing signed by a duly authorized officer of each of the Parties hereto. The Parties, however, agree to amend this Data Use Agreement from time to time as necessary, in order to allow Covered Entity's to comply with the requirements of the Privacy Rule.

6.9 Assignment of Rights and Delegation of Duties. This Data Use Agreement is binding upon and inures to the benefit of the Parties hereto and their respective successors and permitted assigns. However, neither Party may assign any of its rights or delegate any of its obligations under this Data Use Agreement without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed.

6.10 No Waiver. Failure or delay on the part of either Party to exercise any right, power, privilege or remedy hereunder shall not constitute a waiver thereof. No provision of this Data Use Agreement may be waived by either Party except by a writing signed by an authorized representative of the Party making the waiver.

6.11 Severability. The provisions of this Data Use Agreement shall be severable, and if any provision of this Data Use Agreement shall be held or declared to be illegal, invalid or unenforceable, the remainder of this Data Use Agreement shall continue in full force and effect as though such illegal, invalid or unenforceable provision had not been contained herein.

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IN WITNESS WHEREOF, the parties have caused this Data Use Agreement to be executed by their duly authorized representatives effective as of the day and year set forth above.

**“Covered Entity”**

By: \_\_\_\_\_  
(Signature)

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

**Data Recipient.**

By: \_\_\_\_\_  
(Signature)

Name: \_\_\_\_\_  
(Please Print)

Title: Chief Information Security and Privacy Officer

Date: \_\_\_\_\_