

## BUSINESS ASSOCIATE AGREEMENT

This Business Associate Agreement (the "Agreement") is entered into this \_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_, by and between \_\_\_\_\_ ("Covered Entity") and the University of Maine System, acting through the University of \_\_\_\_\_ ("Business Associate").

WHEREAS, Covered Entity and Business Associate are parties to an agreement (the "Underlying Agreement"), under which Business Associate provides certain services to Covered Entity and, in connection with those services, Covered Entity discloses to Business Associate and/or Business Associate discloses and/or uses certain protected health information ("PHI") that is subject to protection under the Health Insurance Portability and Accountability Act of 1996, as amended from time to time ("HIPAA");

WHEREAS, the parties desire to comply with the HIPAA standards for the privacy and security of PHI of Individuals at Covered Entity;

NOW THEREFORE, for and in consideration of the recitals above and the mutual covenants and conditions herein contained, Covered Entity and Business Associate enter into this Agreement to provide a full statement of their respective responsibilities.

### **SECTION I - DEFINITIONS**

Unless otherwise provided herein, capitalized terms shall have the same meaning as set forth in HIPAA, as amended, and its implementing regulations.

**ARRA** shall mean the Health Information Technology for Economic and Clinical Health Act provisions of the American Recovery and Reinvestment Act of 2009, Pub. Law No. 111-5 and its implementing regulations. References in this Agreement to a section or subsection of title 42 of the United States Code are references to sections of ARRA, and any reference to provisions of ARRA in this Agreement shall be deemed a reference to that provision and its existing and future implementing regulations, when and as each is effective.

**Compliance Date** shall mean in each case the date by which compliance is required under the referenced provision of ARRA.

**HIPAA** - The term "HIPAA" shall mean the Health Insurance Portability and Accountability Act of 1996, as amended from time to time.

**Individual** - The term "Individual" shall have the same meaning as the term "Individual" in 45 CFR Section 160.103 and shall include a person who qualifies as a personal representative in accordance with 45 CFR §164.502(g).

**Privacy Rule** - The term "Privacy Rule" shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 CFR Part 160 and Part 164, Subparts A, D and E.

**Protected Health Information or PHI** - The term "Protected Health Information" or "PHI" 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.

**Required by Law** - The term "required by law" shall have the same meaning as the term "required by law" in 45 CFR §164.103.

**Secretary** - The term "Secretary" shall mean the Secretary of the United States Department of Health and Human Services or his/her designee.

**Security Rule** - The term "Security Rule" shall mean the Security Standards for the Protection of Electronic Protected Health Information at 45 CFR Parts 160, 162 and 164, Subpart C.

**Underlying Agreement** - The term “underlying agreement” shall mean that certain agreement dated \_\_\_\_\_, 20\_\_ under which Business Associate provides certain services to Covered Entity and, in connection with those services, Business Associate uses or discloses certain PHI that is subject to protection under HIPAA from or on behalf of Covered Entity.

## **SECTION II - OBLIGATIONS AND ACTIVITIES OF BUSINESS ASSOCIATE**

- 2.1 Performance of Agreement. Business Associate, its agents and employees (collectively referred to as “Business Associate”) agrees not to use or further disclose PHI other than as permitted or required by this Agreement or as Required by Law.
- 2.2 Safeguards for Protection of PHI. Business Associate shall develop, implement, maintain and use appropriate administrative, technical and physical safeguards to prevent the use or disclosure of PHI, in any form or media, received from, or created or received by Business Associate on behalf of, the Covered Entity, other than as provided for by this Agreement. Business Associate shall document and keep such security measures current.
- 2.3 Reporting of Unauthorized Use and/or Security Breach. Business Associate will promptly report to Covered Entity any breach of security or use or disclosure of PHI not provided for in this Agreement upon becoming aware of it, as soon as possible and in no case later than sixty (60) calendar days after discovery, and all in accordance with 42 USC § 17932(b) as of its Compliance Date. Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a security breach or use or disclosure of PHI by Business Associate in violation of the requirements of this Agreement.
- 2.4 Use of Subcontractors. Business Associate agrees to ensure that any agent and/or subcontractor, to whom it provides PHI received from, or created or received by Business Associate on behalf of, Covered Entity, adheres to the same restrictions and conditions that apply through this Agreement to Business Associate with respect to such information.
- 2.5 Access to PHI. Business Associate agrees to provide access to PHI in a Designated Record Set in order to meet the requirements under 45 CFR §164.524 and Maine law. In the event that Business Associate, in connection with the services, uses or maintains an Electronic Health Record of information of or about an Individual, then the Business Associate shall upon request by the Covered Entity provide an electronic copy of the PHI to the Covered Entity or to the Individual or a third party designated by the Individual, all in accordance with 42 USC §17935(e), as of its Compliance Date.
- 2.6 Amendments by Business Associate. Business Associate agrees to make available for amendment and incorporate any amendment(s) to PHI in a Designated Record Set that the Covered Entity directs or agrees to pursuant to 45 CFR §164.526.
- 2.7 Access by DHHS. 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, or created or received by Business Associate on behalf of, Covered Entity available to the Covered Entity, or to the Secretary, in a time and manner designated by the Covered Entity or the Secretary, for the purposes of the Secretary determining Covered Entity’s and Business Associate’s compliance with HIPAA and its implementing regulations.
- 2.8 Documentation of Disclosures. Business Associate agrees to document such disclosures of PHI and information related to such disclosures and to make such information available 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 and, as of its Compliance Date, in accordance with 42 USC §17935(c).
- 2.9 Security of Electronic Information. Business Associate shall develop, implement, maintain and use appropriate administrative, technical and physical security measures to preserve the confidentiality, integrity and availability of all electronically maintained or transmitted health information received from, or created or received by Business Associate on behalf of, the

Covered Entity, which pertains to an Individual. As of the Compliance Date of 42 USC §17931, Business Associate shall comply with the requirements set forth in 45 CFR §§164.308, 164.310, 164.312 and 164.316.

- 2.10 Electronic Transactions and Code Set Standards. If Business Associate conducts any Standard Transaction for, or on behalf of, the Covered Entity, Business Associate shall comply, and shall require any subcontractor or agent conducting such Standard Transaction to comply, with each applicable requirement of 45 CFR Part 162.

### **SECTION III - PERMITTED USES AND DISCLOSURES BY BUSINESS ASSOCIATE**

- 3.1 General. Except as otherwise limited in this Agreement or as provided in section 3.2, 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 Agreement, provided that such use or disclosure would not violate HIPAA if done by Covered Entity or the “minimum necessary” policies and procedures of the Covered Entity. Except as permitted by this Agreement, the Covered Entity shall not request or require Business Associate to use or disclose PHI in any manner that would not be permissible under HIPAA if done by the Covered Entity.
- 3.2 Specific. Except as otherwise limited in this Agreement, Business Associate may use PHI if necessary for the proper management and administration of the Business Associate or to carry out the legal responsibilities of the Business Associate. Except as otherwise limited in this Agreement, Business Associate may disclose PHI if necessary for the proper management and administration of the Business Associate, or to carry out the legal responsibilities of the Business Associate, provided that disclosure is 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. 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 §164.503(e)(2)(i)(B). Business Associate may use PHI to report violations of law to appropriate Federal and State authorities, consistent with 45 CFR §164.502(j)(1).
- 3.3 Minimum Necessary. Business Associate shall request, use and/or disclose only the minimum amount of PHI necessary to accomplish the purpose of the request, use and/or disclosure; provided that it shall comply with 42 U.S.C. §17935(b) as of its Compliance Date.
- 3.4 Remuneration. Business Associate shall not directly or indirectly receive remuneration in exchange for any PHI in accordance with 42 USC §17935(d) as of its Compliance Date.
- 3.5 Marketing. Business Associate shall not make or cause to be made any communication about a product or service that is prohibited by 42 USC §17936(a) as of its Compliance Date.
- 3.6 Fund-Raising. Business Associate shall not make or cause to be made any written fund-raising communication that is prohibited by 42 USC §17936(b) as of its Compliance Date.

### **SECTION IV - OBLIGATIONS OF COVERED ENTITY**

- 4.1 Consent. Covered Entity agrees to obtain any consent, authorization or permission that may be required by the Privacy Rule or applicable state laws and/or regulations prior to furnishing Business Associate the PHI pertaining to an Individual. The Covered Entity will notify Business Associate of any changes in, or revocation of, permission by the Individual to use or disclose PHI, to the extent that such changes may affect Business Associate’s use or disclosure of PHI.
- 4.2 Restrictions. Covered Entity agrees that it will inform Business Associate of any PHI that is subject to any arrangements permitted or required of Covered Entity under the Privacy Rule that may materially impact in any manner the use and/or disclosure of PHI by Business Associate under this Agreement, including, but not limited to, restrictions on the use and/or

disclosure of PHI as provided for in 45 CFR §164.522 or 42 USC §17935(a) as of its Compliance Date.

- 4.3 Notice of Privacy Practices. Covered Entity agrees that it will notify Business Associate of any limitation(s) in its Notice of Privacy Practices of the Covered Entity in accordance with 45 CFR §164.520, to the extent that such limitation may affect Business Associate's use or disclosure of PHI.
- 4.4 Minimum Necessary. Covered Entity shall request, use and/or disclose only the minimum amount of PHI necessary to accomplish the purpose of the request, use and/or disclosure; provided that it shall comply with 42 U.S.C. §17935(b) as of its Compliance Date.
- 4.5 Indemnification. Covered Entity shall indemnify, defend, and hold Business Associate and its employees, directors, trustees, officers, representatives and agents (collectively the Indemnitees) harmless from and against all claims, causes of action, liabilities, judgments, fines, assessments, penalties, damages, awards or other expenses, of any kind or nature whatsoever, including, without limitation, attorneys' fees, expert witness fees, and costs of investigation, litigation or dispute resolution, incurred by the Indemnitees and relating to or arising out of any breach or alleged breach of the terms of this Agreement by Covered Entity or any other act or omission of Covered Entity, its employees or agents.
- 4.6 Permission. Covered Entity will notify Business Associate of any changes in, or revocation of, permission by the Individual to use or disclose PHI, to the extent that such changes may affect the Business Associate's use or disclosure of PHI.

## **SECTION V - TERM/ TERMINATION**

- 5.1 Term and Termination. The term of this Agreement shall be effective as of \_\_\_\_\_ and shall terminate 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 infeasible to return or destroy the PHI, protections are extended to such PHI in accordance with the termination provisions in this section.
- 5.2 Termination for Cause. If either party knows of a pattern of activity or practice of the other party that constitutes a material breach or violation of this Agreement, then the non-breaching party shall either:
  - A. Provide an opportunity for the other party to cure the breach or end the violation and terminate this Agreement if the other party does not cure the breach or end the violation within the time specified;
  - B. Immediately terminate this Agreement if the other party has breached a material term of this Agreement and cure is not possible; or
  - C. If neither termination nor cure are feasible, the non-breaching party shall report the violation to the Secretary.
- 5.3 Effect of Termination:
  - 5.3.1 Except as provided in Section 5.3.2, upon termination of this Agreement, for any reason, Business Associate shall cease and desist all uses and disclosures of Covered Entity's PHI and shall immediately return or destroy (if Covered Entity gives written permission to destroy) in a reasonable manner consistent with HIPAA, all PHI received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity, provided, however that Business Associate shall cooperate with Covered Entity to ensure that no original PHI records are destroyed. This provision shall apply to PHI that is in the possession of subcontractors or agents of Business Associate. Except as provided in Section 5.3.2, Business Associate shall retain no copies of the PHI. Except as provided in Section 5.3.2, Business Associate shall certify to Covered Entity that all PHI has been returned (or destroyed) within 30 days after termination or expiration of this Agreement.

5.3.2 In the event that Business Associate determines that returning or destroying the PHI 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 PHI is infeasible, 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.

**SECTION VI - MISCELLANEOUS**

6.1 Construction. This Agreement shall be construed as broadly as necessary to implement and comply with HIPAA, ARRA and the HIPAA regulations. The parties agree that any ambiguity in this Agreement shall be resolved in favor of a meaning that complies and is consistent with HIPAA, ARRA and HIPAA regulations.

6.2 Notice. Any notice or other communication required, or which may be given, pursuant to this Agreement, shall be in writing. Any such notice shall be deemed delivered (i) on the day of delivery in person; (ii) five (5) days after deposit in first class registered mail, with return receipt requested; (iii) on the actual delivery date if deposited with an overnight courier; or (iv) on the date sent by facsimile, if confirmed with a copy sent contemporaneously by first class, certified, registered or express mail; in each case properly posted and fully prepaid to the appropriate address set forth below, or such other address of which a party may provide notice in accordance with this section:

_____	_____
_____	_____
_____	_____
_____	_____

6.3 Modification of Agreement. The parties recognize that this Agreement may need to be modified from time to time to ensure consistency with amendments to and changes in applicable federal and state laws and regulations, including, but not limited to HIPAA. The parties agree to execute any additional amendments to this Agreement reasonably necessary for each party to comply with HIPAA. This Agreement shall not be waived, amended or altered, in whole or in part, except in writing signed by the parties.

6.4 Transferability. Covered Entity has entered into this Agreement in specific reliance on the expertise and qualifications of Business Associate. Consequently, Business Associate's interest and obligations under this Agreement may not be transferred or assigned or assumed by any other person, in whole or in part, without the prior written consent of Covered Entity.

6.5 Governing Law and Venue. This Agreement shall be governed by, and interpreted in accordance with, the internal laws of the State of Maine, except that its conflicts of law provisions shall not apply.

6.6 Binding Effect. This Agreement shall be binding upon, and shall extend to the benefit of, the parties hereto and their respective permitted successors and assigns.

6.7 Execution. This Agreement may be executed in multiple counterparts, each of which shall constitute an original and all of which shall constitute but one Agreement.

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

6.9 Relationship of Parties. Business Associate is an independent contractor of the Covered Entity, not a partner, agent or joint venturer of the Covered Entity and neither party shall hold itself out contrary to these terms by advertising or otherwise, nor shall either party be bound by any representation, act or omission whatsoever of the other.

- 6.10 Survival. The respective rights and obligations of the parties under sections 4.5 and 5.3 of this Agreement shall survive the termination of this Agreement.
- 6.11 Priority of Agreement. If any portion of this Agreement is inconsistent with the terms of the Underlying Agreement, the terms of this Agreement shall prevail. Except as set forth above, the remaining provisions of the Underlying Agreement shall remain unchanged.
- 6.12 Non-Discrimination. The parties shall not discriminate and shall comply with applicable laws prohibiting discrimination on the basis of race, color, religion, sex, sexual orientation, including transgender status or gender expression, national origin or citizenship status, age, disability, or veteran status. Business Associate encourages the employment of individuals with disabilities.
- 6.13 Non-waiver. The failure of either party to exercise any of its rights under this Agreement for a breach thereof shall not be deemed to be a waiver of such rights, and no waiver by either party, whether written or oral, express or implied, of any rights under or arising from this Agreement shall be binding on any subsequent occasion; and no concession by either party shall be treated as an implied modification of the Agreement unless specifically agreed in writing.
- 6.14 Severability. In the event one or more clauses of this Agreement are declared invalid, void, unenforceable or illegal, that shall not affect the validity of the remaining portions of this Agreement.
- 6.15 Entire Agreement. This Agreement sets forth the entire agreement of the parties, and replaces and supersedes any previous agreement between the parties on the subject, whether oral or written, express or implied.
- 6.16 Force Majeure. Neither party to this Agreement shall be liable for non-performance of any obligation under this Agreement if such non-performance is caused by a Force Majeure. "Force Majeure" means an unforeseeable cause beyond the control of and without the negligence of the party claiming Force Majeure, including, but not limited to, fire, flood, other severe weather, acts of God, labor strikes, interruption of utility services, war, acts of terrorism, and other unforeseeable accidents.
- 6.17 Documentation. Both parties shall retain all documentation required by HIPAA for six years from the date of its creation or the date when the document was last in effect, whichever is later

IN WITNESS WHEREOF, the parties hereto have set their hands effective the day and year first above written.

**UNIVERSITY OF MAINE SYSTEM**

**COVERED ENTITY**

By: \_\_\_\_\_

By: \_\_\_\_\_

Name:

Name:

Title:

Title:

Date:

Date: