### BUSINESS ASSOCIATE AGREEMENT

**THIS BUSINESS ASSOCIATE AGREEMENT** by and between

*NAME* (hereinafter referred to as "Covered Entity"), an Indiana not for profit corporation, with its principal place of business located at *ADDRESS*

and

The Trustees of Indiana University on behalf of the Department of \_\_\_\_\_\_\_\_\_\_\_\_\_\_(hereinafter referred to as "Business Associate"), an Indiana educational institution with its principal place of business located at *ADDRESS*

### WITNESSETH:

**WHEREAS,** Business Associate and Covered Entity have entered into an arrangement where the Business Associate will assist the Covered Entity in identifying patients that may qualify for one or more human subjects trials at Business Associate for which \_\_\_\_\_\_\_\_\_\_\_\_\_\_ serves as Principal Investigator.

**WHEREAS,** the Covered Entity will make available and/or transfer to Business Associate certain Protected Health Information ("PHI") in order for the Business Associate to perform certain functions, activities, and duties on behalf of Covered Entity.

**WHEREAS,** the PHI that is or will be disclosed is confidential and must be afforded special treatment and protection pursuant to the Health Insurance Portability and Accountability Act ("HIPAA") of 1996 and the HITECH Act of 2009;

**WHEREAS,** Business Associate will have access to and/or receive from Covered Entity certain PHI that can be used or disclosed only in accordance with this Agreement and the Privacy Rule;

**WHEREAS,** Covered Entity and Business Associate intend to protect the privacy and provide for the security of PHI disclosed to Business Associate pursuant to this Agreement in compliance with HIPAA and the Privacy Rule, the Security Rule, and other applicable laws;

**WHEREAS,** both parties are required to comply with the Standards for Privacy of Protected Health Information (PHI) and Security Standards for the Protection of Electronic Protected Health Information ("ePHI") 45 C.F.R. Part 160 and Part 164, Subparts A, C and E, ("Privacy and Security Regulations") under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and the American Recovery and Reinvestment Act of 2009, Public Law No. 111-005, Part I, Title XIII, Subpart D, Sections 13401 -13409 ("HITECH") all for the purpose of this Agreement shall mean "HIPAA Regulations", and any and all references in this Agreement shall be deemed to include all associated existing and future implementing regulations pertaining to the Privacy and Security of PHI in any form. Business Associate must grant PHI the same

protection that Covered Entity is required to provide such information under the HIPAA Regulations, and Covered Entity has agreed to disclose PHI to Business Associate only on that condition. This Agreement sets forth the terms and conditions pursuant to which PHI that is provided by, or created or received by, Business Associate from or on behalf of Covered Entity will be handled between Covered Entity and Business Associate and with third parties during the term of the Underlying Agreement and after its termination; and

**NOW, THEREFORE,** in consideration of the terms and conditions set forth herein to address the requirements of the HIPAA Regulations, and other good and valuable consideration, the receipt and sufficiency of which is acknowledged, the parties agree as follows:

# ARTICLE I

## Definitions

* 1. Meaning of Terms. The following terms shall have the meaning ascribed to them in this Section:
     1. **BREACH** shall have the meaning set forth at 45 CFR § 164.402, as amended, and shall generally mean the "unauthorized acquisition, access, use, or disclosure of protected health information which compromises the security or privacy of the protected health information, except where an unauthorized person to whom such information is disclosed would not reasonably have been able to retain such information.11
     2. **BUSINESS ASSOCIATE (BA)** shall generally have the same meaning as the term "business associate" at 45 CFR 160.103, and in reference to the Party to this agreement, shall mean Trustees of Indiana University on behalf of the Department of \_\_\_\_\_\_\_\_.
     3. **COVERED ENTITY (CE)** shall generally have the same meaning as the term "covered entity" at 45 CFR 160.l03, and in reference to the Party lo this agreement, shall mean Hamilton Center Research, LLC.
     4. **MINIMUM Necessary:** The Privacy Rule stipulates that covered entities limit the amount of information disclosed to the minimum necessary to achieve the specified goal [45 CFR l 64.514(d)(l)]. This requirement would not apply if the disclosure were required by law, authorized by the individual, or for treatment purposes.

(c) **SECURITY INCIDENT** shall have the same meaning as the term "Security Incident" in 45 CFR § 164.304, which generally means the attempted or successful unauthorized access, use, disclosure, modification or destruction of information or interference with system operations in an information system.

(f) **UNSECURED PROTECTED HEALTH INFORMATION** (Unsecured PHI) shall have the same meaning set forth at 45 CFR § 164.402, as amended, and

generally means PHI that has not been rendered unusable, unreadable, or indecipherable to unauthorized individuals through the use of a technology or methodology specified by the Secretary in guidance.

1.2 **Other Terms.** Terms used, but not otherwise defined, in this Agreement shall have the meaning ascribed to them in the context in which they first appear. Terms used, but not otherwise defined, in this Agreement shall have the same meaning as those terms in 45 CFR Parts 160, 162, and 164. Any reference to a regulation or section in the Code of Federal Regulations ("CFR") shall include any corresponding regulation subsequently issued regardless of the date of issue.

## ARTICLE II

### General Terms

2.1. Interpretation of Provisions. In the event of an inconsistency between the provisions of this Agreement and the mandatory terms of the HIPAA Regulations (as may be expressly amended from time to time by the HHS or as a result of final interpretations by HHS, an applicable court, or another applicable regulatory agency with authority over the parties), the HIPAA Regulations, as applicable, shall prevail.

2.2. Conflicts with Business Associate Agreement. In the event of an inconsistency between the provisions of this Agreement and any other agreement between the Covered Entity and the Business Associate, the provisions of this Agreement shall control.

## ARTICLE III

### Obligations and Activities of Business Associate

* 1. Application of the HIPAA Regulations Provisions, Business Associate may use and disclose PHI that Business Associate obtains or creates only if such use or disclosure is in compliance with each applicable requirement of 45 CFR §§164.502(c) and 164.504(c). The additional requirements of Subtitle ID of HITECH Act (42 U.S.C. § 17921 et. seq.) that relate to privacy and that are made applicable with respect to Covered Entity shall also be applicable to Business Associate and are hereby incorporated into this Agreement.
  2. Application of the HIPAA Security and Privacy Provisions. Business Associate will comply with the Security Rule requirements set forth in 45 CFR §§ 164.308, 164.310, 164.312, 164, 316 and 164.500, all of which are hereby incorporated into this Agreement. Business Associates are squarely and directly liable for violations of the Security Rule and for violations of the Privacy Rule for impermissible uses and disclosures pursuant to their business associate contracts.
  3. Minimum Necessary. Business Associate agrees that it and its agents and subcontractors shall request, use and/or disclose, to the extent practicable, only a Limited Data Set of

PHI necessary pursuant to a Data Use Agreement, or if needed, the minimum amount and content of PHI necessary, to meet the requirements of Business Associate’s obligations to Covered Entity. Upon issuance of guidance by the Secretary on what constitutes "minimum necessary" for purposes of 45 CPR § 164.502(b) (pursuant to 42 U.S.C. § 17935(b)(1 )(B)), Business Associate agrees that it and its agents and subcontractors shall request, use and/or disclose only the "minimum necessary" PHI as described in such guidance.

* 1. Prohibited Uses and Disclosure. Business Associate will not sell PHI or use or disclose PHI for marketing purposes as defined and proscribed in the Regulations.
  2. Limits on Use and Disclosure. Business Associate agrees not to use or further disclose PHI other than as permitted or required by this Agreement or as required by law. Further, Business Associate shall use and disclose PHI in accordance with Covered Entity's Notice of Privacy Practices as provided by Covered Entity to Business Associate pursuant to Section 5.1.
  3. Safeguards. Business Associate agrees to use reasonable and appropriate administrative, physical and technological safeguards to prevent use or disclosure of the PHI not otherwise permitted under this Agreement or by law. Specifically, Business Associate shall: (i) prevent use or disclosure of the PHI other than as provided for by this Agreement, and (ii) to implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of ePHI that it creates, receives, maintains or transmits on behalf of Covered Entity as required by the Security Rule; and ensures that any agent, including a subcontractor, to whom they provide such information agrees to implement reasonable and appropriate safeguards to protect it. Business Associate represents and warrants that it has implemented, and during the term of this Agreement shall maintain, comprehensive written privacy and security policies and procedures and the necessary administrative, technical and physical safeguards appropriate to the size and complexity of Business Associate’s operations and the nature and scope of its activities. These protections include, but are not limited to, password protection and encryption of data stored on any electronic device. Once work is completed and received by Covered Entity, Business Associate will return or destroy all versions of the record.
  4. Mitigation of Harm. 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 or any agent or subcontractor of Business Associate, in violation of the requirements of this Agreement, the Privacy Rule, or the Security Rule.
  5. Documentation of Disclosures. Business Associate shall document such disclosures of

PHI.

* + 1. Such documentation shall be kept with regard to ail disclosures of PHI except disclosures described in 45 CFR *§* l 64.528(a)(l). For each such disclosure, Business Associate shall document the following information: (i) the date of the disclosure; (ii) the name of the

entity or person who received the PHI and, if known, the address of such entity or person;

(iii) a brief description of the PHI disclosed; and (iv) a brief statement of the purpose of the disclosure that reasonably states the basis for the disclosure.

* + 1. Business Associate shall provide to Covered Entity in the lime and manner designated by Covered Entity, information collected in accordance with subsection (a) of this Section 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. In the event that a request for an accounting is delivered directly to Business Associate or its agent or subcontractor by an Individual or a party other than Covered Entity, Business Associate shall within three (3) days of such request forward it to Covered Entity in writing. Business Associate shall, unless otherwise directed by Covered Entity or as Required by Law, supply an accounting of disclosures of PHI only to Covered Entity.
  1. Report of Improper Use or Disclosure or of Security Incidents. Business Associate agrees promptly to report to Covered Entity any actual or suspected Breach of security, intrusion, or unauthorized use or disclosure of the PHI not provided for by this Agreement, or any Security Incident of which Business Associate (or any of its agents or subcontractors) becomes aware. Such report shall be in writing and shall be reported to Covered Entity as soon as practicable after Business Associate becomes aware of such use or disclosure or Security Incident, but in no event more than forty-eight (48 hours) following such discovery. Business Associate shall take prompt corrective action to cure any such deficiencies and any action pertaining to such unauthorized disclosure required by applicable Federal and State laws and regulations. Business Associate is directly liable for failing to make reasonable efforts to limit PHI to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request, pursuant to 45 CFR § 164.502(b).
  2. Report of Breach of Unsecured PHI. In addition to the general obligations of Business Associate under Section 3.9 regarding reporting the improper use or disclosure of' PHI and Security Incidents, Business Associate shall also promptly notify Covered Entity of a Breach of Unsecured PHI within forty-eight (48) hours of when Business Associate discovers such Breach. The Breach shall be treated as discovered by Business Associate as of the first day on which such Breach is known, or by exercising reasonable diligence would have been known, to any person, other than the person committing the Breach, who is an employee, officer, or other agent of Business Associate. Business Associate’s notification shall be in writing and shall include identification of each Individual whose Unsecured PHI bas been, or is reasonably believed by Business Associate to have been subject to the Breach. Business Associate shall include the following information in its notification of Breach lo Covered Entity:
     1. the date of the Breach and the date of discovery of the Breach, if known
     2. a description of the types of unsecured PHI that were involved (such as full name, social security number, date of birth or other types of PHI were involved);
     3. Any steps an individual should take to protect themselves from potential harm resulting from the Breach;
     4. Contact procedures for Individuals to ask questions or learn additional information, which shall include a toll free telephone number, an e-mail address, website or postal address;
     5. identification of each individual whose unsecured PHI has been, or is reasonably believed to have been, accessed, acquired, or disclosed; and
     6. any other details necessary to complete an assessment of the risk of harm to the individual.

In the event that some of the above listed information is not known by Business Associate at the time of notification of Covered Entity of the Breach, Business Associate shall provide such information to Covered Entity as soon as it becomes available to Business Associate, but in no event later than thirty (30) days after Business Associate discovers such Breach. Business Associate shall also provide such assistance and further information with regard to the Breach to Covered Entity as reasonably requested by Covered Entity.

* 1. Agents and Subcontractors. Business Associate agrees to ensure any agent, including a subcontractor, to whom it provides PHI received from, or created or received, maintained or transmitted, by Business Associate on behalf of, Covered Entity, agrees in writing to the same restrictions and conditions that apply through this Agreement to Business Associate with respect to PHI. Such written agreement shall also require the agent or subcontractor to implement reasonable and appropriate administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of ePHI that it creates, receives, maintains or transmits on behalf of Covered Entity. Any use or disclosure of PHI by a subcontractor that is inconsistent with this Agreement is a violation of law and can result in direct liability for the subcontractor.
  2. Agents and Subcontractors Material Breach. If Business Associate becomes aware of a pattern or practice of activity of a subcontractor that would constitute a material breach, then Business Associate must take reasonable steps to cure the Breach or terminate the agreement, if feasible.
  3. Availability of Internal Practices, Books and Records. Business Associate shall make internal practices, books and records 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 Secretary, in a reasonable time and manner designed by the Secretary or Covered Entity, in a lime and manner designated by Covered Entity or the Secretary, for purposes of determining Covered Entity’s compliance with the Privacy Rule or the Security Rule. Business Associate shall notify Covered Entity, in writing, of any request by the Secretary under this Section 3.13, and shall I provide Covered Entity with a copy of any practices, books and records.
  4. Access to PHI. To the extent Business Associate maintains PHI in a Designated Record Set, Business Associate agrees to provide access, at the request of Covered Entity, and in a lime and manner reasonably requested by Covered Entity, to PHI 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.

* 1. Amendment of PHI. Business Associate agrees to make any amendment(s) to PHI 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 lime and manner reasonably requested by Covered Entity.

* 1. Notification of Claims. Each Party shall promptly notify the other Party upon notification or receipt of any civil or criminal demands, causes of action, lawsuits governmental enforcement actions arising out of or related to this Agreement, Data Set, Limited Data Set, or the PHI, regardless of whether the other Party is named as a party in such claims, demands, causes of action, lawsuits, or enforcement actions.

## ARTICLE IV

**Permitted Uses and Disclosures bv Business Associate**

* 1. Use or Disclosure to Perform Functions. Activities or Services. Except as otherwise limited in this Agreement. Business Associate may use or disclose PHI to perform the Services that Business Associate performs for or on behalf of, Covered Entity provided that such use or disclosure would not violate the Privacy Rule if clone by Covered Entity. Any such use or disclosure shall be limited to those reasons and those individuals as necessary to meet Business Associate’s obligations.
  2. Disclosures to Workforce. Business Associate shall not disclose PHI to any member of its workforce unless necessary to fulfill a purpose described in Section 4.l and unless Business Associate bas advised such person of Business Associate's obligations under this Agreement and of the consequences for such person and for Business Associate of violating this Agreement. Business Associate shall take appropriate disciplinary action against any member of its workforce who uses or discloses PHI in contravention of this Agreement or the Privacy Rule. Business Associate must comply with the requirements of the Privacy Rule pursuant to 45 CFR §164.500 that apply to Covered Entity in the performance of such obligation.
  3. Appropriate Uses of PHI. Except as otherwise limited in this Agreement or HIPAA, 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.
  4. Appropriate Disclosures of PHI. Except as otherwise limited in this Agreement or HIPAA, Business Associate may disclose PHI for the proper management and administration of the Business Associate, provided that disclosures arc required by law. or Business Associate obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidcntial 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 Business Associate of any instances of which it is aware in which the

confidentiality of the information bas been breached.

* 1. Data Aggregation Services. If Business Associate provides data aggregation functions, Business Associate may use PHI to provide Data Aggregation functions to Covered Entity as permitted by 42 CFR *§* 164.504( c)(i)(B), except as otherwise provided by this Agreement.

### ARTICLE V

**Obligations of Covered Entity**

* 1. Notice of Privacy Practices 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.
  2. Change or Revocation of Permission. Covered Entity shall provide Business Associate with any changes in or revocation of, permission by an individual to use or disclose PHI, if such changes affect Business Associate's permitted or required uses and disclosures. Business Associate shall comply with any such changes or revocations. Business Associate shall not be responsible for any use or disclosure that fails to comply with any such change or revocation that occurs prior to being notified by Covered Entity pursuant to this Section 5.2.
  3. Restrictions on Use or Disclosure Covered Entity shall notify Business Associate of any restrictions to the use or disclosure of PHI that Covered Entity has agreed to in accordance with 45 CFR § 164.522. Business Associate shall not be responsible for any use or disclosure that fails to comply with any such restriction that occurs prior to being notified by Covered Entity pursuant to this Section 5.3.
  4. Breach Notification Requirement. Covered Entity shall be responsible to notify the lndividual(s) involved in a Breach after being notified by the Business Associate.
  5. No Request to Use or Disclose in Impermissible Manner. Except as necessary for the management and administrative activities of Business Associate as allowed in Sections

4.3 and 4.4, Covered Entity shall not request Business Associate to use or disclose PHI in any manner that would not be permissible under the Privacy Rule if done by Covered Entity.

### ARTICLE VI

**Term and Termination**

* 1. Term. The Term of this Agreement shall be effective as the Effective Date as defined above and shall terminate when all PHI provided by the Covered Entity to the Business Associate, and created or received by Business Associate on behalf of Covered Entity, is destroyed or returned to Covered Entity.
  2. Termination with Cause. Upon Covered Entity’s knowledge of a material breach by Business Associate, Covered Entity shall:
     1. Provide an opportunity for Business Associate to cure the breach. If Business Associate does not cure the Breach within a lime period to be determined by Covered Entity after considering the nature and scope of the Breach, terminate this Agreement.
     2. Immediately terminate this Agreement, if Business Associate has breached a material term of this agreement and cure is not possible.

If the Business Associate fails to correct the breach within the specified lime period, the Business Associate agrees that the Covered Entity may deem this failure as a material breach that may require the Covered Entity to immediately terminate any and all other agreements or arrangements with the Business Associate. The termination provisions of this Section 6.2 shall supersede any termination provisions of any other agreements between the Covered Entity and the Business Associate.

* 1. Termination for Convenience. This Agreement may be terminated by either Party providing the other Party receives written notice thirty (30) days prior to the effective date of termination. The Effect of Termination as set forth in Section 6.5 shall apply to such termination.
  2. Changes in Law. ln the event of passage of a law or promulgation of a regulation or an action or investigation by any regulatory body which would prohibit the relationship between the parties, or the operations of either party with regard to the subject of this Agreement, the parties shall attempt in good faith to renegotiate the Underlying Agreement to delete the unlawful provision(s) so that the Underlying Agreement can continue. If the parties arc unable to renegotiate the Underlying Agreement within thirty

(30) days, the Underlying Agreement shall terminate immediately, upon written notice of either Party.

* 1. Effect of Termination.
     1. Except as provided in paragraph (b) of this Section 6.5, upon termination of this Agreement for any reason, Business Associate shall return or destroy all PH[ 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.

* + 1. In the event that Business Associate determines that returning or destroying the PHI is not feasible, Business Associate may retain the PHI, but shall extend the protections of this Agreement to such PHI and limit further uses and disclosures of such PH] to those purposes that make the return or destruction not feasible, for so long as Business Associate maintains such PHI.

# ARTICLE VII

### Miscellaneous

7.1 Amendment. The parties agree to take such action as it necessary to amend this Agreement from lime to time as is necessary for compliance with the requirements of the HIPAA Regulations and any other applicable laws.

* 1. Disclaimer. Covered Entity makes no warranty or representation that compliance by Business Associate with this Agreement, HIPAA, the Privacy Rule or the Security Rule will be adequate or satisfactory for Business Associate's own purposes. Business Associate is solely responsible for all decisions made by Business Associate regarding the safeguarding of PHI.
  2. Property Rights. All PHI shall be and remain the exclusive properly of Covered Entity. Business Associate agrees that it acquires no title or rights to the PHI, including any de­ identified information, as a result of this Agreement.
  3. 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 HIPAA.
  4. Regulatory References. A reference in this Agreement to sections of HIPAA means the section as in effect or as amended, and for which compliance is required.
  5. Governing Law. This Agreement shall be governed by and constructed in accordance with the laws of the State of Indiana to the extent that the provisions of HIPAA, the Privacy Rule, the Security Rule and the HITECH Act do not preempt the laws of the State of Indiana.
  6. Modifications. Any modifications to this Agreement shall be valid only if made in writing and signed by a duly authorized agent of both parties.
  7. Notice. Any notice required or permitted to be given by either Party under this Agreement shall be sufficient if in writing and hand delivered (including delivery by courier) or sent by postage prepaid certified mail return receipt requested, as follows:

If to Covered Entity:

ADDRESS

If to Business Associate:

ADDRESS

* 1. Severability. The parties agree that if a court determines, contrary to the intent of the parties, that any of the provisions or terms of this Agreement are unreasonable or contrary to public policy, or invalid or unenforceable for any reason in fact, law, or equity, such unenforceability or validity shall not affect the enforceability or validity of the remaining provisions and terms of this Agreement. Should any particular provision of this Agreement be held unreasonable or unenforceable for any reason, then such provision shall be given effect and enforced to the fullest extent that would be reasonable and enforceable.
  2. Waiver of Breach. No failure or delay by either Party in exercising its rights under this Agreement shall operate as a waiver of such rights, and no waiver of any Breach shall constitute a waiver of any prior, concurrent, or subsequent Breach.
  3. Titles. Titles or headings are used in this Agreement for reference only and shall not have any effect on the construction or legal effect of this Agreement.
  4. Independent Contractors. For purposes of this Agreement, Covered Entity and Business Associate are and will act at ail limes as independent contractors. None of the provisions of this Agreement are intended to create, nor shall be deemed or construed to create, any relationship other than that of independent entities contracting with each other for the purpose of effecting this Agreement. None of the provisions of this Agreement shall

establish or be deemed or construed to establish any partnership, agency, employment agreement or joint venture between the parties.

* 1. No Third Party Beneficiaries. It is the intent of the parties that this Agreement is to be effective only in regards to their rights and obligations with respect to each other. It is expressly not the intent of the parties to create any independent rights in any third party or to make any third-party beneficiary of this Agreement and no privity of contract shall exist between third parties and each party.
  2. Survival. The respective rights and obligations of Business Associate under Section 6.5 Effect of Termination of this Agreement shall survive the termination of this Agreement.

**Each party to this Agreement warrants that it has full power and authority to enter into this Agreement, and the person signing this Agreement on behalf of either party warrants that he/she has been duty authorized and empowered to enter into this Agreement.**

**COVERED ENTITY: BUSINESS ASSOCIATE:**