

**MSA Template:** This Master Service Agreement is intended to be used when it is anticipated that there will be multiple projects between an organization and an outside entity. It defines general governance issues and allows each project to be added as an attachment or Scope of Work (SOW). Each attachment may include additional governance as is need for the specific project. The design of this MSA is such that either partner can initiate and/or fund projects described in the subsequent SOWs. It is especially useful when not all of the anticipated projects have been defined.

**Data Use Template:** This Data Use agreement is intended to define the use and distribution of a variety of data collected by an organization with an outside entity. It includes sections for description of the data, the specific use of the data, and who may access the data. It is not intended for data that are protected by HIPPA.

**Template BAA:** This Business Associate Agreement is intended for the situation where an organization is receiving data protected by HIPPA. In general, it shifts the responsibility for data integrity, data protection, and breach notification from the Covered Entity to the organization receiving the data. This agreement can also be used when the organization is the Covered Entity and is sharing data with a business associate.

**Template Subcontractor BAA for Company (Company as Business Associate):** This agreement is specifically intended for the situation where an organization has received data under a BAA with a Covered Entity and needs to share the data with a third party. It is designed to transfer the responsibility for data integrity, data protection, and breach notification from the organization to the subcontractor.

**Master Services/Collaboration Agreement  
Between**

\_\_\_\_\_  
**and Company, Inc.**

THIS MASTER \_\_\_\_\_ AGREEMENT the ("Agreement"), effective \_\_\_\_\_ ("Effective Date"), is entered into by and between \_\_\_\_\_, having a principal place of business or an address at \_\_\_\_\_, and **COMPANY, INC.**, an independent nonprofit organization (501(c)(3)), having a principal place of business at \_\_\_\_\_, (hereinafter called "Company") (\_\_\_\_\_ and Company, the "Party" or "Parties").

**Background**

\_\_\_\_\_ is \_\_\_\_\_.

The purpose of this Agreement is to further advance scientific knowledge, discoveries, and clinical service through the conduct of collaborative research in the type 1 diabetes space.

**Guidance principles to develop a collaboration to serve clinical, research and educational purposes among the Parties**

The following principles shall be used to develop the framework for the terms and conditions set forth in this Agreement:

1. The interests of the Parties will be furthered by this collaboration.
2. Clinical service, research and educational opportunities will be enhanced for all participants.
3. The relationship sought is one of true collaboration where investment and value are recognized bilaterally both in economic and non-economic terms.
4. The Parties are interested in generating results to further each Party's respective missions.
5. The areas of collaboration will advance the Parties' predetermined strategic priorities in type 1 diabetes.

**1. TERM**

The term of this Agreement will be from the Effective Date until terminated as provided in Section 15. (the "Term").

**2. SCOPE OF SERVICES**

\_\_\_\_\_ and Company hereby agree to collaborate on research related activities and studies, pursuant to statements of work ("Statements of Work" or "SOWs") to this Agreement. The SOW shall describe the respective contribution and services of each Party. Any services provided by one of the Parties under this Agreement are referred to as the "Services." For purposes of this Agreement, the Party engaged to perform the Services is the "Performing Party" and the Party for which the Services are to be performed is the "Engaging Party."

All SOWs that are negotiated between the Parties shall be in writing and executed by both Parties and shall be attached hereto as supplemental Exhibits, and shall be incorporated into, and governed by, this Agreement. Each SOW will set forth, among other things: (a) a description of the Services to be performed; (b) the responsibilities of the Parties; (c) an estimated timeline; (d) project milestones and any deliverables to be created for Company (the "Deliverables") and (e) detailed budget ("Budget") for the Services.

If a Party requests a change to an SOW, the Parties shall execute a written change order (the "Change Order"), which shall identify in reasonable detail: (a) a complete summary of the change requested; (b) the impact on the project schedule; (c) the impact on the Deliverable and the Services; and (d) the impact on the project Fees, if any. For the avoidance of doubt, all Change Orders are subject to the written approval of \_\_\_\_\_ and Company.

### **3. COMPENSATION**

The Budget and the payment deadline will be defined in each SOW.

Except as otherwise provided in such SOW, undisputed invoices shall be payable within 30 calendar days after the receipt of the invoice. Payment shall be made as follows:

### **4. INDEPENDENT CONTRACTOR**

The relationship between \_\_\_\_\_ and shall, within the context of the SOW, be that of an independent contractor, and nothing in this Agreement should be construed to create a partnership, joint venture, or employer-employee relationship. Each Party shall, at all times during the term of this Agreement, perform the duties and responsibilities herein without any control by the other Party. Either Party may realize a profit or loss in connection with performing the services. Either Party may render similar services for the benefit of others. Neither Party is an agent of the other Party and is not authorized to make any representation, contract, or contract commitment on behalf of the other Party.

### **5. CONFIDENTIALITY**

Subject to Articles 7 (Publication/Dissemination of Study Information) below, Confidential Information shall be treated as confidential during the term of this Agreement and for a period of seven (7) years thereafter. During such period, the Parties will not: (a) disclose the Confidential Information of the Disclosing Party to any third party, using at least the same degree of care as it uses to protect its own confidential information, but not less than reasonable care or (b) use such information for any purpose other than to perform its obligations under this Agreement (including the Research Plans). Confidential Information does not include information which (i) has previously been made generally available to the public, (ii) becomes publicly known, without fault on the part of the Receiving Party, subsequent to disclosure by the Disclosing Party of such information to the Receiving Party, (iii) is received by the Receiving Party at any time from a source, other than the Disclosing Party, lawfully having possession of and the right to disclose such information, (iv) otherwise becomes known by the Receiving Party prior to disclosure by the Disclosing Party to the receiving party of such information, or (v) is independently developed

by the Receiving Party without use of such information. The Receiving Party will not disclose Confidential Information of the Disclosing Party except to the Receiving Party's officers, directors, employees, agents, and consultants who are under obligation of confidentiality upon a "need to know" basis in connection with negotiations amongst the Parties or if required to be disclosed by law, government regulation, or court order, provided that the Receiving Party promptly notifies the Disclosing Party upon learning of any such legal requirement, and cooperates with the Disclosing Party in the exercise of its right to protect the confidentiality. Upon termination of this Agreement, each party will, upon request, return all copies of Confidential Information received from the other.

## **6. INTELLECTUAL PROPERTY**

The term "Inventions" means inventions (including, without limitation, a new use of the Study Drug/Device) and other intellectual property reduced to practice, whether solely or jointly, by the Parties as a result of the work performed under this Agreement. Inventorship of Inventions shall be determined according to applicable United States patent laws.

## **7. PUBLICATION/DISSEMINATION OF STUDY INFORMATION**

To the extent not otherwise prohibited by any other agreement between \_\_\_\_\_ and Company or an applicable SOW, Company is free to publish or present with respect to studies conducted under this Agreement without the prior approval of \_\_\_\_\_. Authorship of Results of the applicable SOW will be based on contributions to the SOW and in accordance with academic standards and custom. Proper acknowledgment will be made for the contributions of each Party to the results being published.

## **8. WARRANTIES AND LIABILITY**

\_\_\_\_\_ and Company warrant that they shall use commercially reasonable efforts to carry out their duties in accordance with applicable Good Clinical Practice Guidelines, and shall comply with applicable requirements of the U.S. investigational new drug regulations, the Code of Federal Regulations governing informed consent and ethical review boards, and all other applicable federal and state regulations and laws. EXCEPT AS EXPRESSLY PROVIDED IN THIS SECTION 8, EACH PARTY HEREBY DISCLAIMS ANY WARRANTIES, REPRESENTATIONS, OR CONDITIONS, INCLUDING WITHOUT LIMIT, ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR TITLE WITH RESPECT TO THE PERFORMANCE OF SERVICES HEREUNDER. EXCEPT WITH RESPECT TO SECTION 9 (Indemnification) BELOW, IN NO EVENT SHALL THE PERFORMING PARTY BE LIABLE TO THE ENGAGING PARTY (OR THE ASSOCIATED INDEMNIFIED PARTIES AS DEFINED THEREIN) FOR ANY SPECIAL, EXEMPLARY, INCIDENTAL, INDIRECT, PUNITIVE, OR CONSEQUENTIAL DAMAGES, OR LOST PROFITS, REVENUE, OR BUSINESS, WHETHER BASED ON BREACH OF CONTRACT, TORT, STATUTE, EQUITY, PRODUCT LIABILITY, OR OTHERWISE ARISING OUT OR RELATED TO THIS AGREEMENT, REGARDLESS OF WHETHER OR NOT SUCH OTHER PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF ANY SUCH DAMAGES. EXCEPT WITH RESPECT TO SECTION 9 (Indemnification) BELOW, THE PERFORMING PARTY'S TOTAL LIABILITY TO THE ENGAGING PARTY (OR THE ASSOCIATED INDEMNIFIED PARTIES) UNDER THIS AGREEMENT, REGARDLESS OF THE FORUM AND REGARDLESS OF WHETHER ANY ACTION OR CLAIM IS BASED ON

CONTRACT, TORT, OR OTHERWISE, SHALL NOT EXCEED THE GREATER OF THE TOTAL AMOUNT PAID BY THE ENGAGING PARTY TO THE PERFORMING PARTY DURING THE PREVIOUS 12 MONTHS UNDER THIS AGREEMENT AND \$1,000.

## **9. INDEMNIFICATION.**

9.1. \_\_\_\_\_ shall, to the fullest extent permitted by law, defend, indemnify and hold harmless Company and its members, directors, officers, employees and agents (the "Company Indemnified Parties") from and against any and all third party claims, liabilities, losses and expenses (including reasonable attorneys' fees), directly or indirectly, wholly or partially arising from or in connection with any negligent, gross negligent or intentional tortious act or omission of \_\_\_\_\_, its employees or agents, in performing the Services and performing its obligations under this Agreement, except to the extent that such claims, liabilities, losses or expenses arise from or in connection with the negligence, gross negligence, or intentional tortious act or omission of the Company Indemnified Parties.

9.2. Company shall, to the fullest extent permitted by law, defend, indemnify and hold harmless \_\_\_\_\_ and its respective directors, members, trustees, officers, employees, and agents (the "\_\_\_\_\_ Indemnified Parties"), from and against any and all third party claims, liabilities, losses and expenses (including reasonable attorneys' fees), directly or indirectly, wholly or partially arising from or in connection with any negligent, gross negligent or intentional tortious act or omission of Company, its employees or agents, in performing its duties and performing its obligations under this Agreement, except to the extent that such claims, liabilities, losses or expenses arise from or in connection with the negligence, gross negligence, or intentional tortious act or omission of the \_\_\_\_\_ Indemnified Parties.

## **10. FORCE MAJEURE**

Any delay or failure of a Party hereto to perform its obligations hereunder will be excused if and to the extent that it was caused by an event or occurrence beyond such Party's reasonable control and without its fault or negligence ("Force Majeure"). Force Majeure includes, but is not limited to, acts of God, actions by any government authority (whether valid or invalid), fires, floods, windstorms, explosions, riots, natural disasters, wars, sabotage, acts of terrorism, or court injunction or order. A Party claiming Force Majeure must provide the other Party with written notice of such delay (including the anticipated duration of the delay) within ten days of the occurrence of Force Majeure. If the delay lasts more than 30 days, or if the Party claiming Force Majeure does not provide adequate assurances to the other Party that the delay will cease within 30 days, such other Party may terminate this Agreement upon written notice to the Party claiming Force Majeure.

## **11. DISPUTES**

In the event one Party believes the other Party to be in breach of this Agreement ("Dispute"), the aggrieved Party shall notify the other Party or its counsel ("Notice") of the alleged breach or violation, and the Parties shall attempt in good faith to resolve or clarify the Dispute ("Negotiation"). In the event the parties are unable to cooperatively resolve the Dispute, they shall attempt, in good faith, to mediate the matter in a mutually acceptable location

("Mediation"), engaging the services of a mediator familiar with subject matter at issue and acceptable to both Parties. Applicable mediation fees shall be borne equally by the Parties. The requirement of Mediation shall be deemed satisfied if the filing Party proposed a qualified mediator and offered to make itself reasonably available during the 60 days following Notice, but Mediation did not take place or conclude within such 60-day period.

The requirement of Mediation and Negotiation may be waived upon mutual written consent of the Parties. Further, notwithstanding the foregoing, either Party may seek injunctive relief against a Party related to the acts or omissions of such Party that breach this Agreement and cause or are likely to cause irreparable harm to the other Party, without the requirement of Mediation or Negotiation.

## **12. STUDY RECORDS**

Unless otherwise provided by an SOW, the Performing Party shall retain records, including but not limited to accounts, notes, work product, CRFs and data, related to a study for a reasonable time period subject to applicable regulatory requirement(s).

## **13. APPLICABLE LAW**

This Agreement shall be governed by the laws of the Commonwealth of Massachusetts, without regard to its conflict of laws rules.

## **14. NOTICE**

Any notice required or permitted hereunder shall be in writing and shall be deemed given as of the date it is:

- (a) delivered by hand;
- (b) received by Registered or Certified Mail, postage prepaid, return receipt requested; or
- (c) received by facsimile, as can be presumptively demonstrated by return fax or letter demonstrating successful facsimile transmission, and addressed to the Party to receive such notice at the address(es) and/or facsimile telephone number(s) set forth below, or such other address as is subsequently specified to the notifying Party by the receiving Party in writing.

**If to Company:**

**If to \_\_\_\_\_:**

## **15. TERMINATION**

This Agreement may be terminated by either Party upon 30 days' prior written notice following expiration of the last remaining SOW, or if the other Party materially breaches this Agreement and such breach is not cured within 30 days following receipt of written notice of termination.

Termination of this Agreement by either Party shall not affect the rights and obligations of the Parties accrued prior to the effective date of the termination. Upon termination of this Agreement, an Engaging Party shall pay a Performing Party any unpaid Fees set forth in an associated SOW for Services provided through the date of termination, unless such termination was in connection with a breach or alleged breach of such Performing Party.

**16. AMENDMENTS**

This Agreement may only be extended, renewed or otherwise amended by the mutual written consent of Parties hereto or as otherwise provided in this Agreement.

**17. ENTIRE AGREEMENT**

This Agreement, the exhibits hereto, including any related SOWs, constitute and contain the entire agreement and final understanding between the Parties concerning the Services and all other subject matters addressed herein or pertaining thereto. This Agreement supersedes and replaces all prior negotiations and all prior or contemporaneous representations, promises or agreements, proposed or otherwise between the parties, whether written or oral, concerning the Services, any study and all other subject matters addressed herein or pertaining thereto. The provisions of Sections 3, 4, 5-7, 8 (related to disclaimers and liability), 9, 10, 11, 12, 13, 14, 15 (related to fees owed), 17 and 19, and any other provision which by its nature is intended to survive termination or expiration shall survive termination or expiration of this Agreement indefinitely.

**18. ASSIGNMENT**

Neither Party hereto may assign, cede, or transfer any of its rights or obligations under this Agreement without the written consent of the other Party, whether by merger, acquisition, sale, operation of law, or otherwise.

**19. WAIVER**

No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition, or of any other term, provision or condition of this Agreement.

IN WITNESS WHEREOF, the Parties have indicated their acceptance of the terms of this Agreement by the latest of the signatures set forth below, effective on the Effective Date.

**COMPANY, INC.**

\_\_\_\_\_

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

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

Name: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_

## CONFIDENTIAL DATA USE AGREEMENT

This Confidential Data Use Agreement (this "Agreement") is made and entered into as of this \_\_\_\_ day of \_\_\_\_\_, 20\_\_, by and between \_\_\_\_\_ ("Company") an independent nonprofit organization (501(c)(3)), having a principal place of business at \_\_\_\_\_, and \_\_\_\_\_ (the "Recipient").

1. This Agreement sets forth the terms and conditions under which COMPANY will disclose the following data (the "Data Set") to the Recipient (describe data to be disclosed):  
\_\_\_\_\_  
\_\_\_\_\_
2. Except as otherwise specified herein, Recipient may not make any uses or disclosures of the Data Set, and such Data Set may only be used for research purposes properly approved by an IRB if required under applicable law or pursuant to Recipient policies and procedures governing human subject research: Recipient may only use the Data Set for the purpose outlined in Appendix A (Statement of Work). Analyses must be conducted in accordance with the informed consent form signed by the study participants.
3. In addition to Recipient, the following individuals, or classes of individuals, are permitted to use or receive the Data Set for purposes of the research project, provided that they agree in writing to be bound by the terms of this Agreement: \_\_\_\_\_  
\_\_\_\_\_
4. Recipient agrees that it and any employees, agents and subcontractors to whom it discloses the Data Set will keep such Data Set strictly confidential and not use, further disclose, or transfer the Data Set other than as permitted by this Agreement or as otherwise required by law or regulation. Recipient will notify COMPANY the results of the analyses of the data set and will work with COMPANY on preparation of manuscript for publication. Authorship of manuscript prepared on the basis of results from analysis of the Data Set will be based on contributions and in accordance with academic standards and custom. The Recipient agrees to acknowledge the source of the Data Set in any publications reporting use of it. The Recipient further grants to COMPANY a perpetual, non-exclusive, nontransferable, royalty free, fully paid-up license, without the right to sublicense, to use Research Data for internal, non-commercial research, educational and COMPANY's mission oriented purposes.
5. Recipient agrees to use appropriate administrative, technical, and physical safeguards to protect the Data Set from misuse or inappropriate disclosure and to prevent use or disclosure of the Data Set other than as provided for by this Agreement or as otherwise required by law or regulation. The Recipient agrees to secure the Data Set using appropriate computer technology and other industry standard measures, such as password protection, encryption of data, and access restrictions to computer and data storage areas. Recipient agrees not to attempt to re-identify the source of any information provided through the Data Set.
6. Recipient agrees to promptly report to COMPANY any use or disclosure of the Limited Data Set not provided for by the Agreement of which he/she becomes aware. Recipient will take reasonable steps to limit any such further use or disclosure.
7. Recipient agrees to ensure that any agent or third party, including a subcontractor, to whom he/she provides the Limited Data Set, agrees in writing to the same restrictions and conditions that apply through this Agreement.
8. Recipient shall not attempt to identify the individuals to whom the PHI pertains or attempt to contact such individuals.
9. COMPANY makes no, and hereby disclaims, any warranties or representations related to the Data Set, including without limit, any implied warranties of merchantability, title, or fitness for a particular purpose.

**CONFIDENTIAL DATA USE AGREEMENT**

Recipient accepts all responsibility for, and agrees to indemnify, defend, and hold harmless COMPANY from, any claims, damages, or liability arising out of Recipient’s data analysis, results from analyses, and any consequences resulting from a breach of research participant privacy in connection with the Data Set or breach of this Agreement, negligence or intentional misconduct, or violation of applicable rule, law, or regulation by Recipient or its agents or contractors. In no event shall COMPANY’s liability to Recipient or any third party related to this Agreement exceed the greater of the amount, if any, Recipient paid COMPANY for such Data Set.

- 10. Except for the limited, non-exclusive right of Recipient to use the Data Set solely as provided in this Agreement during the Term (as defined below), as between the Recipient and COMPANY, COMPANY retains all right, title, and interest to the Data Set, and the Recipient shall have no other rights to the Data Set.
- 11. The Recipient acknowledges that use, disclosure, or distribution of the Data Set contrary to the terms of this Agreement may cause irreparable harm for which damages by law may not be an adequate remedy, and agrees that the provisions of this Agreement prohibiting disclosure or distribution of the Data Set or use contrary to the provisions hereof may be specifically enforced by a court of competent jurisdiction in addition to any and all other remedies available at law or in equity.
- 12. This Agreement shall be effective on the Effective Date set forth above and shall continue as long as Recipient (or any agent or subcontractor of Recipient) retains the data, unless terminated by applicable law or regulation or as follows (the “Term”). Recipient may terminate this Agreement by returning or destroying the Data Set and providing written notice thereof to COMPANY. COMPANY may immediately terminate this Agreement if Recipient materially breaches this Agreement. If Recipient materially breaches this Agreement, at COMPANY’s request, Recipient shall promptly return to COMPANY or destroy any Data Set.
- 13. Recipient may not assign this Agreement or any rights or obligations of Recipient arising under this Agreement.
- 14. This Agreement shall be governed by the laws of the Commonwealth of Massachusetts without regard to its conflict of law provisions.
- 15. The provisions of Sections 2, 4-9, 10 (related to COMPANY’s rights), 11, 12 (related to return of the Data Set), and 13-15 of this Agreement shall survive termination or expiration of this Agreement.

_____	(“Recipient”)
Signature: _____	Signature: _____
Print Name: _____	Print Name: _____
Title: _____	Title: _____

## **BUSINESS ASSOCIATE AGREEMENT ADDENDUM**

**THIS BUSINESS ASSOCIATE AGREEMENT ADDENDUM** ("Addendum") supplements that \_\_\_\_\_ ("Agreement") made by and between \_\_\_\_\_ ("Covered Entity"), and [\_\_\_\_\_ ENTITY] ("Business Associate") (Covered Entity and Business Associate are each referred to herein as a "Party," and collectively the "Parties"), and is effective the later of the \_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_ and the date of the Agreement (the "Effective Date").

### **WHEREAS**

A. The Covered Entity is subject to, and must comply with, the provisions of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") as amended from time to time including Sections 13400 through 13424 of the Health Information Technology for Economic Clinical Health Act (the "HITECH Act") and the corresponding Standards for Privacy of Individually Identifiable Health Information (the "Privacy Rule"), Security Standards for the Protection of Electronic Protected Health Information (the "Security Rule"), and the Notification in the Case of Breach of Unsecured Protected Health Information (the "Breach Notification Rule"), each of which are incorporated herein by reference.

B. Business Associate is a contractor that provides services to the Covered Entity and that the Covered Entity deems to be a "business associate" under the Privacy Rule and/or Security Rule.

C. Business Associate is subject to, and must comply with, certain provisions of the Privacy Rule, the Security Rule and the Breach Notification Rule, as required by the HITECH Act.

D. Business Associate acknowledges that the Covered Entity must comply with HIPAA and its corresponding regulations, and that in order to achieve such compliance, the Agreement must contain certain satisfactory assurances that Business Associate will appropriately safeguard Protected Health Information and Electronic Protected Health Information (collectively referred to herein as "PHI") that it receives from, or creates or receives on behalf of, the Covered Entity.

E. The Covered Entity seeks certain assurances from Business Associate, and Business Associate wishes to provide such assurances to the Covered Entity, to help it achieve and maintain compliance with the Privacy Rule, Security Rule and Breach Notification Rule.

F. By this Addendum, the Covered Entity and Business Associate wish to supplement the terms and conditions of the Agreement to include provisions required by the HITECH Act, the Privacy Rule, the Security Rule and the Breach Notification Rule in order to bring the relationship between the Parties into compliance therewith.

Now therefore, for and in consideration of the mutual covenants and agreements contained herein, the Covered Entity and Business Associate agree as follows:

**ARTICLE I**  
**DEFINITIONS**

Unless otherwise defined herein, terms used in this Addendum have the same meanings as those terms defined in the Privacy Rule (45 C.F.R. § 160.103 and § 164.501), the Security Rule (45 C.F.R. Parts 160, 162 and 45 C.F.R. § 164.304), and the Breach Notification Rule (45 C.F.R. § 164.402).

**ARTICLE II**  
**PERMITTED USES AND DISCLOSURES OF PHI**

Pursuant to the Agreement, Business Associate provides \_\_\_\_\_ services ("Services") for the Covered Entity that may involve the use and/or disclosure of PHI that may be obtained from Covered Entity. Except as otherwise specified herein, Business Associate may use or disclose such PHI only in accordance with the Privacy Rule and Security Rule (as applicable) and only to perform those functions, activities or services for, or on behalf of, the Covered Entity as specified in the Agreement, provided that use or disclosure would not violate (i) the Privacy Rule or Security Rule if done by the Covered Entity or (ii) the minimum necessary policies and procedures of the Covered Entity.

Business Associate may use and disclose PHI created or received by Business Associate on behalf of Covered Entity if necessary for the proper management and administration of Business Associate or to carry out Business Associate's legal responsibilities, if (i) the disclosure is required by law, or (ii) Business Associate obtains reasonable assurances from the person to whom the PHI is disclosed that (1) the PHI will be held confidentially and used or further disclosed only as required by law or for the purpose for which it was disclosed to the person; and (2) the Business Associate will be notified of any instances of which the person is aware in which the confidentiality of the information is breached.

**ARTICLE III**  
**RESPONSIBILITIES OF BUSINESS ASSOCIATE**

With regard to its use and/or disclosure of PHI, Business Associate agrees to do the following:

**3.1 Use.** Business Associate agrees to use and/or disclose PHI only as permitted or required by this Addendum or as otherwise required by law.

**3.2 Safeguards.** Business Associate will implement administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of the PHI it creates, receives, maintains or transmits on behalf of Covered Entity, and that reasonably prevent the use or disclosure of the PHI except as described in this Addendum. Business Associate shall comply, as applicable, with the requirements of the Security Rule.

**3.3 Reporting to Covered Entity.** Business Associate will report to the Covered Entity any security incident or use or disclosure of PHI of which it becomes aware that is not permitted or required by this Addendum.

**3.4 Mitigation.** Business Associate agrees to mitigate, to the extent practicable, any harmful effect known to it resulting from a use or disclosure of PHI in violation of the terms of this Addendum.

**3.5 Agents.** Business Associate agrees to require all of its subcontractors and agents that create, receive, maintain or transmit PHI under the Agreement to agree, in writing, to adhere to the same restrictions and conditions on the use and/or disclosure of PHI and to implement the same safeguards to protect PHI that apply to Business Associate. Business Associate agrees to make available to Covered Entity at its reasonable request documentation evidencing its subcontractors' and agents' agreements described in the preceding sentence.

**3.6 Access to Records.** Except as protected by state or federal privilege, Business Associate agrees to make available all records, books, agreements, policies and procedures relating to the safeguards implemented and the use or disclosure of PHI to the Covered Entity, or at the request of the Covered Entity to the Secretary of the Department of Health and Human Services (the "Secretary"), in a time and manner designated by the Covered Entity or the Secretary, for the purpose of determining the Parties' compliance with the Privacy Rule, Security Rule, Breach Notification Rule and/or the Enforcement Rule (45 C.F.R. Part 160, Subparts C, D and E).

**3.7 Documentation of Disclosures.** Business Associate agrees to document the disclosures of PHI and information related to those disclosures that would be required for the 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. Business Associate agrees to provide the Covered Entity with documentation of all of Business Associate's disclosures of PHI as and to the extent reasonably requested by Covered Entity to permit the Covered Entity to respond to an Individual's request for an accounting of disclosures of PHI in accordance with 45 C.F.R. § 164.528.

**3.8 Access to Designated Record Set.** Business Associate agrees to provide access to the Covered Entity, or to an Individual or an Individual's designee as directed by the Covered Entity, to PHI contained in a Designated Record Set in the time and manner designated by the Covered Entity. If an individual requests an electronic copy of PHI maintained electronically in a Designated Record Set, Business Associate agrees to provide access to the Covered Entity, or to an Individual or an Individual's designee as directed by the Covered Entity, to PHI in a readable electronic form and format as agreed to by the Covered Entity and the Individual, with respect to the PHI maintained electronically in a Designated Record Set.

**3.9 Amendments to Designated Record Set.** Business Associate agrees to make any amendment(s) to PHI contained in a Designated Record Set that the Covered Entity directs or agrees to pursuant to 45 C.F.R. § 164.526.

**3.10 Minimum Necessary.** Business Associate agrees to request from the Covered Entity, and disclose to its subcontractors, agents or applicable third parties, only the minimum PHI necessary to fulfill a specific function required or permitted hereunder.

**3.11 Covered Entity's Obligations under the Privacy Rule.** To the extent that Business Associate is to carry out one or more of the Covered Entity's obligation(s) under the Privacy Rule,

Business Associate agrees to comply with the requirements of the Privacy Rule that apply to the Covered Entity in the performance of such obligation(s).

**3.12 Breach Notification.** Business Associate shall, following the discovery of a breach of Unsecured PHI, notify Covered Entity of such breach without unreasonable delay and in no event later than one (1) business day after discovery of the breach. When notifying Covered Entity, Business Associate shall include, to the extent possible, the identification of each individual whose Unsecured PHI has been, or is reasonably believed by Business Associate to have been, accessed, acquired, used, or disclosed during the breach.

#### **ARTICLE IV** **RESPONSIBILITIES OF THE COVERED ENTITY**

With regard to the use or disclosure of PHI by Business Associate, the Covered Entity hereby agrees to do the following:

- a. Inform Business Associate of any changes in, or revocation of, an Individual's consent or authorization to use or disclose PHI, if such changes affect Business Associate's permitted or required uses and disclosures.
- b. Notify Business Associate of any restriction to the use or disclosure of PHI in its notice of privacy practices to the extent that such restriction may affect Business Associate's use or disclosure of PHI.
- c. Request Business Associate to use or disclose PHI only in a manner permissible under the Privacy Rule or Security Rule if done by the Covered Entity.

Covered Entity acknowledges and agrees that PHI which has been de-identified in accordance with the requirements of HIPAA shall not be subject to this Agreement.

#### **ARTICLE V** **TERM AND TERMINATION**

**5.1 Term.** This Addendum shall become effective on the Effective Date and shall continue in effect until all of the PHI provided by the Covered Entity to Business Associate, or created or received by Business Associate on behalf of the Covered Entity, is (i) destroyed and documentation of such destruction is provided to the Covered Entity, (ii) returned to the Covered Entity or (iii) if it is infeasible to return or destroy such PHI, until protections are extended to such information in accordance with **Section 5.3**.

**5.2 Termination by the Covered Entity for Cause.** Upon the Covered Entity's knowledge of a material breach of this Addendum by Business Associate with respect to the Privacy Rule, the Covered Entity shall provide Business Associate an opportunity to cure the breach or end the violation and terminate this Addendum and the Agreement if Business Associate does not cure the breach or end the violation within the time period specified by the Covered Entity, or immediately terminate this Addendum and the Agreement if Business Associate has breached a material term of this Addendum and cure is not possible.

**5.3 Effect of Termination.** Except as otherwise provided in this **Section 5.3**, Business Associate agrees to return or destroy all PHI received from the Covered Entity, or created or received by Business Associate on behalf of the Covered Entity, upon termination of this Addendum for any reason. Business Associate also agrees to provide the Covered Entity with documentation of the destruction of PHI. This provision shall also apply to PHI that is in the possession of subcontractors or agents of Business Associate. In the event that Business Associate determines that returning or destroying PHI is infeasible, Business Associate shall provide the Covered Entity with notification of the conditions that make return or destruction infeasible. Upon the mutual agreement of the Parties that the return or destruction of PHI is infeasible, Business Associate shall extend the protections of this Addendum 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.

## **ARTICLE VI**

### **INDEMNIFICATION AND LIMITATION OF LIABILITY**

**6.1 Indemnification.** Covered Entity shall defend, indemnify and hold harmless the Business Associate, its affiliates, officers, directors, employees and agents, from and against any claims or liabilities, and shall pay all losses, damages, liabilities, claims and actions, and all related expenses (including reasonable attorneys' fees and expenses) based on or arising out of any breach by Covered Entity of any duty or obligation of the Agreement or this Addendum that pertains in any way, directly or indirectly, to PHI or the protection of the confidentiality thereof. Business Associate shall defend, indemnify and hold harmless the Covered Entity, its affiliates, officers, directors, employees and agents, from and against any claims or liabilities, and shall pay all losses, damages, liabilities, claims and actions, and all related expenses (including reasonable attorneys' fees and expenses) based on or arising out of any breach by Business Associate of any duty or obligation of the Agreement or this Addendum that pertains in any way, directly or indirectly, to PHI or the protection of the confidentiality thereof.

**6.2 Limitation of Liability.** The indemnification provisions of **Section 6.1** shall in no event be subject to any limitation of liability or damages set forth in the Agreement, and no express or implied agreement or arrangement between the Parties shall in any way reduce or limit a Party's liability thereof.

## **ARTICLE VII**

### **MISCELLANEOUS**

**7.1 Regulatory References.** References in this Addendum to a section in the Privacy Rule, Security Rule and/or Breach Notification Rule shall refer to the section in effect or as amended.

**7.2 Survival.** The respective rights and obligations of Business Associate and the Covered Entity under the provisions of this Addendum shall survive termination of this Addendum.

**7.3 Changes, Modifications or Alterations.** The Parties agree to take such action to amend this Addendum from time to time as is necessary for the Parties to comply with the Privacy Rule, Security Rule and/or Breach Notification Rule. No changes or modifications of this Addendum shall be valid unless the same shall be in writing and signed by both Covered Entity and Business Associate.

**7.4 Counterparts.** This Addendum may be executed in any number of counterparts, each of which shall be deemed an original, but all such counterparts together shall constitute one and the same instrument. Facsimile copies hereof shall be deemed to be originals.

**7.5 Interpretation.** Any ambiguity in this Addendum shall be resolved in favor of a meaning that permits the Parties to comply with HIPAA, the Privacy Rule, the Security Rule, the Breach Notification Rule and the HITECH Act, as applicable.

**7.6 Governing Law.** This Addendum shall be interpreted, construed and enforced pursuant to and in accordance with the laws of the Commonwealth of Massachusetts, without regard to its conflicts of law principles.

**7.7 Notices.** Any notice required or permitted to be given hereunder shall be (i) personally delivered, (ii) transmitted by postage pre-paid first class certified United States mail, (iii) transmitted by pre-paid, overnight delivery with delivery tracking service, (iv) transmitted by facsimile transmission, (v) transmitted by electronic mail, or (vi) communicated orally over the telephone and documented by notice in writing, via electronic mail or via facsimile within five (5) business days of the oral notification. All notices and other communications shall be deemed to have been duly given, received and effective on (i) the date of receipt if delivered personally or if provided orally over the telephone, (ii) three (3) business days after the date of posting if transmitted by mail, (iii) the business day after the date of transmission if by overnight delivery with proof of delivery, or (iv) if transmitted by facsimile or electronic mail transmission, the date of transmission with confirmation by the originating facsimile transmission machine of receipt by the receiving facsimile machine of such transmission for notice provided by facsimile, addressed to the Parties at the addresses below:

<b>As to Covered Entity:</b>	<b>As to Business Associate:</b>
_____	_____
_____	_____
_____	_____
_____	_____
Ph: _____	Ph: _____
Fax: _____	Fax: _____
Email: _____	Email: _____

or to such other address, or to the attention of such other person(s) or officer(s), as either Party may designate by written notice to the other Party.

**7.8 Incorporation.** Any provisions now or hereafter required to be included in this Addendum by applicable state or federal law, including without limitation, the Privacy Rule, the Security Rule, the Breach Notification Rule and the HITECH Act, or by the Department of Health and Human Services or the Centers for Medicare and Medicaid Services shall be binding upon and enforceable against the Parties and be deemed incorporated herein, irrespective of whether or not such provisions are expressly set forth in this Addendum or elsewhere in the Agreement.

**7.9 Severability.** The provisions of this Addendum shall be deemed severable, and, if any portion shall be held invalid, illegal or unenforceable for any reason, the remainder of the Addendum shall be effective and binding upon the Parties.

**7.10 Waiver.** A waiver of any provision of this Addendum must be in writing, signed by the Parties hereto. The waiver by either Party of any provision of this Addendum or the failure of any Party to insist on the performance of any of the terms or conditions of this Addendum shall not operate as, nor be construed to be, a waiver or the relinquishment of any rights granted hereunder and the obligation of the Parties with respect thereto shall continue in full force and effect.

**7.11 Force and Effect.** The Parties acknowledge and agree that this Addendum shall be of no force and effect unless and until a duly authorized representative of each party has signed the following signature page where indicated.

**IN WITNESS WHEREOF,** the undersigned have caused this Business Associate Agreement Addendum to be duly executed as of the Effective Date.

**COVERED ENTITY**

**BUSINESS ASSOCIATE**

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

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

Print Name: \_\_\_\_\_

Print Name: \_\_\_\_\_

Print Title: \_\_\_\_\_

Print Title: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_

## **SUBCONTRACTOR BUSINESS ASSOCIATE AGREEMENT ADDENDUM**

**THIS SUBCONTRACTOR BUSINESS ASSOCIATE AGREEMENT ADDENDUM** ("Addendum") supplements that \_\_\_\_\_ ("Agreement") made by and between [ **ENTITY** ] ("Business Associate"), and \_\_\_\_\_ ("Subcontractor Business Associate") (Business Associate and Subcontractor Business Associate are each referred to herein as a "Party," and collectively the "Parties"), and is effective the later of the \_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_ and the date of the Agreement (the "Effective Date").

### **WHEREAS**

A. The Business Associate is subject to, and must comply with, certain provisions of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") as amended from time to time including Sections 13400 through 13424 of the Health Information Technology for Economic Clinical Health Act (the "HITECH Act") and the corresponding Standards for Privacy of Individually Identifiable Health Information (the "Privacy Rule"), Security Standards for the Protection of Electronic Protected Health Information (the "Security Rule"), and the Notification in the Case of Breach of Unsecured Protected Health Information (the "Breach Notification Rule"), each of which are incorporated herein by reference.

B. Subcontractor Business Associate is a contractor that provides services to the Business Associate and that the Business Associate deems to be a "business associate" under the Privacy Rule and/or Security Rule.

C. Subcontractor Business Associate is subject to, and must comply with, certain provisions of the Privacy Rule, the Security Rule and the Breach Notification Rule, as required by the HITECH Act.

D. Subcontractor Business Associate acknowledges that the Business Associate must comply with certain provisions of HIPAA and its corresponding regulations, and that in order to achieve such compliance, the Agreement must contain certain satisfactory assurances that Subcontractor Business Associate will appropriately safeguard Protected Health Information and Electronic Protected Health Information (collectively referred to herein as "PHI") that it receives from, or creates or receives on behalf of, the Business Associate.

E. The Business Associate seeks certain assurances from Subcontractor Business Associate, and Subcontractor Business Associate wishes to provide such assurances to the Business Associate, to help it achieve and maintain compliance with the Privacy Rule, Security Rule and Breach Notification Rule.

F. By this Addendum, the Business Associate and Subcontractor Business Associate wish to supplement the terms and conditions of the Agreement to include provisions required by the HITECH Act, the Privacy Rule, the Security Rule and the Breach Notification Rule in order to bring the relationship between the Parties into compliance therewith.

Now therefore, for and in consideration of the mutual covenants and agreements contained herein, the Business Associate and Subcontractor Business Associate agree as follows:

**ARTICLE I**  
**DEFINITIONS**

Unless otherwise defined herein, terms used in this Addendum have the same meanings as those terms defined in the Privacy Rule (45 C.F.R. § 160.103 and § 164.501), the Security Rule (45 C.F.R. Parts 160, 162 and 45 C.F.R. § 164.304), and the Breach Notification Rule (45 C.F.R. § 164.402).

**ARTICLE II**  
**PERMITTED USES AND DISCLOSURES OF PHI**

Pursuant to the Agreement, Subcontractor Business Associate provides \_\_\_\_\_ services ("Services") for the Business Associate that may involve the use and/or disclosure of PHI that may be obtained from Business Associate. Except as otherwise specified herein, Subcontractor Business Associate may use or disclose such PHI only in accordance with the Privacy Rule and Security Rule (as applicable) and only to perform those functions, activities or services for, or on behalf of, the Business Associate as specified in the Agreement, provided that use or disclosure would not violate (i) the Privacy Rule or Security Rule if done by a covered entity or (ii) the minimum necessary policies and procedures of the covered entity for which Business Associate provides services.

Subcontractor Business Associate may use and disclose PHI created or received by Subcontractor Business Associate on behalf of Business Associate if necessary for the proper management and administration of Subcontractor Business Associate or to carry out Subcontractor Business Associate's legal responsibilities, if (i) the disclosure is required by law, or (ii) Subcontractor Business Associate obtains reasonable assurances from the person to whom the PHI is disclosed that (1) the PHI will be held confidentially and used or further disclosed only as required by law or for the purpose for which it was disclosed to the person; and (2) the Subcontractor Business Associate will be notified of any instances of which the person is aware in which the confidentiality of the information is breached.

**ARTICLE III**  
**RESPONSIBILITIES OF SUBCONTRACTOR BUSINESS ASSOCIATE**

With regard to its use and/or disclosure of PHI, Subcontractor Business Associate agrees to do the following:

**3.1 Use.** Subcontractor Business Associate agrees to use and/or disclose PHI only as permitted or required by this Addendum or as otherwise required by law.

**3.2 Safeguards.** Subcontractor Business Associate will implement administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of the PHI it creates, receives, maintains or transmits on behalf of Business Associate, and that reasonably prevent the use or disclosure of the PHI except as described in this Addendum. Subcontractor Business Associate shall comply, as applicable, with the requirements of the Security Rule.

**3.3 Reporting to Business Associate.** Subcontractor Business Associate will report to the Business Associate any security incident or use or disclosure of PHI of which it becomes aware that is not permitted or required by this Addendum.

**3.4 Mitigation.** Subcontractor Business Associate agrees to mitigate, to the extent practicable, any harmful effect known to it resulting from a use or disclosure of PHI in violation of the terms of this Addendum. These efforts will include, but not be limited to, ensuring that the improper use of PHI is discontinued immediately, seeking return or destruction of the improperly disclosed PHI, and ensuring that any person to whom PHI was improperly disclosed will not redisclose such information.

**3.5 Agents.** Subcontractor Business Associate agrees to require all of its subcontractors and agents that create, receive, maintain or transmit PHI under the Agreement to agree, in writing, to adhere to the same restrictions and conditions on the use and/or disclosure of PHI and to implement the same safeguards to protect PHI that apply to Subcontractor Business Associate. Subcontractor Business Associate agrees to make available to Business Associate at its reasonable request documentation evidencing its subcontractors' and agents' agreements described in the preceding sentence.

**3.6 Access to Records.** Except as protected by state or federal privilege, Subcontractor Business Associate agrees to make available all records, books, agreements, policies and procedures relating to the safeguards implemented and the use or disclosure of PHI to the Business Associate, or at the request of the Business Associate to the Secretary of the Department of Health and Human Services (the "Secretary"), in a time and manner designated by the Business Associate or the Secretary, for the purpose of determining the Parties' compliance with the Privacy Rule, Security Rule, Breach Notification Rule and/or the Enforcement Rule (45 C.F.R. Part 160, Subparts C, D and E).

**3.7 Documentation of Disclosures.** Subcontractor Business Associate agrees to document the disclosures of PHI and information related to those disclosures that would be required for a 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. The documentation shall include: (i) the date of the disclosure; (ii) the name of the person receiving the PHI, and, if known, the address of such person; (iii) a brief description of the PHI disclosed; and (iv) a brief statement of the purpose of the disclosure or, instead of such statement, a copy of the request for disclosure. Subcontractor Business Associate agrees to provide the Business Associate with documentation of all of Subcontractor Business Associate's disclosures of PHI as and to the extent reasonably requested by Business Associate to permit a covered entity to respond to an Individual's request for an accounting of disclosures of PHI in accordance with 45 C.F.R. § 164.528.

**3.8 Access to Designated Record Set.** Subcontractor Business Associate agrees to provide access to the Business Associate, or to an Individual or an Individual's designee as directed by the Business Associate, to PHI contained in a Designated Record Set in the time and manner designated by the Business Associate. If an individual requests an electronic copy of PHI maintained electronically in a Designated Record Set, Subcontractor Business Associate agrees to provide access to the Business Associate, or to an Individual or an Individual's designee as directed by the Business Associate, to PHI

in a readable electronic form and format as agreed to by a covered entity and the Individual, with respect to the PHI maintained electronically in a Designated Record Set.

**3.9 *Amendments to Designated Record Set.*** Subcontractor Business Associate agrees to make any amendment(s) to PHI contained in a Designated Record Set that the Business Associate directs or agrees to pursuant to 45 C.F.R. § 164.526.

**3.10 *Minimum Necessary.*** Subcontractor Business Associate agrees to request from the Business Associate, and disclose to its subcontractors, agents or applicable third parties, only the minimum PHI necessary to fulfill a specific function required or permitted hereunder.

**3.11 *Business Associate's Obligations under the Privacy Rule.*** To the extent that Subcontractor Business Associate is to carry out one or more of a covered entity's obligation(s) under the Privacy Rule, Subcontractor Business Associate agrees to comply with the requirements of the Privacy Rule that apply to the covered entity in the performance of such obligation(s).

**3.12 *Breach Notification.*** Subcontractor Business Associate shall, following the discovery of a breach of Unsecured PHI, notify Business Associate of such breach without unreasonable delay and in no event later than one (1) business day after discovery of the breach. When notifying Business Associate, Subcontractor Business Associate shall include, to the extent possible, the identification of each individual whose Unsecured PHI has been, or is reasonably believed by Subcontractor Business Associate to have been, accessed, acquired, used, or disclosed during the breach.

#### **ARTICLE IV**

#### **RESPONSIBILITIES OF THE BUSINESS ASSOCIATE**

With regard to the use or disclosure of PHI by Subcontractor Business Associate, the Business Associate hereby agrees to do the following:

- a. Inform Subcontractor Business Associate of any changes in, or revocation of, an Individual's consent or authorization to use or disclose PHI, if such changes affect Subcontractor Business Associate's permitted or required uses and disclosures.
- b. Notify Subcontractor Business Associate of any restriction to the use or disclosure of PHI in the notice of privacy practices of the covered entity for which Business Associate provides services to the extent that such restriction may affect Subcontractor Business Associate's use or disclosure of PHI.
- c. Request Subcontractor Business Associate to use or disclose PHI only in a manner permissible under the Privacy Rule or Security Rule if done by a covered entity.

**ARTICLE V**  
**TERM AND TERMINATION**

**5.1 Term.** This Addendum shall become effective on the Effective Date and shall continue in effect until all of the PHI provided by the Business Associate to Subcontractor Business Associate, or created or received by Subcontractor Business Associate on behalf of the Business Associate, is (i) destroyed and documentation of such destruction is provided to the Business Associate, (ii) returned to the Business Associate or (iii) if it is infeasible to return or destroy such PHI, until protections are extended to such information in accordance with **Section 5.3**.

**5.2 Termination by the Business Associate for Cause.** Upon the Business Associate's knowledge of a material breach of this Addendum by Subcontractor Business Associate with respect to the Privacy Rule, the Business Associate shall provide Subcontractor Business Associate an opportunity to cure the breach or end the violation and terminate this Addendum and the Agreement if Subcontractor Business Associate does not cure the breach or end the violation within the time period specified by the Business Associate, or immediately terminate this Addendum and the Agreement if Subcontractor Business Associate has breached a material term of this Addendum and cure is not possible.

**5.3 Effect of Termination.** Except as otherwise provided in this **Section 5.3**, Subcontractor Business Associate agrees to return or destroy all PHI received from the Business Associate, or created or received by Subcontractor Business Associate on behalf of the Business Associate, upon termination of this Addendum for any reason. Subcontractor Business Associate also agrees to provide the Business Associate with documentation of the destruction of PHI. This provision shall also apply to PHI that is in the possession of subcontractors or agents of Subcontractor Business Associate. In the event that Subcontractor Business Associate determines that returning or destroying PHI is infeasible, Subcontractor Business Associate shall provide the Business Associate with notification of the conditions that make return or destruction infeasible. Upon the mutual agreement of the Parties that the return or destruction of PHI is infeasible, Subcontractor Business Associate shall extend the protections of this Addendum 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 Subcontractor Business Associate maintains such PHI.

**ARTICLE VI**  
**INDEMNIFICATION AND LIMITATION OF LIABILITY**

**6.1 Indemnification.** Subcontractor Business Associate shall defend, indemnify and hold harmless Business Associate, its affiliates, officers, directors, employees and agents, from and against any claims or liabilities, and shall pay all losses, damages, liabilities, claims and actions, and all related expenses (including reasonable attorneys' fees and expenses) based on or arising out of any breach by Subcontractor Business Associate of any duty or obligation of the Agreement or this Addendum that pertains in any way, directly or indirectly, to PHI or the protection of the confidentiality thereof.

**6.2 Patient Notifications Indemnification.** In the event Business Associate or a covered entity for which Business Associate provides services is required, pursuant to the Breach Notification Rule, to notify Individuals that their Unsecured PHI has been impermissibly acquired, accessed, used or disclosed due to a breach of this Addendum, Subcontractor Business Associate further agrees to

indemnify Business Associate for all reasonable costs, expenses and fees related to the breach notification and any costs to mitigate the breach.

**6.3 Limitation of Liability.** The indemnification provisions of **Article VI** shall in no event be subject to any limitation of liability or damages set forth in the Agreement, and no express or implied agreement or arrangement between the Parties shall in any way reduce or limit Subcontractor Business Associate's liability thereof.

## **ARTICLE VII** **MISCELLANEOUS**

**7.1 Regulatory References.** References in this Addendum to a section in the Privacy Rule, Security Rule and/or Breach Notification Rule shall refer to the section in effect or as amended.

**7.2 Survival.** The respective rights and obligations of Subcontractor Business Associate and the Business Associate under the provisions of this Addendum shall survive termination of this Addendum.

**7.3 Changes, Modifications or Alterations.** The Parties agree to take such action to amend this Addendum from time to time as is necessary for the Parties to comply with the Privacy Rule, Security Rule and/or Breach Notification Rule. No changes or modifications of this Addendum shall be valid unless the same shall be in writing and signed by both Business Associate and Subcontractor Business Associate.

**7.4 Counterparts.** This Addendum may be executed in any number of counterparts, each of which shall be deemed an original, but all such counterparts together shall constitute one and the same instrument. Facsimile copies hereof shall be deemed to be originals.

**7.5 Interpretation.** Any ambiguity in this Addendum shall be resolved in favor of a meaning that permits the Parties to comply with HIPAA, the Privacy Rule, the Security Rule, the Breach Notification Rule and the HITECH Act, as applicable.

**7.6 Governing Law.** This Addendum shall be interpreted, construed and enforced pursuant to and in accordance with the laws of the Commonwealth of Massachusetts, without regard to its conflicts of law principles.

**7.7 Notices.** Any notice required or permitted to be given hereunder shall be (i) personally delivered, (ii) transmitted by postage pre-paid first class certified United States mail, (iii) transmitted by pre-paid, overnight delivery with delivery tracking service, (iv) transmitted by facsimile transmission, (v) transmitted by electronic mail, or (vi) communicated orally over the telephone and documented by notice in writing, via electronic mail or via facsimile within five (5) business days of the oral notification. All notices and other communications shall be deemed to have been duly given, received and effective on (i) the date of receipt if delivered personally or if provided orally over the telephone, (ii) three (3) business days after the date of posting if transmitted by mail, (iii) the business day after the date of transmission if by overnight delivery with proof of delivery, or (iv) if transmitted by facsimile or electronic mail transmission, the date of transmission with confirmation by the originating facsimile transmission machine or receipt by the receiving facsimile machine of such

transmission for notice provided by facsimile, addressed to the Parties at the addresses below:

As to Business Associate:	As to Subcontractor Business Associate:
_____	_____
_____	_____
_____	_____
_____	_____
Ph: _____	Ph: _____
Fax: _____	Fax: _____
Email: _____	Email: _____

or to such other address, or to the attention of such other person(s) or officer(s), as either Party may designate by written notice to the other Party.

**7.8 Incorporation.** Any provisions now or hereafter required to be included in this Addendum by applicable state or federal law, including without limitation, the Privacy Rule, the Security Rule, the Breach Notification Rule and the HITECH Act, or by the Department of Health and Human Services or the Centers for Medicare and Medicaid Services shall be binding upon and enforceable against the Parties and be deemed incorporated herein, irrespective of whether or not such provisions are expressly set forth in this Addendum or elsewhere in the Agreement.

**7.9 Severability.** The provisions of this Addendum shall be deemed severable, and, if any portion shall be held invalid, illegal or unenforceable for any reason, the remainder of the Addendum shall be effective and binding upon the Parties.

**7.10 Waiver.** A waiver of any provision of this Addendum must be in writing, signed by the Parties hereto. The waiver by either Party of any provision of this Addendum or the failure of any Party to insist on the performance of any of the terms or conditions of this Addendum shall not operate as, nor be construed to be, a waiver or the relinquishment of any rights granted hereunder and the obligation of the Parties with respect thereto shall continue in full force and effect.

**7.11 Force and Effect.** The Parties acknowledge and agree that this Addendum shall be of no force and effect unless and until a duly authorized representative of each party has signed the following signature page where indicated.

**IN WITNESS WHEREOF**, the undersigned have caused this Subcontractor Business Associate Agreement Addendum to be duly executed as of the Effective Date.

**BUSINESS ASSOCIATE**

**SUBCONTRACTOR  
ASSOCIATE**

**BUSINESS**

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

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

Print Name: \_\_\_\_\_

Print Name: \_\_\_\_\_

Print Title: \_\_\_\_\_

Print Title: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_