

Emma Eccles Jones College of Education & Human Services

POLICY INFORMATION

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Revision # 1.0	Prepared by: J. Black	Date Prepared: 1/15/2016
Safeguard: Administrative	Approved by: Dean Beth E. Foley 	Date Approved: 9/7/2016

I. POLICY STATEMENT

In accordance with CFR 45 §164.502(e), 164.504(e), 164.308, and 164.314 HCC of CEHS may disclose Protected Health Information (PHI) to a business associate (BA) and may allow such individual or organization to create or receive such information on its behalf, if HCC obtains satisfactory assurances that the BA will appropriately safeguard the information. The HIPAA privacy regulations require satisfactory assurances to be provided in the form of a business associate agreement (BAA) that contains certain elements specifically stated in the regulations. It is the purpose of this policy to identify the process by which PHI can be appropriately released to business associates, and the mechanisms for developing and maintaining contractual agreements with business associates regarding their responsibilities and the HIPAA privacy regulations.

II. DEFINITIONS

See HIPAA Privacy Policy 100

III. AUTHORITY AND RESPONSIBILITIES

CEHS has component units that are listed as a hybrid entity in accordance with USU's HIPAA Hybrid Covered Entity Declaration. Only the Health Care Component/HCC (i.e., covered functions) of CEHS must comply with this policy. All references in this policy to "CEHS" shall be construed to refer only to the health care component of CEHS.

IV. PROCEDURES TO IMPLEMENT

Prior to allowing a HIPAA Business Associate (BA) access to CEHS PHI, the HCC must execute a Business Associate Agreement (BAA) with the BA. CEHS has developed a standardized BAA that must be used. Changes to the BAA, must be reviewed and approved by USU legal department.

Where the HCC knows of a material breach or violation of the BAA by the BA, the HCC is required to take reasonable steps to cure the breach or end the violation. If such steps are unsuccessful, termination of the contract will be necessary. If termination is not feasible, CEHS is required to report the problem to HHS, Office for Civil Rights.

Emma Eccles Jones College of Education & Human Services

Members of the CEHS workforce must report suspected violations of the BAA by the BA to the CEHS HIPAA Privacy Officer.

1. ACTIVITIES THAT REQUIRE A BUSINESS ASSOCIATE AGREEMENT - Each vendor or service provider that may receive, view, access, use, disclose or create PHI for the HCC must enter into a BAA in which it is obligated to protect the privacy and confidentiality of such information in accordance with the HIPAA privacy and security regulations. Examples of activities that require a BAA include:
 - a. Electronic Health Records (EHR) Vendor
 - b. Law firms/attorneys
 - c. External auditors or accountants
 - d. Shredding, destruction and/or documentation storage companies
 - e. Medical transcriptions services
 - f. E-prescribing gateways
 - g. Billing and coding vendors
 - h. Consultants
 - i. Data processing firms or software companies that may collect, access, use, store or disclose PHI, or
 - j. Electronic applications, online back-up, cloud based software companies
 - k. Professional translator services

Each HCC is responsible for identifying any party outside of the covered entity that may access, use, disclose, view, or create PHI from the covered entity. If the business, service provider, vendor or individual will have access to PHI, the HCC will request a BAA. All signed BAA's shall be submitted through the USU contracting process for approval. The HCC shall keep a copy of the signed agreement as well as provide one to the Privacy Officer.

2. CIRCUMSTANCES WHEN A BUSINESS ASSOCIATE AGREEMENT IS NOT REQUIRED -
 - a. CEHS HCC's do not require BAA's with each other.
 - b. BAA's are not required with members of the USU workforce or when a CEHS workforce member performs BA-type functions for the HCC in their capacity as a USU/CEHS workforce member.
 - c. Disclosures for treatment purposes between the HCC and healthcare providers including unaffiliated health care providers do not require a BAA.
 - d. Disclosure between the HCC and a financial institution for purposes of processing certain consumer financial transactions (such as processing or collecting a payment by an individual to the HCC) do not require a BAA. Note: If the HCC initiates such payment activities it must meet the minimum necessary disclosure requirements.
3. EXCLUSIONS AND SPECIAL SITUATIONS - Researchers that may be required to disclose PHI should follow guidance established by the Institutional Review Board.

Emma Eccles Jones College of Education & Human Services

V. ATTACHMENTS

Attachment A - CEHS Business Associate Agreement Template

VI. REFERENCES

45 CFR §164.502(e)

45 CFR §164.504(e)

45 CFR §164.532 (d) (e)

Emma Eccles Jones College of Education & Human Services

**Attachment A
CEHS Business Associate Agreement Template**

This Business Associate Agreement (“Agreement”) between **Utah State University**, on behalf of its [**HCC**] (“Covered Entity”) and [**VENDOR NAME**] (“Business Associate”) (each individually, a “Party,” and collectively, the “Parties”) takes effect on the [**DATE**] (“Effective Date”).

I. Purpose and Intent

1.1 Business Associate has agreed to perform certain services for or on behalf of Covered Entity, which services may involve the use or disclosure of Protected Health Information within the meaning of the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) as it may be amended from time to time and its implementing regulations, 45 CFR Parts 160 and 164 (“the Privacy Rule”) and the Health Information Technology for Economic and Clinical Health Act included in the American Recovery and Reinvestment Act of 2009, (the “HITECH Act”). This Agreement supplements the Parties’ agreement(s) for services and is intended to satisfy the requirements for Business Associate Agreements as set forth in the Privacy Rule, including 45 CFR § 164.504(e) and the HITECH Act. Business Associate hereby agrees to comply with applicable provisions of the Privacy Rule and the HITECH Act and to assist Covered Entity with its compliance as explained below.

II. Definitions

2.1 *HITECH Act* means the “HITECH Act” the Health Information Technology for Economic and Clinical Health Act included in the American Recovery and Reinvestment Act of 2009.

2.2 *Designated Record Set* means (1) medical records and billing records about individuals maintained by or for Covered Entity; and (2) other records used by or for Covered Entity to make decisions about Individuals. See 45 CFR § 164.501.

2.3 *Individual* means the person who is the subject of Protected Health Information, and any person who qualifies as a personal representative of such person in accordance with 45 CFR § 164.502(g). See 45 CFR § 164.501.

2.4 *Protected Health Information (PHI)* means any information which is created or received by Business Associate from or on behalf of Covered Entity, whether oral or recorded in any form or medium, that relates to the past, present, or future physical or mental health or condition of an Individual, the provision of health care to an Individual, or the past, present, or future payment for the provision of health care to an Individual. See 45 CFR § 160.103.

2.5 *Secretary* shall mean the Secretary of the Department of Health and Human Services or his or her designee.

Emma Eccles Jones College of Education & Human Services

Terms used but not otherwise defined in the Agreement shall be defined as set forth in 45 CFR Part 160 and Part 164, Subparts A and E and the HITECH Act.

III. Obligations of Business Associate

3.1 Business Associate agrees to not use or disclose PHI other than as permitted or required by the Agreement or as required by law.

3.2 Business Associate agrees to use appropriate safeguards to maintain the privacy of the PHI and to prevent use and/or disclosure of the PHI other than as provided for by this Agreement. The Business Associate must comply with the “minimum necessary” rules (including the requirement that the business associate limit the information to a “limited data set” to the extent practicable) when using, disclosing or requesting PHI, except when a specific exception applies under HIPAA or the HITECH Act.

3.3 Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of PHI by Business Associate in violation of the requirements of this Agreement.

3.4 Business Associate agrees to immediately report to Covered Entity any use or disclosure of the PHI not provided for by this Agreement of which it becomes aware.

3.5 Business Associate agrees to ensure that any agent to whom it provides PHI, including a subcontractor, agrees to the same restrictions and conditions concerning the information that apply through this Agreement with Business Associate. Business Associate may comply with this section by entering into a contract with such agent or subcontractor, which contract requires the agent or subcontractor to comply with the terms of the Agreement.

3.6 Upon a request by Covered Entity, Business Associate agrees to provide access to PHI maintained 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. Business Associate shall provide access to the PHI in the time and manner designated by Covered Entity.

3.7 Upon a request by Covered Entity or an Individual and at Covered Entity’s direction or agreement, Business Associate agrees to make any amendment(s) to PHI maintained in a Designated Record Set in order to meet the requirements under 45 CFR § 164.526. Business Associate shall act on the amendments in the time and manner designated by Covered Entity.

3.8 Business Associate agrees to make internal practices, books, and records (including policies and procedures and PHI) relating to the use and disclosure of PHI received from Covered Entity or created or received by Business Associate on behalf of Covered Entity, available to Covered Entity or to the Secretary for purposes of the Secretary determining Covered Entity’s compliance with the Privacy Rule. Business Associate shall make the documents available in the time and manner designated by Covered Entity or the Secretary.

Emma Eccles Jones College of Education & Human Services

3.9 Business Associate agrees to document such disclosures of PHI and information related to such disclosures as would be required for Covered Entity to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 CFR § 164.528.

3.10 Business Associate agrees to provide to Covered Entity or an Individual information collected in accordance with the section 3.9 of this Agreement, to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 CFR § 164.528. Business Associate shall act in the time and manner designated by Covered Entity or the Individual.

3.11 Business Associate shall notify Covered Entity of any change(s) in Business Associate’s internal practices and procedures, to the extent that such changes may affect Business Associate’s use and disclosure of PHI and such changes shall be subject to the approval by Covered Entity.

3.12 Business Associate shall comply with the security policies and procedures adopted by the Covered Entity.

3.13 Business Associate shall comply with the additional requirements set forth in the HITECH Act.

IV. Permitted Uses and Disclosures by Business Associate

4.1 General Use and Disclosure Provisions. Except as otherwise limited in the Agreement, Business Associate may use or disclose PHI on behalf of, or to provide services to, Covered Entity for the following purposes, if such use or disclosure of PHI would not violate (1) the Privacy Rule if done by Covered Entity or (2) Covered Entity’s policies and procedures which limit disclosures to the minimum necessary:

Business Associate’s authorized activities are:

All other uses or disclosures of Covered Entity’s PHI are not authorized by this Agreement and shall be prohibited.

4.2 Specific Use and Disclosure Provisions

4.2.1 Except as otherwise limited in this Agreement, Business Associate may use PHI for the proper management and administration of the Business Associate or to carry out the legal responsibilities of the Business Associate.

Emma Eccles Jones College of Education & Human Services

4.2.2 Except as otherwise limited in this Agreement, Business Associate may disclose PHI for the proper management and administration of the Business Associate, provided that disclosures are required by law or 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, and the person notifies the Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached.

4.2.3 Except as otherwise limited in this Agreement, Business Associate may use PHI to provide data aggregation services to Covered Entity as permitted by 45 CFR § 164.504(e)(2)(i)(B).

4.2.4 Business Associate may use PHI to report violations of law to appropriate Federal and State authorities, consistent with 45 CFR § 164.502(j)(i).

4.2.5 In the event Business Associate receives a subpoena, court order or other legal process which mandates the disclosure of PHI, Business Associate agrees to promptly notify and allow the Covered Entity to respond to such legal process.

4.3 Ownership of Protected Health Information. Business Associate acknowledges and agrees that any and all PHI which Covered Entity provides to Business Associate is owned by Covered Entity.

V. Obligations of Covered Entity

5.1 Covered Entity shall notify Business Associate of any limitation(s) in Covered Entity's Notice of Privacy Practices in accordance with 45 CFR § 164.520, to the extent that such limitation may affect Business Associate's use or disclosure of PHI.

5.2 Covered Entity shall notify Business Associate of any changes in, or revocation of, permission by an Individual to use or disclose PHI, to the extent that such changes may affect Business Associate's use or disclosure of PHI.

5.3 Covered Entity shall notify Business Associate of any restriction to the use or disclosure of PHI to which Covered Entity has agreed in accordance with 45 CFR § 164.522, to the extent that such restriction may affect Business Associate's use or disclosure of PHI.

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

Emma Eccles Jones College of Education & Human Services

VII. VI. Term and Termination

6.1 Term. The Term of this Agreement shall be effective as of the Effective Date identified below and shall terminate when the last of the Parties' related agreements for Business Associate's services terminate, or when all of the PHI 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 not feasible to return or destroy PHI, protections are extended to such information, in accordance with the termination provision in this section.

6.2 Termination for Cause. Upon Covered Entity's knowledge of a material breach of the Agreement by Business Associate, Covered Entity shall either:

6.2.1 Provide an opportunity for Business Associate to cure the breach or end the violation and, if Business Associate fails to cure the breach or end the violation within the time specified by the Covered Entity, Covered Entity shall terminate this Agreement and all related agreements for Business Associate's services involving the use or disclosure of PHI.

6.2.2 Immediately terminate this Agreement together with any related agreement for Business Associate's services involving the use and disclosure of PHI if Business Associate has breached a material term of this Agreement, and if cure is not possible, Covered Entity shall be entitled to seek any and all available remedies to compensate it for any damages, losses, costs, and/or expenses it incurs.

6.2.3 If neither termination nor cure is feasible, Covered Entity shall report the violation to the Secretary of the Department of Health and Human Services.

6.2.4 Business Associate acknowledges that remedies at law for the breach or violation of this Agreement by Business Associate may be inadequate and, therefore, Covered Entity shall also be entitled to injunctive relief, and to all costs and expenses, including reasonable attorney's fees, relating to the pursuit of such injunctive relief. Such injunctive relief shall not be exclusive, but shall be in addition to any other rights and remedies that Covered Entity may have for such breach or violation.

6.3 Effect of Termination. Except as provided in subsection 6.3.1, upon termination of this Agreement for any reason, Business Associate shall return or destroy (at Business Associate's election) all PHI received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity. This provision shall apply to PHI that is in the possession of subcontractors or agents of Business Associate. Business Associate shall retain no copies of the PHI.

Emma Eccles Jones College of Education & Human Services

6.3.1 In the event that Business Associate determines that returning or destroying the PHI is not feasible, Business Associate shall provide to Covered Entity notification of the conditions that make return or destruction infeasible. Upon Covered Entity's determination that return or destruction of PHI is not feasible, Business Associate shall extend the protections of this Agreement to such PHI and limit further uses and disclosures of such PHI to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such PHI.

VIII. VII. Indemnification

7.1 Indemnification. In addition to any indemnification obligations undertaken by Business Associate under the Parties' separate agreement for services, Business Associate shall indemnify, defend, and hold harmless Covered Entity from any and all claims, causes of action, and demands whatsoever made for loss, damage, or injury to any person to the extent caused by the breach by Business Associate, or its agents or employees, of the security, privacy or confidentiality obligations set forth under this Agreement.

IX. VIII. Miscellaneous

8.1 Regulatory References. A reference in this Agreement to a section in the Privacy Rule means the section as in effect or as amended.

8.2 Amendment. 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 Privacy Rule and HIPAA.

8.3 Survival. The respective rights and obligations of Business Associate under Section 6.3, "Effect of Termination," of this Agreement shall survive the termination of the Agreement.

8.4 Interpretation. Any ambiguity in this Agreement shall be resolved to permit Covered Entity to comply with the Privacy Rule and the HITECH Act.

8.5 Governing Law and Venue. The laws of the State of Utah shall govern the validity, construction, interpretation, and effect of this Agreement, and any disputes pertaining hereto shall be adjudicated in the state courts of Utah with venue being located in Cache County, Utah.

8.6 No Third-Party Beneficiary Rights. This is not a third-party beneficiary contract. This is an Agreement between Covered Entity and Business Associate, and it can only be enforced by Covered Entity and Business Associate. Covered Entity and Business Associate do not intend to create in any third-party a right to enforce this Agreement or to claim losses or damages under this Agreement.

Emma Eccles Jones College of Education & Human Services

8.7 Notices. Any notices to be given hereunder to a Party will be made by U.S. Mail or express courier to such Party's address as below:

If to Covered Entity:

Utah State University
CEHS Privacy Officer
2800 Old Main Hill
Logan, UT 84322-2800

If to Business Associate:

X. IX. Effective Date

9.1 By their authorized signatures below, the Parties have executed this Agreement, which shall be effective as of the Effective Date.

<p>Covered Entity:</p> <p>Utah State University [HCC]: _____</p> <p>By: _____</p> <p>Date: _____</p>	<p>Business Associate:</p> <p>_____</p> <p>By: _____</p> <p>Name: _____</p> <p>Title: _____</p> <p>Date: _____</p>
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