

BUSINESS ASSOCIATE ADDENDUM

In addendum to the **[insert reference and date of Service Agreement]**, the parties agree to the following terms and conditions:

1) DEFINITIONS

Terms used, but not otherwise defined, in this Agreement shall have the same meaning as those terms in 45 CFR 160.103 and 164.501. For purposes of this section:

- a) Business Associate. “Business Associate” shall mean **[insert the name of the Business Associate,]**.
- b) Covered Entity. “Covered Entity” shall mean Individual. “Individual” shall have the same meaning as the term “individual” in 45 CFR 164.501 and shall include a person who qualifies as a personal representative in accordance with 45 CFR 164.502(g).
- c) Privacy Rule. “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.
- d) Protected Health Information. “Protected Health Information” shall have the same meaning as the term “protected health information” in 45 CFR 164.501, limited to the information created or received by Business Associate from or on behalf of Covered Entity.
- e) Required By Law. “Required By Law” shall have the same meaning as the term “required by law” in 45 CFR 164.501.
- f) Secretary. “Secretary” shall mean the Secretary of the Department of Health and Human Services or his designee.

2) OBLIGATIONS AND ACTIVITIES OF BUSINESS ASSOCIATE

Business Associate agrees to:

- a) Not use or further disclose Protected Health Information other than as permitted or required by the Agreement or as Required By Law.
- b) Use appropriate safeguards to prevent use or disclosure of the Protected Health Information other than as provided for by this Agreement.
- c) 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 Agreement.

- d) Report to Covered Entity any use or disclosure of the Protected Health Information not provided for by this Agreement.
- e) Ensure that any agent, including a subcontractor, to whom it provides Protected Health Information received from, or created or received by Business Associate on behalf of Covered Entity agrees to the same restrictions and conditions that apply through this Agreement to Business Associate with respect to such information.
- f) In the event that Business Associate maintains records in a designated records set, to provide access, at the request of Covered Entity, and in the time and manner designated by Covered Entity, to Protected Health Information 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.
- g) In the event that Business Associate maintains records in a designated records set, 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 at the request of Covered Entity or an Individual, and in the time and manner designated by Covered Entity.
- h) Make internal practices, books, and records relating to the use and disclosure of Protected Health Information received from, or created or received by Business Associate on behalf of, Covered Entity available to the Covered Entity, or at the request of the Covered Entity to the Secretary, in a time and manner designated by the Covered Entity or the Secretary, for purposes of the Secretary determining Covered Entity's compliance with the Privacy Rule. In the event such a request comes directly from the Secretary, Business Associate agrees to notify Covered Entity immediately of such request.
- i) Document such disclosures of Protected Health Information 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 Protected Health Information in accordance with 45 CFR 164.528.
- j) Provide to Covered Entity or an Individual, in time and manner designated by Covered Entity, information collected in accordance with this section, to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR 164.528.

3) PERMITTED USES AND DISCLOSURES BY BUSINESS ASSOCIATE

- a) Except as otherwise limited in this Agreement, Business Associate may use or disclose Protected Health Information to perform functions, activities, or services for, or on behalf of, Covered Entity as specified in

[Insert Name of Services Agreement], provided that such use or disclosure would not violate the Privacy Rule if done by Covered Entity.

- b) Except as otherwise limited in this Agreement, 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 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) OBLIGATIONS OF COVERED ENTITY

Covered Entity shall provide Business Associate with the notice of privacy practices that Covered Entity produces in accordance with 45 CFR 164.520, as well as any changes to such notice.

5) PERMISSIBLE REQUESTS BY COVERED ENTITY

Covered Entity shall not request Business Associate to use or disclose Protected Health Information in any manner that would not be permissible under the Privacy Rule if done by Covered Entity.

6) TERM AND TERMINATION

- a) Term. The obligations set forth in this section shall be effective as of the date the first protected health information is released to Business Associate pursuant to this Addendum, and shall terminate only 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.
- b) Termination for Cause. Upon Covered Entity's knowledge of a material breach by Business Associate, Covered Entity shall provide an opportunity for Business Associate to cure the breach or end the violation. Covered Entity may terminate this Agreement if Business Associate does not cure the breach or end the violation within the time specified by Covered Entity.
- c) Effect of Termination
 - (i) Except as provided in paragraph (ii) of this section, upon termination of this Agreement, for any reason, Business Associate shall return or destroy all Protected Health Information received from Covered Entity, or 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.

- (ii) In the event that Business Associate determines that returning or destroying the Protected Health Information is infeasible, Business Associate shall provide to Covered Entity notification of the conditions that make return or destruction infeasible. Upon mutual agreement of the Parties that return or destruction of Protected Health Information is infeasible, Business Associate shall extend the protections of this Agreement to such Protected Health Information and limit further uses and disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such Protected Health Information.

- d) Survival. The respective rights and obligations of Business Associate under this section shall survive the termination of this Agreement.

7) OWNERSHIP OF INFORMATION

Covered Entity holds all right, title, and interest in and to the PHI and Business Associate does not hold and will not acquire by virtue of this Agreement or by virtue of providing goods or services to Covered Entity, any right, title, or interest in or to the PHI or any portion thereof. Except as specified in **Paragraph ___ above [delete if there is no provision allowing such requirements/right to compile reports, aggregate data, etc. Otherwise, include specific paragraph reference in this Addendum or in the Service Agreement that references that obligation of the BA specifically]**, or as otherwise agreed to in writing by the parties, Business Associate will have no right to compile and/or distribute statistical analyses and reports utilizing aggregated data derived from the PHI or any other health and medical data obtained from Covered Entity.

8) RIGHT TO INJUNCTIVE RELIEF

Business Associate expressly acknowledges and agrees that the breach, or threatened breach, by it of any provision of this Agreement may cause Covered Entity to be irreparably harmed and that Covered Entity may not have an adequate remedy at law. Therefore, Business Associate agrees that upon such breach, or threatened breach, Covered Entity will be entitled to seek injunctive relief to prevent Business Associate from commencing or continuing any action constituting such breach without having to post a bond or other security and without having to prove the inadequacy of any other available remedies. Nothing in this paragraph will be deemed to limit or abridge any other remedy available to Covered Entity at law or in equity.

9) MISCELLANEOUS

- a) Regulatory References. A reference in this Agreement to a section in the Privacy Rule means the section as in effect or as amended, and for which compliance is required.
- b) 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 the Privacy Rule and the Health Insurance Portability and Accountability Act, Public Law 104-191.
- c) Interpretation. Any ambiguity in this Agreement shall be resolved in favor of a meaning that permits Covered Entity to comply with the Privacy Rule.

University of Iowa

By: _____
University of Iowa

Date: _____

BUSINESS ASSOCIATE

By: _____
Name: _____
Title: _____

Date: _____