

BUSINESS ASSOCIATE AGREEMENT

(UNIVERSITY OF UTAH
ACTING AS BUSINESS ASSOCIATE)

This Business Associate Agreement (the “BA Agreement”) is entered into this day of , 2016 between the University of Utah, on behalf of its Data Coordinating Center, Department of Pediatrics, University of Utah School of Medicine (the “Business Associate”) and _____ (“Covered Entity”) 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”) and the Health Information Technology for Economic and Clinical Health Act, Public Law 111-005 (the “HITECH Act”).

RECITALS

- A. Business Associate provides certain services to or on behalf of Covered Entity;
- B. Covered Entity and Business Associate have entered into certain contract(s) existing as of the effective date of this BA Agreement and may enter into other future contracts (the “Underlying Agreements”), as more specifically defined at Section 3.0 below; and
- C. In connection with these services, Covered Entity discloses to Business Associate certain protected health information that is subject to protection under the Privacy Rule and the HITECH Act;
- D. The Privacy Rule and the HITECH Act require that Covered Entity receive adequate assurances that Business Associate will comply with certain obligations with respect to the PHI received in the course of providing services to or on behalf of Covered Entity; and

NOW THEREFORE, in consideration of the foregoing and other good and valuable consideration, the parties agree to the following terms and conditions which govern any Protected Health Information created, received, maintained, or transmitted by the Business Associate from or on behalf of Covered Entity, as follows:

1.0 DEFINITIONS.

The following terms are defined for purposes of this BA Agreement. Terms used, but not otherwise defined in this BA Agreement shall have the same meaning as those terms in the Privacy and Security Rule(s) and the HITECH Act

- (a) “Business Associate” shall mean the Data Coordinating Center, Department of Pediatrics, University of Utah School of Medicine.
- (b) “Covered Entity” shall mean .
- (c) “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).

- (d) “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.
- (e) “Security Rule” shall mean the Standards for Security of Individually Identifiable Health Information at 45 CFR parts 160, 162 and 164.
- (f) “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.
- (g) “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.
- (h) “Required By Law” shall have the same meaning as the term “required by law” in 45 CFR 160.103.
- (i) “Secretary” shall mean the Secretary of the Department of Health and Human Services or his designee.
- (j) “Breach” shall have the same meaning given to such term under 42 U.S.C 17921.
- (k) “Electronic Health Record” shall have the same meaning given to such term under 42 U.S.C. 17921.
- (l) “Unsecured PHI” shall have the same meaning given to such term under the HITECH Act and any guidance issued pursuant to this act.

2.0 **OBLIGATIONS AND ACTIVITIES OF BUSINESS ASSOCIATE.**

- (a) Business Associate agrees to not use or disclose Protected Health information other than as permitted or required by the BA Agreement or as Required by Law. Business Associate shall not use or disclose PHI for fundraising or marketing purposes, in accordance with 42 USC 17936(a). Business Associate 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. Business Associate shall not directly or indirectly receive remuneration in exchange for PHI, except with the prior written consent of Covered Entity and as permitted by the HITECH Act; however, this prohibition shall not affect payment by Covered Entity to Business Associate for services provided pursuant to the Underlying Agreements which is defined below in Section 3.0(b).
- (b) Mitigation: Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of Protected Health Information by Business Associate in violation of the requirements of this BA Agreement.
- (c) Reporting: Business Associate shall notify Covered Entity of any access, use or disclosure of PHI for a purpose that is not provided for in this BA Agreement, and any Breach of Unsecured PHI, of which Business Associate becomes aware without unreasonable delay and within a reasonable period of time.

- (d) Disclosure to Agents and Subcontractors: Business Associate shall ensure that any agent, including a subcontractor, to whom it provides PHI received from, or created or received by Business Associate on behalf of Covered Entity, agrees to substantially similar restrictions and conditions that apply through this BA Agreement to Business Associate with respect to such information.
- (e) Designated Record Set: If applicable, Business Associate shall provide access, at the request of Covered Entity to PHI in a Designated Record Set, to Covered Entity or, as directed by Covered Entity, to an Individual in order to meet the requirements under 45 CFR 164.524. If Business Associate maintains an Electronic Health Record, Business Associate shall provide such information in electronic format to Covered Entity to fulfill its obligations under the HITECH Act.
- (f) Amendments: If applicable, Business Associate agrees to make any amendment(s) to Protected Health Information in a Designated Record Set that the Covered Entity directs or agrees to pursuant to 45 CFR 164.526 in the time and manner as reasonably requested by Covered Entity or an Individual.
- (g) Internal Practices, Policies and Procedures: Business Associate shall make available its internal practices, books, and records, including policies and procedures and PHI, relating to the use and disclosure of PHI received from, or created or received by Business Associate on behalf of Covered Entity available to the Secretary for purposes of the Secretary determining Covered Entity's compliance with the Privacy Rule and the HITECH Act.
- (h) Accounting for Disclosures. Business Associate agrees to maintain the information required to provide an accounting of disclosures of PHI in accordance with 45 CFR 164.528 and to make this information available to Covered Entity upon Covered Entity's request in order to allow Covered Entity to respond to an Individual's request for accounting of disclosures. For PHI maintained as an Electronic Health Record, Business Associate shall, beginning at such time as the law requires, maintain such information necessary to provide an accounting of disclosures for treatment, payment or health care operations for a period of three years after such PHI is made in accordance with 42 U.S.C. 13405(c).
- (i) Security Obligations. Business Associate 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 BA Agreement including, but not limited to, administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of electronic PHI.
- (j) Breach Notification: Business Associate Breach Notification should include the identification of each individual whose unsecured PHI has been, or is reasonably believed by the Business Associate to have been, accessed, acquired or disclosed during the Breach. Business Associate shall cooperate in covered entity's risk assessment to determine whether Breach Notification is required including any other information Covered Entity needs to discharge its notification obligations under HIPAA.
- (k) Books: Business Associate agrees to make its policies, procedures and documentation required by the Security Rule relating to the administrative, physical, and technical safeguards available to the Secretary of HHS for purposes of determining Covered Entity's compliance with the Security Rule.
- (l) Other: To the extent the Business Associate is to carry out one or more of Covered Entity's obligation(s) under Subpart E of 45 CFR Part 164, comply with the requirements of Subpart E that apply to the Covered Entity in the performance of such obligation(s).

3.0 **PERMITTED USES AND DISCLOSURES BY BUSINESS ASSOCIATE.**

(a) **Permitted Uses and Disclosures:** Except as otherwise limited in this BA Agreement, Business Associate may use or disclose PHI to perform functions, activities, or services for, or on behalf of, Covered Entity as specified in the Underlying Agreements provided such use or disclosure would not violate the Privacy Rule including, but not limited to, each requirement of 45 CFR 164.504(e) and the HITECH Act if done by the Covered Entity.

(b) **Inclusions:** For purposes of this BA Agreement, the Underlying Agreements shall include the activities listed below and all other existing or future agreements between the parties. Failure to list any other agreements between the parties shall not limit the application of this BA Agreement to any such other arrangements. The authorized activities include:

The Business Associate may use Protected Health Information to create research datasets that are necessary to accomplish research protocols in which the Covered Entity is a participant, and for which the Business Associate is the data coordinating center, as specifically approved by the Institutional Review Board (IRB) of the Covered Entity.

(c) **Uses for Management and Administration:** Business Associate may use Protected Health Information for the proper management and administration of the Business Associate or to carry out the legal responsibilities of the Business Associate.

(d) **Disclosure for Management and Administration:** Business Associate may disclose Protected Health Information for the proper management and administration of the Business Associate, provided that disclosures are Required By Law, or the Business Associate obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and used or further disclosed only as Required By Law or for the purpose for which it was disclosed to the person.

(e) **Minimum Necessary.** Business Associate (and its agents or subcontractors) shall request, use, and disclose only the minimum amount of PHI necessary to accomplish the purpose of the request, use, or disclosure, in accordance with 42 USC 17935(b). Business Associate understands and agrees that the definition of “minimum necessary” is subject to change from time to time and shall keep itself informed of guidance issued by the Secretary with respect to what constitutes “minimum necessary.”

(f) **Data Aggregation:** Business Associate may use Protected Health Information to provide Data Aggregation services to Covered Entity as permitted by 45 CFR 164.504(e)(2)(i)(B).

(g) **Report Violations of Law:** Business Associate may use Protected Health Information to report violations of law to appropriate Federal and State authorities, consistent with 45 CFR 164.502(j) (1).

4.0 **OBLIGATIONS OF COVERED ENTITY.**

- (a) Notice of Privacy Practices: Covered Entity shall notify Business Associate of any limitation(s) in its notice of privacy practices of Covered Entity in accordance with 45 CFR 164.520, to the extent that such limitation may affect Business Associate's use or disclosure of Protected Health Information.
- (b) Changes in Permission: Covered Entity shall notify Business Associate of any changes in, or revocation of, permission by Individual to use or disclose Protected Health Information, to the extent that such changes may affect Business Associate's use or disclosure of protected Health Information.
- (c) Notification of Restrictions: Covered Entity shall notify Business Associate of any restriction to the use or disclosure of Protected Health Information that Covered Entity has agreed to in accordance with 45 CFR 164.522, to the extent that such restriction may affect Business Associate's use or disclosure of Protected Health Information.

5.0 **PERMISSIBLE REQUESTS BY COVERED ENTITY.**

Permissible Requests by Covered Entity. Covered Entity shall not request Business Associate to use or disclose PHI in any manner that would not be permissible under the Privacy Rule and the HITECH Act if done by Covered Entity.

The Covered Entity's use of research datasets provided by the Business Associate shall comply with Standard Operating Procedures specific to the research network or other entity having authority over the relevant study data.

6.0 **TERM AND TERMINATION.**

- (a) Term. The Term of this BA 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 Business Associate, or created or received by Business Associate 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, regardless of the termination date of any of the Underlying Agreements.
- (b) Termination for Cause. Upon Covered Entity's knowledge of a material breach by Business Associate, Covered Entity shall either:
- (1) Provide notice specifying the nature of the breach or violation to Business Associate. Business Associate shall have 60 days from the date of the notice in which to remedy the breach or violation;
 - (2) Immediately terminate this BA Agreement if Business Associate has breached a material term of this BA Agreement; or
 - (3) If neither termination nor cure is feasible, Covered Entity shall report the violation to the Secretary.

- (c) Effect of Termination.

(1) Except as provided in paragraph (c) (2) of this Section 6, upon termination of this BA Agreement, for any reason, the Business Associate shall return or destroy all Protected Health Information received from Covered Entity, created or received by Business Associate on behalf of Covered Entity. This provision shall apply to Protected Health Information that is in the possession of subcontractors or agents of Business Associate. Business Associate shall retain no copies of the Protected Health Information.

(2) In the event that Business Associate determines that returning or destroying the Protected Health Information is infeasible, Business Associate shall extend the protections of this BA Agreement to such Protected Health Information and limit further uses and disclosures of such Protected Health Information to only those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such Protected Health Information.

7.0 **MISCELLANEOUS.**

(a) **Regulatory References.** Any reference in this BA Agreement to HIPAA or the Privacy or Security Rule shall mean the referenced section as is then in effect or as amended.

(b) **Amendments.** The Parties agree to take such action as is necessary to amend this BA Agreement from time to time for Covered Entity to comply with the requirements of the Privacy and Security Rule(s) and the HITECH Act.

(c) **Survival.** The respective rights and obligations of Business Associate under Section 6(c) of this BA Agreement shall survive the termination of this BA Agreement.

(d) **Interpretation.** Any ambiguity in this BA Agreement shall be resolved to permit Covered Entity to comply with the Privacy Rule and the HITECH Act.

(e) **Compliance with Laws.** In performing their respective obligations under this BA Agreement, Covered Entity and Business Associate shall at all times comply with all provisions of HIPAA, the Privacy and Security Rule(s), and the HITECH Act.

(f) **Notices.** Any notices pertaining to this BA 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 Business Associate:

University of Utah
295 Chipeta Way
PO Box 581289
Salt Lake City, UT 84158-1289
Attn: Director, Data Coordinating Center DCC

If to Covered Entity:

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

BUSINESS ASSOCIATE
UNIVERSITY OF UTAH

By: _____
(Signature)

Name: _____

Title: Chief Compliance/University Information Security and Privacy Officer

Date: _____

By: _____
(Signature)

Name: _____

Title: _____

Date: _____

COVERED ENTITY

By: _____
(Signature)

Name: _____
(Please Print)

Title: _____

Date: _____