

HIPAA BUSINESS ASSOCIATE AGREEMENT

THIS HIPAA BUSINESS ASSOCIATE AGREEMENT (“BAA”) is entered into effective the ____ day of _____, _____ (“Effective Date”), by and between _____ (“Covered Entity”), and the Regents of the University of Michigan, a Michigan constitutional corporation on behalf of its affiliates (“Business Associate” “BA” or “UM”).

Business Associate may perform functions or activities on behalf of Covered Entity involving the creation, receipt, maintenance, access, transmission, use and/or disclosure of protected health information (“PHI”) received from or on behalf of Covered Entity. Therefore, Business Associate agrees to the following terms and conditions set forth in this BAA.

1.0 Definitions. For purposes of this BAA, any terms used herein, unless otherwise defined, shall have the same meanings as used in the HIPAA Privacy and Security Standards, as amended by the Health Information Technology for Economic and Clinical Health Act (Title XIII of the American Recovery and Reinvestment Act of 2009) and its implementing regulations (“HITECH”) including modifications to the HIPAA Privacy, Security, Enforcement and Breach Notification Rules under HITECH.

2.0 Scope and Interpretation. This BAA shall apply only if and to the extent UM is considered a BA to Covered Entity. Subject to this limitation, the terms and conditions of this BAA shall provide for Business Associate’s creation, receipt, maintenance, transmission, use and/or disclosure of PHI, in any form or medium, including electronic PHI (“ePHI”), in Business Associate’s capacity as “Business Associate” to Covered Entity. Any ambiguity in this BAA shall be resolved to permit Covered Entity to comply with HIPAA.

3.0 Compliance with Applicable Law. Beginning with the relevant effective date, to the extent Business Associate meets the definition of a “business associate” of Covered Entity as such term is defined under HIPAA, Business Associate shall comply with its obligations under this BAA and with all obligations of a business associate under HIPAA, HITECH, as modified, and other related laws, for so long as Business Associate creates, receives, maintains, accesses, or transmits PHI.

4.0 OBLIGATIONS OF BUSINESS ASSOCIATE

4.1 Permissible Use and Disclosure of PHI. In addition to the uses and disclosures permitted by any base agreement(s) or this BAA, Business Associate may use and disclose PHI:

- a. For its own proper management and administration,
- b. To carry out its legal responsibilities,
- c. To aggregate PHI in its possession to provide data aggregation services to Covered Entity as described in 42 C.F.R. § 164.504(e)(2)(i)(B),
- d. To create De-Identified Data Sets and/or Limited Data Sets in compliance with the Privacy Rule; and to use or disclose information in such De-Identified Data Sets without further restriction; and to use or disclose information in such Limited Data Sets pursuant to a Data Use Agreement as permitted by the Privacy Rule; and
- e. To report violations of law to appropriate Federal and State authorities, consistent with 45 C.F.R. § 164.502(j)(1).

4.2 Limitations on Use and Disclosure of PHI. Business Associate shall not, and shall ensure that its directors, officers, employees, agents, and subcontractors do not, use or disclose PHI in any manner that is not permitted or required by any Base Agreement(s) or this BAA, or as Required By Law. All uses and disclosures of, and requests by Business Associate for, PHI are subject to the Privacy Standards' Minimum Necessary Rule and shall be limited to the information contained in a Limited Data Set, to the extent practical, unless additional information is needed to accomplish the intended purpose, or as otherwise permitted in accordance with Section 13405(b) of HITECH, and any other subsequently adopted guidance. Additionally, Business Associate shall ensure that neither it nor its directors, officers, employees, agents, or subcontractors, access, store, share, maintain, use or disclose PHI beyond the borders of the United States of America without agreement of Covered Entity.

4.3 Security. To the extent that Business Associate creates, receives, maintains, or transmits ePHI on behalf of Covered Entity, Business Associate shall:

- a. Comply with the security provisions found at 45 C.F.R. §§ 164.308, .310, .312, and .316 in the same manner as such provisions apply to Covered Entity, pursuant to Section 13401(a) of HITECH, and otherwise implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of ePHI;
- b. Ensure that any agent to whom Business Associate provides ePHI agrees in writing to implement reasonable and appropriate safeguards to protect such ePHI; and
- c. Report to Covered Entity promptly after its discovery any Security Incident of which Business Associate becomes aware and which results in a use or disclosure of ePHI in violation of any Base Agreement(s) or this BAA. For those Security Incidents that do not result in a use or disclosure of ePHI in violation of any Base Agreement(s) or this BAA, reports may be made in the aggregate on at least a quarterly basis. In this context, the term "Security Incident" shall have the same meaning as such term is defined at 45 C.F.R. § 164.304.

4.4 Privacy. To the extent that Business Associate is to carry out one or more of Covered Entity's obligations under Subpart E of 45 C.F.R. Part 164, Business Associate shall comply with the requirements of Subpart E that apply to Covered Entity in the performance of its obligation(s) under this BAA. Business Associate shall also otherwise implement appropriate safeguards in accordance with the Privacy Standards to prevent the use or disclosure of PHI other than pursuant to the terms and conditions of this BAA.

4.5 Mitigation of Harmful Effects. Business Associate agrees to mitigate, to the extent practicable, any harmful effect of a use or disclosure of PHI by Business Associate in violation of the requirements of this BAA, including, but not limited to, compliance with any state law or contractual data breach requirements.

4.6 Breach of Security or Privacy Obligations.

- a. Business Associate shall report to Covered Entity, within ten (10) business days of discovery, a use or disclosure of PHI not provided for in this BAA by Business Associate, its officers, directors, employees, agents, or subcontractors or by a third party to whom Business Associate disclosed PHI.
- b. Business Associate shall report to Covered Entity, within ten (10) business days of discovery, a breach of unsecured PHI in accordance with the requirements set forth in 45 C.F.R. §§ 164.400-

.414. Business Associate shall fully cooperate with Covered Entity's breach notification and mitigation activities, and shall be responsible for all costs incurred by Covered Entity for those activities.

4.7 Agreements by Third Parties. Business Associate shall enter into an agreement with any agent or subcontractor of Business Associate that will have access to PHI hereunder. Pursuant to such agreement, the agent or subcontractor shall agree to be bound by the same restrictions, terms, and conditions that apply to Business Associate under this BAA with respect to such PHI. Business Associate agrees to provide Covered Entity a list of all its agents or subcontractors upon request.

4.8 Access to Information. Covered Entity acknowledges and agrees that Business Associate does not, within the scope of its services, collect, retain or maintain Designated Record Set information. Accordingly, Business Associate has no obligation to comply with the access provisions of 45 C.F.R. § 164.524.

4.9 Availability of PHI for Amendment. Covered Entity acknowledges and agrees that Business Associate does not, within the scope of its services, collect, retain or maintain Designated Record Set information. Accordingly, Business Associate has no obligation to comply with the amendment provisions of 45 C.F.R. § 164.526.

4.10 Documentation of Disclosures. Business Associate agrees to document uses and disclosures of PHI and information related to such uses and disclosures as required for Covered Entity to respond to a request by an individual for an accounting of disclosures of PHI in accordance with 45 C.F.R. § 164.528.

4.11 Accounting of Disclosures. Within ten (10) business days of notice by Covered Entity to Business Associate that Covered Entity has received a request for an accounting of disclosures of PHI regarding an individual during the six (6) year period prior to the date on which the accounting was requested, Business Associate shall make available to Covered Entity information to permit Covered Entity to respond to the request for an accounting of disclosures of PHI, as required by 45 C.F.R. § 164.528. In the case of an electronic health record maintained or hosted by Business Associate on behalf of Covered Entity, the accounting period shall be three (3) years and the accounting shall include disclosures for treatment, payment, and health care operations, in accordance with the applicable effective date of Section 13402(a) of HITECH. In the event the request for an accounting is delivered directly to Business Associate, Business Associate shall forward such request to Covered Entity within five (5) business days of receipt.

4.12 Restrictions. Business Associate shall comply with any restrictions on disclosure of PHI requested by an individual and agreed to by Covered Entity in accordance with 45 C.F.R. §164.522.

4.13 Judicial and Administrative Proceedings. In the event Business Associate receives a subpoena, court or administrative order or other discovery request or mandate for release of PHI, Business Associate shall notify Covered Entity in writing prior to responding to such request to enable Covered Entity to object. Business Associate shall notify Covered Entity of the request as soon as reasonably practicable, but in any event within two (2) business days of receipt of such request.

4.14 Availability of Books and Records. Business Associate agrees to make its internal practices, books, and records relating to the use and disclosure of PHI available to the Secretary of the

Department of Health and Human Services for purposes of determining Covered Entity's compliance with the Privacy Standards.

4.15 Breach of Contract by Business Associate. In addition to any other rights Covered Entity may have in the Base Agreement(s), this BAA, or by operation of law or in equity, Covered Entity may, upon a breach or violation of this BAA, provide a reasonable opportunity for Business Associate to cure or end any such violation within the time specified by Covered Entity. If cure is not possible or if Business Associate does not cure such breach or violation, Covered Entity may immediately terminate the Base Agreement(s). Covered Entity's option to have a breach cured shall not be construed as a waiver of any other rights Covered Entity has in the Base Agreement(s), this BAA, or by operation of law or in equity.

4.16 Effect of Termination of Agreement(s). Upon the termination of the Base Agreement(s) or this BAA for any reason, Business Associate shall return all PHI created by Business Associate or received from Covered Entity to Covered Entity or, at Covered Entity's direction, destroy all PHI received from Covered Entity that Business Associate maintains in any form, recorded on any medium, or stored in any storage system. This provision shall apply to PHI that is in the possession of Business Associate, its agents and subcontractors. If it is not feasible for the Business Associate to return or destroy PHI, Business Associate further agrees to extend any and all protections, limitations, and restrictions contained herein to Business Associate's use and disclosure of any PHI retained after termination of this BAA, and to limit any further uses and/or disclosures to the purposes that make the return or destruction of PHI infeasible. Business Associate shall retain no copies of the PHI. Business Associate shall remain bound by the provisions of this BAA, even after termination of the Base Agreement(s) or this BAA, until all PHI has been returned or otherwise destroyed as provided in this Section.

4.17 Indemnification. Business Associate shall indemnify and hold harmless Covered Entity and its officers, trustees, employees, agents, and subcontractors from any and all claims, penalties, fines, costs, liabilities, or damages, including but not limited to reasonable attorney fees, incurred by Covered Entity arising from a violation by Business Associate of its obligations under this BAA.

5.0 OBLIGATIONS OF COVERED ENTITY

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

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

5.3 Restrictions on Use and Disclosure. Covered Entity shall notify Business Associate of any restriction on the use or disclosure of PHI that Covered Entity has agreed to in accordance with 45 C.F.R. § 164.522, to the extent such restriction may affect Business Associate's use or disclosure of PHI.

6.0 MISCELLANEOUS

6.1 Third Party Rights. The terms of this BAA do not grant any rights to any third parties.

6.2 Independent Contractor Status. For the purposes of this BAA, Business Associate is an independent contractor of Covered Entity, and shall not be considered an agent of Covered Entity.

6.3 Changes in the Law. The parties shall amend this BAA to conform to any new or revised legislation, rules, or regulations to which Covered Entity is subject now or in the future including, without limitation, HIPAA, HITECH, the Privacy Standards, Security Standards or Transactions Standards.

6.4 Owner of PHI. Under no circumstances shall Business Associate be deemed in any respect to be the owner of any PHI of Covered Entity.

This BAA becomes binding when signed by authorized representatives of both parties.

THE REGENTS OF THE UNIVERSITY OF MICHIGAN:

By: _____

Name: _____

Title: _____

Date: _____

COVERED ENTITY:

By: _____

Name: _____

Title: _____

Date: _____