Business Associate Agreement

This Business Associate Agreement ("BAA") is entered into as of ("Effective Date")
by and between University Hospital, a body corporate and politic, and an instrumentality of the State
of New Jersey, having its principal offices at 150 Bergen Street, Newark, New Jersey 07103
(hereinafter referred to as "Covered Entity") and, having its principal offices at
(hereinafter referred to as "Business Associate") ("Covered Entity" and "Business
Associate" hereinafter individually referred to as a "Party" and collectively referred to as the
"Parties").
The Parties also have entered into a made effective on
("Underlying Agreement"). Any conflict between the terms of this BAA and the Underlying
Agreement between the Parties shall be governed by the terms of this BAA.

WITNESSETH

WHEREAS, the purpose of this BAA is to satisfy certain requirements of the Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act (Title XIII of the American Recovery and Reinvestment Act of 2009) and associated federal rules (collectively, "HIPAA") which require Covered Entity to obtain satisfactory assurances in writing from Business Associate that Business Associate will appropriately safeguard protected health information ("PHI") it receives or creates on behalf of Covered Entity;

WHEREAS, Business Associate recognizes and is willing to comply with the specific requirements pursuant HIPAA; and

WHEREAS, in connection with the Underlying Agreement, Covered Entity has or shall engage Business Associate to provide services involving the use or disclosure of Covered Entity's PHI.

NOW, THEREFORE, in consideration of the promises and mutual covenants set forth in the Underlying Agreement and contained herein, the Parties, intending to be legally bound, hereby agree as follows:

1. **Definitions**

- 1.1. General. The following terms used in this BAA shall have the same meaning as those terms in the HIPAA Rules: Breach; Business Associate; Covered Entity; Data Aggregation; Designated Record Set; Disclosure; Encryption; Health Care Operations; Individual; Minimum Necessary; PHI; Required by Law; Secretary; Security Incident; Subcontractor; Unsecured PHI; Workforce. Terms used, but not otherwise defined in this BAA, shall have the same meaning as those terms are given when defined in HIPAA.
- 1.2. Specific Definition. "HIPAA Rules" shall mean the regulations promulgated under HIPAA by the United States Department of Health and Human Services including, but not limited to, the HIPAA Privacy Regulations (45 C.F.R. Part 160 and 45 C.F.R. Part 164, Subparts A and E); the HIPAA Security Regulations (45 C.F.R. Part 160 and 45 C.F.R. Part 164, Subparts A and C); and the

HIPAA Breach Notification Regulations (45 C.F.R. Part 160 and 45 C.F.R. Part 164, Subparts A and D), all as may be amended from time to time.

2. Obligations and Duties of Business Associate

- 2.1. Business Associate shall not use or disclose Covered Entity's PHI other than as permitted or required by this BAA, or as Required by Law.
- 2.2. Business Associate shall use appropriate safeguards, and comply with Subpart C of 45 C.F.R. Part 164 with respect to electronic PHI, to prevent use or disclosure of Covered Entity's PHI other than as provided for by this BAA.
- 2.3. In accordance with this Section 2.3, Business Associate shall immediately report to Covered Entity any use or disclosure of Covered Entity's PHI by Business Associate, its Subcontractors and/or Workforce not provided for by this BAA (an "Unauthorized Disclosure") of which it becomes aware, including, but not limited to, any Breach of Covered Entity's Unsecured PHI, as required by 45 CFR § 164.410(b), and any Security Incident. Upon discovery of an Unauthorized Disclosure, Breach or Security Incident impacting Covered Entity's Unsecured PHI, Business Associate shall provide immediate oral notification of the same to Covered Entity's Privacy Officer. Business Associate shall also provide written notification to Covered Entity of any Breach of Covered Entity's Unsecured PHI no later than five (5) days after discovery of the Breach, and the content of such notice shall be consistent with 45 CFR § 164.410(c). If Business Associate has been advised, orally or in writing, by law enforcement officials that notification of affected individuals may impede a criminal investigation, Business Associate shall so inform Covered Entity. Notwithstanding any other provision of this BAA, Business Associate agrees to reimburse Covered Entity for any and all reasonable expenses (e.g., cost of mailing, media, credit monitoring, etc.) incurred by Covered Entity in carrying out the obligations of Covered Entity under the HIPAA Rules to notify individuals affected by a Breach of Covered Entity's PHI originating from Business Associate or its Subcontractor. In the alternative, and upon agreement of the Parties, Business Associate may directly undertake all or parts of such obligations and expenses in lieu of the herein provided reimbursement.
- 2.4. Business Associate shall mitigate, to the extent commercially reasonable, any harmful effect that is known to Business Associate of a use or disclosure of Covered Entity's PHI by Business Associate, or a Subcontractor of Business Associate, in violation of the requirements of this BAA, and consult with Covered Entity regarding such mitigation.
- 2.5. In accordance with 45 C.F.R. §§164.502(e)(1)(ii) and 164.308(b)(2), if applicable, Business Associate shall require any subcontractors (including, without limitation, independent contractors or agents, ("Subcontractor")) that create, receive, maintain, or transmit Covered Entity's PHI on behalf of the Business Associate to enter into a written agreement with Business Associate whereby Subcontractor agrees to the same restrictions, conditions, and requirements that apply to Business Associate with respect to Covered Entity's PHI. Such agreement shall identify Covered Entity as a third-party beneficiary with rights of enforcement in the event of any violations. If Business Associate discovers a material breach or violation of the agreement between itself and any Subcontractor, Business Associate must require the Subcontractor to correct the violation, or terminate said agreement. Business Associate shall be permitted to engage the use of a Subcontractor to perform or assist in the performance of services that involve use or disclosure of Covered Entity's

PHI by or to the Subcontractor, or creation of PHI by the Subcontractor only if approved in writing by the Covered Entity.

- 2.6. Business Associate shall make Covered Entity's PHI maintained in a Designated Record Set available to Covered Entity or, as directed by Covered Entity, to an Individual as necessary to satisfy Covered Entity's obligations under 45 C.F.R. §164.524, no later than thirty (30) days from the date on which Covered Entity makes the request, including, upon the direction of Covered Entity, providing the Individual with an electronic copy of his/her PHI, if it is readily producible in such form and format or, when requested by the Individual, transmitting such PHI maintained in an electronic health record (EHR) directly to a third party designated by the Individual. Notwithstanding the forgoing, Covered Entity acknowledges and agrees that if Business Associate is an "Actor," as such term is defined in the ONC final rule governing "Interoperability, Information Blocking, and the ONC Health IT Certification Program" published at 85 Fed Reg 25642 (May 1, 2020) (hereinafter, the "Information Blocking Rule" or "IBR"), Business Associate may make certain Electronic Health Information available to a requesting Individual and/or Legal Representative if it is required by the Information Blocking Rule to do so, subject to Section 2.11. For purposes of this Section 2.6 and hereinafter, "Electronic Health Information" and "Legal Representative" shall have such meanings as defined in the IBR.
- 2.7. Business Associate shall make any amendment(s) to Covered Entity's PHI maintained in a Designated Record Set as directed or agreed to by Covered Entity pursuant to 45 C.F.R. §164.526, or take other measures as necessary to satisfy Covered Entity's obligations under 45 C.F.R. §164.526, no later than fifteen (15) days from the date on which Covered Entity makes the request.
- 2.8. Business Associate shall maintain and make available the information required to provide an accounting of disclosures to Covered Entity as necessary to satisfy Covered Entity's obligations under 45 C.F.R. §164.528.
- 2.9. To the extent the Business Associate is to carry out one or more of Covered Entity's obligation(s) 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 such obligation(s).
- 2.10. Business Associate shall make its internal practices, books, and records available to the Secretary of HHS for purposes of determining compliance with the HIPAA Rules.
- 2.11. In the event Business Associate receives a request directly from an Individual or his/her Personal Representative in connection with any of such Individual's PHI (whether a request for access, amendment, accounting of disclosures or any other request of any nature or description), Business Associate shall immediately notify Covered Entity of such request and cooperate with Covered Entity's instructions in responding to such request.
- 2.12. Business Associate shall immediately cooperate with Covered Entity upon request to amend, restrict or change any use or disclosure of any Individual's PHI in Business Associate's control or within the control of its Subcontractor. Notwithstanding the forgoing, Covered Entity acknowledges that it may not engage in any practice that, except as required by law or covered by an exception set forth in the IBR, is likely to interfere with access, exchange or use of Electronic Health Information and that Covered Entity knows is unreasonable and likely to interfere with such access, exchange, or use.

2.13. Business Associate shall implement and use such technologies and methodologies, including, without limitation, Encryption and destruction, which the Secretary of HHS identifies from time to time as rendering PHI unusable, unreadable, or indecipherable to unauthorized individuals, as appropriate to safeguard PHI.

3. Permitted Uses and Disclosures by Business Associate

3.1. Except as otherwise limited in this BAA, Business Associate may use and/or disclose Covered Entity's PHI to perform functions, activities, or services for or on behalf of Covered Entity as specified in the Underlying Agreement, provided that such uses and/or disclosures would not violate the HIPAA Rules, if done by Covered Entity, and otherwise shall meet the terms of this BAA.

3.2. Business Associate may <u>use</u> Covered Entity's PHI:

- 3.2.1 to provide services as necessary to perform its obligations to Covered Entity as set forth in the Underlying Agreement that involve the receipt, creation, or other uses of any nature or disclosure of Covered Entity's PHI, provided that Business Associate agrees to use or disclose Covered Entity's PHI only as necessary to perform such services for the Covered Entity and otherwise only as provided for in this BAA; and
- 3.2.2 if necessary for the proper management and administration of Business Associate, or to carry out the legal responsibilities of Business Associate, provided that any such use of Covered Entity's PHI shall not extend to disclosure of Covered Entity's PHI for such purposes unless the requirements of Section 3.3 are also met.
- 3.3. Business Associate may <u>disclose</u> Covered Entity's PHI for the proper management and administration of Business Associate or to carry out the legal responsibilities of Business Associate, provided the disclosures are Required by Law or Business Associate obtains the following:

3.3.1. Written approval from Covered Entity; and

- 3.3.2. Reasonable assurances from the person to whom or entity to which Covered Entity's PHI will be disclosed that (i) the PHI will remain confidential and used or further disclosed only as Required by Law or for the purposes for which it was disclosed to the person or entity, and (ii) the person or entity will immediately notify Business Associate of any instances of which it is aware in which Covered Entity's PHI has been Breached.
- 3.4. Business Associate agrees to make uses and disclosures of and requests for Covered Entity's PHI consistent with the Covered Entity's Minimum Necessary policies and/or procedures.
- 3.5. Business Associate may provide Data Aggregation services relating to the Health Care Operations of the Covered Entity if requested by the Covered Entity in writing.
- 3.6. Business Associate may use Covered Entity's PHI to complete de-identification of such PHI in accordance with 45 CFR 164.514(a) & (b), provided that Business Associate does not disclose any such de-identified PHI in any manner without the prior express written authorization of Covered Entity.

4. Remedies in Event of Breach; Indemnification

- 4.1. Business Associate agrees and acknowledges that irreparable harm will result to Covered Entity and to its business in the event of a breach by Business Associate of any covenants, duties, obligations and assurances in this BAA, and further agrees that remedy at law for any such breach may be inadequate and that damages resulting therefrom are not susceptible to being measured in monetary terms. In the event of any such breach or threatened breach by Business Associate, Covered Entity shall be entitled to (i) immediately enjoin and restrain Business Associate from any continuing violations and (ii) reimbursement for reasonable attorneys' fees, costs and expenses incurred as a proximate result of the breach. The remedies in this Section 4.1 shall be in addition to any action for damages and/or other remedy available to Covered Entity.
- 4.2. Business Associate shall defend, indemnify, and hold Covered Entity and Covered Entity's owners, governors, trustees, shareholders, members, partners, directors, managers, officers, employees, agents, representatives, successors and assigns (collectively, the "Covered Entity Parties") harmless from and against any and all claims, demands, losses, expenses, costs, obligations, damages, liabilities, of any nature or description including, without limitation, interest, penalties and reasonable attorneys' fees which the Covered Entity Parties may incur, suffer or sustain, which arise, result from or relate to any breach of or action by Business Associate or a Subcontractor to perform any of such party's representations, warranties, covenants, or agreements under this BAA. The obligations of Business Associate under this Section shall survive termination of this BAA.

5. Term and Termination

- 5.1. Term. The term of this BAA shall commence on the Effective Date of the BAA and shall terminate upon the expiration of the Underlying Agreement, provided that if it is infeasible to return or destroy Covered Entity's PHI in a manner rendering it unrecoverable after termination of the BAA, Business Associate will continue to safeguard Covered Entity's PHI in accordance with Section 5.3 below.
- 5.2. Termination by Covered Entity. The Covered Entity may terminate this BAA upon five (5) days' written notice, if the Covered Entity determines that the Business Associate has violated a material term of this BAA and Business Associate has not cured the breach to the satisfaction of Covered Entity during then five (5) day notice period.
- 5.3. Obligations of Business Associate Upon Termination. Upon expiration or termination of this BAA for any reason, Business Associate, with respect to PHI received from the Covered Entity, or created, maintained, or received by Business Associate on behalf of Covered Entity, shall: (i) retain only that PHI which is necessary for Business Associate to continue its proper internal management and administration or to carry out its legal responsibilities, as approved by the Covered Entity in writing after the Covered Entity has an opportunity to confirm that it is infeasible for Business Associate to return such PHI due to such reasons; (ii) return to Covered Entity or, if agreed to by Covered Entity in writing, destroy the remaining PHI that Business Associate and/or any of its Subcontractors still maintain in any form; (iii) continue to use appropriate safeguards and comply with Subpart C of 45 C.F.R. Part 164 with respect to Covered Entity's electronic PHI to prevent use or disclosure of such PHI, other than as provided for in this Section, for as long as Business Associate retains any PHI as approved by the Covered Entity in writing; (iv) not use or disclose PHI retained

by the Business Associate (and ensure that any Subcontractors agree to also not use or disclose) other than for the purposes for which such PHI was retained and subject to the same conditions set forth in this Section 5.3, and in accordance with all protections and restrictions on the use and disclosure of such PHI as contained in this BAA; and (v) return to the Covered Entity (or, if agreed to by the Covered Entity in writing, destroy the PHI) retained by the Business Associate when it is no longer needed by the Business Associate for its proper internal management and administration or to carry out its legal responsibilities.

5.4. Survival. The obligations of Business Associate under this Section 5 shall survive the expiration or termination of this BAA.

6. No Third Party Rights

Except as expressly provided in Section 2.5 above, nothing in this BAA, expressed or implied, is intended or shall be construed to confer upon or give to any person, firm, corporation, association, or legal entity other than the Parties, any rights, remedies or other benefits under or by reason of the BAA. Accordingly, no third party shall have the right to enforce the provisions of the BAA or any other document relating to this BAA.

7. Miscellaneous

- 7.1. Severability. In the event that any provision of this BAA is held by a court of competent jurisdiction to be invalid or unenforceable, the remainder of the provisions of this BAA will remain in full force and effect.
- 7.2. Regulatory References. A reference in this BAA to a section in the HIPAA Rules means the section as in effect or as amended.
- 7.3. Interpretation. Any ambiguity in this BAA shall be interpreted to permit compliance with the HIPAA Rules.
- 7.4. Notices. Any notice required or permitted under this BAA to be given, unless otherwise specified, shall be made in writing and shall be sent either by hand delivery and/or by overnight mail through a courier with a reliable system for tracking delivery to:

To: UNIVERSITY HOSPITAL

To: BUSINESS ASSOCIATE

Name/Title: Privacy Officer Name/Title:

Office of Ethics & Compliance

Address: University Hospital Address:

65 Bergen Street, Suite 1214 Newark, NJ 07101-6750

Email: Phone #

- 7.5. Assignment. This BAA applies to the services being provided by Business Associate and may not be assigned without the written consent of Covered Entity. An agreement with a Subcontractor that complies with the requirements of this BAA shall not be an assignment for the purposes of this BAA.
- 7.6. Governing Law; Venue. This BAA shall be governed by, construed, interpreted and enforced under the laws of the State of New Jersey, without regard to its choice of law provisions.
- 7.7. Modification. This BAA may only be modified by a writing signed by the Parties. The Parties agree to take such action subsequent to this BAA as necessary to amend the BAA from time to time as necessary for the Parties to comply with the requirements of any applicable law.
- 7.8. Headings. Section headings contained in this BAA are for convenience or reference only and shall not be deemed a part of this BAA or have any binding legal effect.
- 7.9. Counterparts. This BAA may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.
- 7.10 Information Blocking. Any restriction, requirement, term or condition in this BAA and/or the Underlying Agreement which would result in impermissible "Information Blocking" by Covered Entity or Business Associate shall be revised, deleted and implemented in a manner intended to comply with the Information Blocking Rule. To implement the foregoing, the Parties specifically hereby agree:
- 7.10.1 to evaluate their respective internal policies, procedures and activities to ensure that each does not engage in any practice which could result in impermissible interference with access, use or exchange of Electronic Health Information ("EHI");
- 7.10.2 to comply with all federal and state laws which require any condition to be satisfied (e.g., consent) before EHI may be accessed, exchanged or used, including not allowing requested EHI to be accessed, used or disclosed if expressly prohibited by federal and/or state law;
- 7.10.3 to train, as necessary and appropriate, each Workforce member who handles, determines, controls, or has the discretion to administer how EHI is accessed, exchanged, on the Information Blocking Rule; and
- 7.10.4 to take any and all other reasonable steps as necessary to ensure the BAA and Underlying Agreement and each Party's practices comply with the Information Blocking Rule.

(Signatures begin on the next page)

IN WITNESS WHEREOF, the Parties hereto agree to the above as written.

COVERED ENTITY: UNIVERSITY HOSPITAL	BUSINESS ASSOCIATE:
By: Name: Title:	By: Name: Title:
Date:	Date: