Sample Business Associate Agreement

This Agreement is entered into between **ENTITY NAME**, a "Covered Entity" as that term is defined by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 45, C.F.R. Part 160 and Part 164, Subparts A and E, the Standards for Privacy of Individually Identifiable Health Information (the "Privacy Rule"), and **ENTITY NAME**, a "Business Associate," as that term is also defined by HIPAA, including the requirements for Business Associates set forth as 45 C.F.R. § 164.504(e).

Whereas, Covered Entity and Business Associate desire to enter into a contract under which Business Associate will be a Subcontractor providing services on behalf of covered entity.

Whereas, in connection with the provision of such services by Business Associate, the Covered Entity may disclose to Business Associate certain Protected Health Information (as defined below).

Whereas, Business Associate and the Covered Entity desire to enter into a Business Associate Agreement for the purpose of addressing the Privacy Rule, the Security Rule, and the Electronic Transaction Rule, (as those terms are defined below), and for addressing the privacy and security provisions set forth in the Health Information Technology for Economic and Clinical Health Act (the "HITECH Act"), contained in Title XIII, Subtitle D, of the American Recovery and Reinvestment Act of 2009.

Therefore, in consideration of the premises and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, Business Associate and the Covered Entity agree as follows:

ARTICLE 1. DEFINITIONS

- 1.1. "Agreement" shall mean this document, including all exhibits, attachments, and properly executed amendments and addendums.
- 1.2 "Breach" shall have the same meaning as the term "breach" in 45 C.F.R. § 164.402.
- 1.3 "Electronic Health Record" shall have the same meaning as the term "electronic protected health information" in § 13400(5) of the American Recovery and Reinvestment Act of 2009.
- 1.4 "Electronic Protected Health Information" shall have the same meaning as the term "electronic protected health information" in 45 C.F.R. § 160.103.

- 1.5 "Electronic Transaction Rule" shall mean the final regulations issued by the U.S. Department of Health and Human Services concerning standard transactions and code sets under 45 C.F.R. Parts 160 and 162.
- 1.6 "*Individual*" shall mean the person who is the subject of the Protected Health Information or a person who qualifies as the personal representative of the individual in accordance with 45 C.F.R. § 164.502(g).
- 1.7 *"Privacy Rule"* shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 C.F.R. Part 160 and Part 164, Subparts A and E.
- 1.8 "Protected Health Information" shall mean any information that: (a) relates to the past, present, or future physical or mental health or condition of an Individual; (b) the provision of health care to an Individual; (c) or the past, present, or future payment for the provision of health care to an Individual; and (d) that identifies the Individual for or with respect to which there is a reasonable basis to believe the information can be used to identify the Individual.
- 1.9 "Required By Law" shall have the same meaning as the term "required by law" in 45 C.F.R. § 160.103.
- 1.10 "Secretary" shall mean the Secretary of the Department of Health and Human Services ("HHS") and any other officer or employee of HHS to whom authority has been delegated.
- 1.11 *"Security Incident"* shall have the same meaning as the term "security incident" in 45 C.F.R. § 160.103.
- 1.12 "Security Rule" shall mean the Security Standards and Implementation Specifications at 45 C.F.R. Parts 160 and 164, Subparts A and C.
- 1.13 "*Transaction*" shall have the same meaning as the term "transaction" in 45 C.F.R. § 160.103.
- 1.14 "Unsecured Protected Health Information" shall have the same meaning as the term "unsecured protected health information" in 45 C.F.R. § 164.402.

ARTICLE 2. SAFEGUARDING PRIVACY AND SECURITY OF PROTECTED HEALTH INFORMATION

2.1 <u>Permitted Uses and Disclosures.</u> Business Associate hereby agrees that it shall be prohibited from using or disclosing Protected Health Information provided or made

available by the Covered Entity (or another Business Associate of the Covered Entity) for any purpose other than as expressly permitted or required by the Subcontractor Contract.

a. Functions and Activities on Covered Entity's Behalf. Except as otherwise set forth in this Agreement, the parties hereby agree that Business Associate shall be permitted to use and/or disclose Protected Health Information provided or made available by the Covered Entity (or another business associate of the Covered Entity) only for the purpose of conducting the transactions contemplated for the Business Associate under the underlying Subcontractor Contract and only for purposes within the scope of such underlying Subcontractor Contract.



- b. **Business Operations**. Business Associate is permitted to use and/or disclose Protected Health Information if necessary for the proper management and administration of Business Associate's responsibilities under the Subcontractor Contract, or to carry out any legal responsibilities of Business Associate, provided that, with respect to any disclosure of Protected Health Information, either:
 - (1) the disclosure is Required By Law; or
 - (2) Business Associate obtains reasonable assurances from the person to whom the Protected Health Information is disclosed that: (a) the Protected Health Information will be held in confidence and used or further disclosed only as or for the purposes for which Business Associate disclosed the Protected Health Information to the person or as Required by Law; (b) the person will use appropriate safeguards to prevent use or disclosure of the Protected Health Information; and (c) the person immediately notifies Business Associate of any instance of which it is aware in which the confidentiality of the Protected Health Information has been breached.
- c. **Data Aggregation Services**. Business Associate is permitted to use or disclose Protected Health Information to provide data aggregation services, as that term is defined by 45 C.F.R. § 164.501, relating to health care operations of the Covered Entity.
- d. **Minimum Necessary.** Business Associate will, in its performance of the functions, activities, services, and operations specified above, make reasonable efforts to use, to disclose, and to request only the minimum amount of Covered Entity's Protected Health Information reasonably necessary to accomplish the intended purpose of the use, disclosure or request, except that Business Associate will not be obligated to comply with this minimum-necessary limitation if neither Business Associate nor Covered Entity is required to limit its use, disclosure or request to the minimum necessary. Business Associate and Covered Entity acknowledge that the phrase "minimum necessary" shall be interpreted in accordance with the HITECH Act.

2.2 <u>Information Safeguards.</u>

- a. **Privacy of Covered Entity's Protected Health Information.** Business Associate will develop, implement, maintain, and use appropriate administrative, technical, and physical safeguards to protect the privacy of Covered Entity's Protected Health Information. The safeguards must reasonably protect Covered Entity's Protected Health Information from any intentional or unintentional use or disclosure in violation of the Privacy Rule and limit incidental uses or disclosures made pursuant to a use or disclosure otherwise permitted by this Agreement.
- b. Security of Covered Entity's Electronic Protected Health Information. Business Associate will develop, implement, maintain, and use administrative, technical, and physical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of Electronic Protected Health Information that Business Associate creates, receives, maintains, or transmits on Covered Entity's behalf as required by the Security Rule.
- 2.3 Employees, Subcontractors, Independent Contractors, and Agents. Business Associate will require any of its Employees, Subcontractors, Independent Contractors, and Agents to which Business Associate is permitted by this Agreement, or in writing by Covered Entity, to disclose Covered Entity's Protected Health Information and/or Electronic Protected Health Information, to provide assurance in writing that Employee, Resource Parent, Subcontractor, Independent Contractor, or Agent understands the requirements to safeguard and protect PHI and will comply with the same privacy and security safeguard obligations with respect to Covered Entity's Protected Health Information and/or Electronic Protected Health Information as are applicable to Business Associate under this Agreement.
- 2.4 Prohibition on Sale of Records. Business Associate shall not directly or indirectly receive remuneration in exchange for any Protected Health Information of an Individual unless the Covered Entity or Business Associate obtains from the Individual, in accordance with 45 C.F.R. § 164.508, a valid authorization that includes a specification of whether the Protected Health Information can be further exchanged for remuneration by the entity receiving Protected Health Information of that Individual, except as otherwise allowed under the HITECH Act.
- 2.5 <u>Penalties For Noncompliance.</u> Business Associate acknowledges that it is subject to civil and criminal enforcement for failure to comply with the Privacy Rule and Security Rule, as amended by the HITECH Act.

ARTICLE 3. COMPLIANCE WITH ELECTRONIC TRANSACTION RULE

If Business Associate conducts in whole or part electronic Transactions on behalf of Covered Entity for which HHS has established standards, Business Associate will comply, and will require any Employees, Subcontractors, Independent Contractors, and Agents it involves with the conduct of such Transactions to comply, with each applicable requirement of the Electronic Transaction Rule. Business Associate shall also comply with the National Provider Identifier requirements, if and to the extent applicable.

ARTICLE 4. INDIVIDUAL RIGHTS

- 4.1 Access. Business Associate will make available to Covered Entity or, at Covered Entity's direction, to an Individual (or the Individual's personal representative) for inspection and obtaining copies Covered Entity's Protected Health Information about the Individual that is in Business Associate's custody or control, so that Covered Entity may meet its access obligations under 45 C.F.R. § 164.524. Effective as of the date specified by HHS, if the Protected Health Information is held in an Electronic Health Record, then the Individual shall have a right to obtain from Business Associate a copy of such information in an electronic format. Business Associate shall provide such a copy to Covered Entity or, alternatively, to the Individual directly, if such alternative choice is clearly, conspicuously, and specifically made by the Individual or Covered Entity.
- 4.2 <u>Amendment</u>. Business Associate will, upon receipt of written notice from Covered Entity, promptly amend or permit Covered Entity access to amend any portion of Covered Entity's Protected Health Information, so that Covered Entity may meet its amendment obligations under 45 C.F.R. § 164.526.
- 4.3 <u>Disclosure Accounting.</u> To allow Covered Entity to meet its disclosure accounting obligations under 45 C.F.R. § 164.528:
 - a. **Disclosures Subject to Accounting.** Business Associate will record the information specified below ("Disclosure Information") for each disclosure of Covered Entity's Protected Health Information, not excepted from disclosure accounting as specified below, that Business Associate makes to Covered Entity or to a third party.
 - b. **Disclosures Not Subject to Accounting.** Business Associate will not be obligated to record Disclosure Information or otherwise account for disclosures of

Covered Entity's Protected Health Information if Covered Entity need not account for such disclosures.

- c. **Disclosure Information.** With respect to any disclosure by Business Associate of Covered Entity's Protected Health Information that is not excepted from disclosure accounting, Business Associate will record the following Disclosure Information as applicable to the type of accountable disclosure made:
 - (1) **Disclosure Information Generally.** Except for repetitive disclosures of Covered Entity's Protected Health Information as specified below, the Disclosure Information that Business Associate must record for each accountable disclosure is (i) the disclosure date, (ii) the name and (if known) address of the entity to which Business Associate made the disclosure, (iii) a brief description of Covered Entity's Protected Health Information disclosed, and (iv) a brief statement of the purpose of the disclosure.
 - (2) **Disclosure Information for Repetitive Disclosures.** For repetitive disclosures of Covered Entity's Protected Health Information that Business Associate makes for a single purpose to the same person or entity (including Covered Entity), the Disclosure Information that Business Associate must record is either the Disclosure Information specified above for each accountable disclosure, or (i) the Disclosure Information specified above for the first of the repetitive accountable disclosures; (ii) the frequency, periodicity, or number of the repetitive accountable disclosures; and (iii) the date of the last of the repetitive accountable disclosures.
- d. Availability of Disclosure Information. Business Associate will maintain the Disclosure Information for at least 6 years following the date of the accountable disclosure to which the Disclosure Information relates (3 years for disclosures related to an Electronic Health Records, starting with the date specified by HHS). Business Associate will make the Disclosure Information available to Covered Entity within 15 calendar days following Covered Entity's request for such Disclosure Information to comply with an Individual's request for disclosure accounting. Effective as of the date specified by HHS, with respect to disclosures related to an Electronic Health Record, Business Associate shall provide the accounting directly to an Individual making such a disclosure request, if a direct response is requested by the Individual.

- 4.4 Restriction Agreements and Confidential Communications. Business Associate will comply with any agreement that Covered Entity makes that either (i) restricts use or disclosure of Covered Entity's Protected Health Information pursuant to 45 C.F.R. § 164.522(a), or (ii) requires confidential communication about Covered Entity's Protected Health Information pursuant to 45 C.F.R. § 164.522(b), provided that Covered Entity notifies Business Associate in writing of the restriction or confidential communication obligations that Business Associate must follow. Covered Entity will promptly notify Business Associate in writing of the termination of any such restriction agreement or confidential communication requirement and, with respect to termination of any such restriction agreement, instruct Business Associate whether any of Covered Entity's Protected Health Information will remain subject to the terms of the restriction agreement. Effective February 17, 2010 (or such other date specified as the effective date by HHS), Business Associate will comply with any restriction request if: (i) except as otherwise Required by Law, the disclosure is to a health plan for purposes of carrying out payment or health care operations (and is not for purposes of carrying out treatment); and
 - (ii) the Protected Health Information pertains solely to a health care item or service for which the health care provider involved has been paid out-of-pocket in full.

ARTICLE 5. BREACHES

- Privacy or Security Breach. Business Associate will report to Covered Entity any use or disclosure of Covered Entity's Protected Health Information not permitted by this Agreement along with any Breach of Covered Entity's Unsecured Protected Health Information. Business Associate will treat the Breach as being discovered in accordance with 45 CFR §164.410. Business Associate will make the report to the Covered Entity not more than 5 calendar days after Business Associate learns of such non-permitted use or disclosure. If a delay is requested by a law-enforcement official in accordance with 45 CFR §164.412, Business Associate may delay notifying Covered Entity for the applicable time period. Business Associate's report will at least:
 - a. Identify the nature of the Breach or other non-permitted use or disclosure, which will include a brief description of what happened, including the date of any Breach and the date of the discovery of any Breach;
 - b. Identify Covered Entity's Protected Health Information that was subject to the non-permitted use or disclosure or Breach (such as whether full name, social security number, date of birth, home address, account number or other information were involved) on an individual basis;
 - c. Identify who made the non-permitted use or disclosure and who received the non-permitted disclosure;

- d. Identify what corrective or investigational action Business Associate took or will take to prevent further non-permitted uses or disclosures, to mitigate harmful effects and to protect against any further Breaches;
- e. Identify what steps the Individuals who were subject to a Breach should take to protect themselves;
- f. Provide such other information, including a written report, as Covered Entity may reasonably request.
- 5.2 **Security Incidents.** Business Associate will report to Covered Entity any attempted or successful (A) unauthorized access, use, disclosure, modification, or destruction of Covered Entity's Electronic Protected Health Information or (B) interference with Business Associate's system operations in Business Associate's information systems, of which Business Associate becomes aware. Business Associate will make this report upon request, except if any such Security Incident resulted in a disclosure not permitted by this Agreement or Breach of Covered Entity's Unsecured Protected Health Information, Business Associate will make the report in accordance with the provisions set forth in Section 5.1.

ARTICLE 6. TERM AND TERMINATION

6.1 <u>Term.</u> This Agreement shall be effective on the date that Business Associate's Subcontractor Contract commences with the Covered Entity and shall terminate when all Protected Health Information provided by Covered Entity to Business Associate, or created or received by Business Associate on behalf of Covered Entity, is destroyed or returned to Covered Entity or the Department, or, if it is infeasible to return or destroy Protected Health Information, protections are extended to such information, in accordance with the termination provisions in this section.

- 6.2 <u>Right to Terminate for Cause.</u> The Covered Entity may terminate the Subcontractor Contract if it determines, in its sole discretion, that Business Associate has breached any provision of this Business Associate Agreement, and upon written notice to Business Associate of the Breach, Business Associate fails to cure the Breach within 30 calendar days after receipt of the notice. Any such termination will be effective immediately or at such other date specified in Covered Entity's notice of termination.
- 6.3 Return or Destruction of Covered Entity's Protected Health Information as Feasible. Upon termination or other conclusion of the Subcontractor Contract, Business Associate agrees to return all Protected Health Information received from the Covered Entity, or created or received by Business Associate on behalf of the Covered Entity, and not to retain any copies of the Protected Health Information after termination of the Subcontractor Contract. If Business Associate elects to destroy the Protected Health Information, it shall certify to the Covered Entity and the Pennsylvania Department of Public Health when applicable that the Protected Health Information has been destroyed.
- 6.4 <u>Continuing Privacy and Security Obligation.</u> If return or destruction of the Protected Health Information is not feasible, Business Associate agrees to extend the protections of this Business Associate Agreement for as long as necessary to protect the Protected Health Information and to limit any further use or disclosure so as to be consistent with the intent of this Business Associate Agreement.

ARTICLE 7. GENERAL PROVISIONS

- 7.1 <u>Access to Books and Records.</u> Business Associate hereby agrees to make its internal practices, books and records relating to the use, disclosure, and safeguards for Protected Health Information received from, or created or received by Business Associate on behalf of the Covered Entity, available to the Secretary or the Secretary's designee for purposes of determining compliance with the Privacy Rule and/or the Security Rule.
- 7.2 <u>Mitigation Procedures.</u> Business Associate agrees to have procedures in place for mitigating, to the extent practicable, any deleterious effect from the use or disclosure of Protected Health Information received from, or created or received by Business Associate on behalf of the Covered Entity, in a manner contrary to this Business Associate Agreement or the Privacy Rule.

- 7.3 Amendment to Business Associate Agreement. Upon the compliance date of any final regulation or amendment to final regulation promulgated by HHS that affects Business Associate or Covered Entity's obligations under this Agreement, this Agreement will be automatically amended such that the obligations imposed on Business Associate or Covered Entity remain in compliance with the final regulation or amendment to final regulation.
- Omnibus Rule. The U.S. Department of Health and Human Services released the Omnibus Rule, effective March 26, 2013 applicable to existing Privacy, Security, and Enforcement Rules for protected health information ("PHI") under HIPAA and improving enforcement under the Health Information Technology for Economic and Clinical health (HITECH) Act. The Omnibus Rule modifies the Breach Notification Rule. Pursuant to the Omnibus Rule, effective March 26, 2013, Business Associate is directly liable for compliance with HIPAA Privacy and Security Rule requirements including: impermissible uses and disclosures; failure to provide breach notification to the Covered Entity; failure to disclose PHI where required by the Secretary to investigate or determine the business associate's compliance with the HIPAA Rules; failure to provide an accounting of disclosures; and failure to comply with the requirements of the Security Rule.
- 7.5 <u>Choice of Law.</u> Except to the extent superseded by the federal law, this Business Associate Agreement shall be governed by the laws of the Commonwealth of Pennsylvania without regard to choice of laws principles; provided, however, that for the purposes of privacy rights of Individuals, the law of the state in which the Individual resided during the event(s) giving rise to the need to determine the rights under this Agreement shall apply.
- 7.6 <u>Disputes.</u> Any controversy or claim arising out of or relating to the underlying Subcontractor Contract or this Business Associate Agreement will be finally settled by compulsory arbitration in accordance with the Commercial Arbitration Rules of the American Arbitration Association ("AAA").
- 7.7 <u>Injunctive Relief.</u> Notwithstanding any rights or remedies provided for in this Agreement, the Covered Entity retains all rights to seek injunctive relief to prevent or stop the unauthorized use or disclosure of Protected Health Information by Business Associate or any Employee, Subcontractors, Independent Contractors, Agents, Contractors, and/or Third Parties that received Protected Health Information from Business Associate.
- 7.8 <u>Notices.</u> Whenever under this Business Associate Agreement one party is required to give notice to the other, such notice shall be deemed given if mailed by a nationally recognized overnight courier service (*e.g.*, Federal Express or United parcel Service), payment paid by sender; or by United States Registered or Certified Mail, Return Receipt Requested, postage prepaid by sender, and addressed as follows:

Covered Entity:

ENTITY NAME ADDRESS 1 ADDRESS 2

Business Associate:

ENTITY NAME ADDRESS 1 ADDRESS 2

- 7.9 <u>Binding Nature and Assignment.</u> This Agreement shall be binding on Business Associate and the Covered Entity and their successors and assigns, but neither Business Associate nor the Covered Entity may assign this Agreement without the prior written consent of the other, which consent shall not be unreasonably withheld.
- 7.10 <u>Headings</u>. The headings in this Agreement are for reference and convenience only, and shall not enter into the interpretation of this Agreement.
- 7.11 <u>Force Majeure.</u> Business Associate shall be excused from performance under this Agreement for any period Business Associate is prevented from performing any services pursuant hereto, in whole or in part, as a result of an act of God, war, civil disturbance, court order, labor dispute or other cause beyond its reasonable control, and such non-performance shall not be grounds for termination.
- 7.12 <u>Attorneys' Fees.</u> Except as otherwise specified in this Business Associate Agreement, if any legal action or other proceeding is brought for the enforcement of this Agreement, or because of an alleged dispute, breach, default, misrepresentation, or injunctive action, in connection with any of the provisions of this Agreement, each party shall bear their own legal expenses and the other costs incurred in that action or proceeding.
- 7.13 <u>Entire Agreement.</u> This Business Associate Agreement constitutes the entire agreement between the parties and shall replace any previous Business Associate Agreement between the parties.

IN WITNESS WHEREOF, Business Associate and the Covered Entity have caused this Business Associate Agreement to be signed and delivered by their duly authorized representatives as of the date set forth above.

Covered Entity	
	Business Associate:
SIGNED	
PRINTED	SIGNED
TITLE	PRINTED
DATE	TITLE
	DATE