This Business Associate Agreement (hereinafter, the “Agreement”) is made as of the _____ day of ________________, 20__ (hereinafter, the “Effective Date”), by and between ______________________ (hereinafter, “Business Associate”) and ________________________________________________ (hereinafter, “Covered Entity”), collectively the “Parties”, to comply with the Health Insurance Portability and Accountability Act of 1996 (hereinafter, “HIPAA”) privacy standards adopted by the U.S. Department of Health and Human Services as they may be amended from time to time, 45 C.F.R. parts 160 and 164 (“the Privacy Rule”) and security standards adopted by the U.S. Department of Health and Human Services as they may be amended from time to time, 45 C.F.R. parts 160, 162, and 164, subpart C (“the Security Rule”), and the Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 and regulations promulgated thereunder and any applicable state confidentiality laws.

RECITALS

WHEREAS, Business Associate has entered into a Service Agreement to provide certain services to or on behalf of Covered Entity;

WHEREAS, in connection with these services, Covered Entity discloses to Business Associate certain PHI that is subject to protection under the HIPAA Rules/Regulations; and

WHEREAS, the HIPAA Rules/Regulations require that Covered Entity receive adequate assurances that Business Associate will comply with certain obligations with respect to the PHI received in the course of providing services to or on behalf of Covered Entity.

NOW THEREFORE, in consideration of the mutual promises and covenants herein, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

A. **Definitions.** Terms used herein, but not otherwise defined, shall have meaning ascribed by the Privacy Rule and the Security Rule.

   1. **Breach:** “Breach” shall mean the unauthorized acquisition, access, use, or disclosure of PHI which compromises the security or privacy of such information.
2. **Designated Record Set:** “Designated Record Set” shall mean a group of records maintained by or for a Covered Entity that is: (i) the medical records and billing records about Individuals maintained by or for a covered health care provider; (ii) the enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or (iii) used, in whole or in part, by or for the covered entity to make decisions about individuals. For purposes of this definition, the term “record” means any item, collection, or grouping of information that includes PHI and is maintained, collected, used, or disseminated by or for a covered entity.

3. **De-Identify:** “De-Identify” shall mean to revise, redact, or otherwise process PHI so that the resulting information meets the requirements in the Privacy Rule, including, but not limited to 45 C.F.R. 164.514 (a) and (b).

4. **HIPAA Rules/Regulations:** The Privacy Rule and the Security Rule and amendments codified and promulgated by the HITECH Act are referred to collectively herein as “HIPAA Rules/Regulations.”

5. **Individual:** “Individual” shall mean the person who is the subject of the protected health information.

6. **Protected Health Information (“PHI”):** “Protected Health Information” or PHI shall mean individually identifiable health information that is transmitted or maintained in any form or medium.

7. **Required by Law:** “Required by Law” shall mean a mandate contained in law that compels a use or disclosure of PHI.

8. **Secretary:** “Secretary” shall mean the United States Secretary of the Department of Health and Human Services or his or her Designee.

9. **Unsecured PHI:** “Unsecured PHI” shall mean PHI that is not rendered unusable, unreadable, or indecipherable to unauthorized individuals through the use of a technology or methodology specified by the Secretary in the guidance issued under section 13402(h)(2) of Public Law 111-5 on the HHS website.

B. **Purposes for which PHI May Be Disclosed to a Business Associate:** In connection with the services provided by Business Associate, as contained in the Service Agreement, to or on behalf of Covered Entity described in this Agreement, Covered Entity may disclose PHI to Business Associate.
C. **Obligations of Covered Entity:** If deemed applicable by Covered Entity, Covered Entity shall:

1. **Privacy Notice:** Provide Business Associate a copy of its Notice of Privacy Practices (“Notice”) produced by Covered Entity in accordance with C.F.R. 164.520 as well as any changes to such Notice;

2. **Changes:** Covered Entity, as necessary, shall notify Business Associate of:
   
   a. Any changes in, or revocation of, authorizations by an Individual pursuant to 45C.F.R. 164.526, relating to the use and/or disclosure of PHI, if such changes affect Business Associate’s permitted or required uses and/or disclosures.

   b. Any restriction to the use and/or disclosure of PHI to which Covered Entity has agreed pursuant to 45 C.F.R. 164.522, to the extent that such restriction may affect Business Associate’s use or disclosure of PHI and;

3. **Covered Entity Compliance:** Covered Entity shall not request Business Associate to use or disclose PHI in a manner that violates applicable law.

D. **Obligations of Business Associate:** Business Associate agrees to comply with applicable federal and state confidentiality and security laws, specifically the provisions of the HIPAA, the HITECH Act and HIPAA Regulations, (collectively “Privacy and Security Laws”), applicable to Business Associate, including;

1. **Use and Disclosure of PHI:** Except as otherwise permitted by this Agreement or applicable law, Business Associate shall not use or disclose PHI except as necessary to provide Services described in the Service Agreement to or on behalf of Covered Entity, and shall not use or disclose PHI that would violate the “Privacy Laws” if used or disclosed by Covered Entity. Also knowing that there are certain restrictions on disclosure of PHI, Business Associate may use and disclose PHI as necessary for the proper management and administration of Business Associate, or to carry out its legal responsibilities. Business Associate shall in such cases:

   a. provide information and training to members of its workforce using or disclosing PHI regarding the confidentiality requirements of the HIPAA Rules and this Agreement;
b. obtain reasonable assurances from the person or entity to whom the PHI is disclosed that: (i) the PHI will be held confidential and further used and disclosed only as Required by Law or for the purpose for which it was disclosed to the person or entity; and (ii) the person or entity will notify Business Associate of any instances of which it is aware in which confidentiality of the PHI has been breached; and

c. agree to notify the designated Privacy Officer of Covered Entity immediately following the discovery of, and in no case later than 20 days following the discovery of, any instances of which it is aware in which PHI is used or disclosed for a purpose that is not otherwise provided for in this Agreement or for a purpose not expressly permitted by the HIPAA Rules/Regulations.

2. Data Aggregation: In the event that Business Associate works for more than one Covered Entity, Business Associate is permitted to use and disclose PHI for data aggregation purposes; however, only in order to analyze data for permitted health care operations, and only to the extent that such use is permitted under the HIPAA Rules/Regulations.

3. De-Identified Information: Business Associate may use and disclose de-identified health information if written approval from the Covered Entity is obtained, and the PHI is de-identified in compliance with the HIPAA Rules/Regulations, 45 C.F.R.164.514.

4. Safeguards: Business Associate agrees to use appropriate safeguards to prevent the use or disclosure of PHI other than permitted by this Agreement or as required by law.

   a. Business Associate shall implement administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and security of any paper or electronic PHI it creates, receives, maintains, or transmits on behalf of Covered Entity consistent with 45 C.F.R. 164.308, 164.310, 164.312 and 164.316.

   b. Business Associate shall assure that all PHI be secured when accessed by Business Associate’s employees, agents or subcontractors. Any access to PHI by Business Associate’s employees, agents or subcontractors shall be limited to legitimate business needs while working with PHI. Any
personnel changes by Business Associate, eliminating the legitimate business needs for employees, agents or contractors access to PHI – either by revision of duties or termination – shall be immediately reported to Covered Entity. Such reporting shall be made no later than the third business day after the personnel change becomes effective.

5. **Minimum Necessary**: Business Associate shall ensure that all uses and disclosures of PHI are subject to the principle of “minimum necessary use and disclosure,” i.e., that only PHI that is the minimum necessary to accomplish the intended purpose of the use, disclosure, or request is used or disclosed; and, the use of limited data sets when possible.

6. **Disclosures to Agents and Subcontractors**: Business Associate shall ensure that all agents and/or subcontractors to whom Business Associate discloses or provides the PHI execute a written Business Associate Agreement in which such third parties expressly agree to the same restrictions and conditions that apply to the Business Associate hereunder. The Business Associate shall obtain reasonable assurance from agents, and/or subcontractors who have access to or are recipients of PHI to implement reasonable and appropriate safeguards to protect the confidentiality, integrity, and security of the paper or electronic PHI that it creates, receives, maintains, or transmits on behalf of the Covered Entity. Business Associate shall be liable to Covered Entity for any acts, failures or omissions of the agent and/or subcontractor in providing the services as if they were Business Associate’s own acts, failures or omissions, to the extent permitted by law.

7. **Sales, Marketing and Fundraising**: Business Associate shall not use PHI for Fundraising or Marketing purposes.

8. **Individual Rights Regarding Designated Record Sets**: If Business Associate maintains a Designated Record Set on behalf of Covered Entity, Business Associate agrees to the following:

   a. **Individual Right to Copy or Inspect**: Business Associate agrees to provide access, at the request of Covered Entity, to PHI in a Designated Record Set to an Individual or personal representative, in order to meet the requirements of 45 C.F.R.164.524.

   b. **Individual Right to Amendment**: Business Associate agrees, if it maintains PHI in a Designated Record Set, to make amendments to PHI
only at the written request and direction of Covered Entity pursuant to 45 C.F.R. 164.526.

c. **Accounting of Disclosures:** Business Associate agrees to maintain documentation of the information required to provide an accounting of disclosures of PHI, whether PHI is paper or electronic format, in accordance with 45 C.F.R. 164.528 and to make this information available to Covered Entity within 20 days of the Covered Entity’s written request, in order to allow Covered Entity to provide an accounting of disclosures to an Individual or personal representative within 60 days of receipt of request and in accordance with HIPAA Rules/Regulations.

9. **Internal Practices, Polices, and Procedures:** Except as otherwise specified herein, and upon written request, Business Associate shall make available its internal practices, policies, procedures, books, records and similar documents that are not protected by applicable legal privilege or work product protection and relating to the use and disclosure of PHI, received from or on behalf of Covered Entity to the Secretary or his or her agents for the purpose of determining Covered Entity’s compliance with the HIPAA Rules/Regulations, or any other health oversight agency, or to Covered Entity. Records requested will be made available in the time and manner specified by Covered Entity or Secretary.

10. **Notices of Privacy Practices:** Business Associate shall abide by the limitations of the Notice of Privacy Practices provided by the Covered Entity. Any use or disclosure permitted by this agreement may be amended by changes to Covered Entity’s Notice; provided, however, that the amended Notice shall not affect permitted uses and disclosures on which Business Associate relied prior to receiving notice of such amended notice.

11. **Withdrawal of Authorization:** If the use or disclosure of PHI in this Agreement is based upon an Individual’s specific authorization for the use or disclosure of his or her PHI, and the Individual revokes such authorization, the effective date of such authorization has expired, or such authorization is found to be defective in any manner that renders it invalid, Business Associate shall, if it has notice of such revocation, expiration, or invalidity, cease the use and disclosure of the Individual’s PHI except to the extent it has relied on such use of disclosure, or if an exception under the Privacy Rule expressly applies.
12. Breach Notification for PHI: Business Associate expressly recognizes that Covered Entity has certain reporting and disclosure obligations to the Secretary and the Individual in case of a privacy/security breach of unsecured PHI. Where Business Associate accesses, maintains, retains, modifies, records, stores, destroys, or otherwise holds, uses or discloses unsecured paper or electronic PHI, Business Associate immediately following the discovery of a breach of such information, shall notify the Privacy Officer for the Covered Entity of such breach. Business Associate must provide Covered Entity with all information necessary in accordance with C.F.R. 164.410 without reasonable delay, and in no case later than 20 days following the discovery of the breach. Business Associate shall be liable for the costs associated with such breach.

13. Breach Notification to Individuals: Business Associate’s duty to notify Covered Entity of any breach does not permit Business Associate to notify those Individuals whose PHI has been breached by Business Associate. Any and all notifications to affected Individuals whose PHI has been breached shall be made by the Covered Entity. The Business Associate will notify the Privacy Officer for the Covered Entity via telephone with follow-up in writing to include: name of Individuals whose PHI was breached, information breached, date of breach, form of breach, etc. The cost of the notification will be paid by the Business Associate.

14. Rights, Ownership and Interest in PHI: The Business Associate acknowledges and agrees that Covered Entity owns all right, title, and interest in and to all PHI, and that such right, title, and interest will be vested in Covered Entity. Neither Business Associate nor any of its employees, agents, contractors or assigns will have any rights in any of the PHI, except as expressly set forth above. Business Associate represents, warrants, and covenants that it will not compile and/or distribute analyses to third parties using any PHI without Covered Entity’s express written consent.

E. Term and Termination:

1. Term: This Agreement shall be effective as of the Effective Date and shall be terminated when all PHI provided to Business Associate by Covered Entity, or created or received by Business Associate on behalf of Covered Entity, is destroyed or returned to Covered Entity.

2. Termination for Cause: Upon Covered Entity’s knowledge of a material breach by Business Associate, Covered Entity shall either:
a. Provide an opportunity for Business Associate to cure the breach or end the violation and terminate this Agreement, whether it is in the form of a standalone Agreement or an Addendum to a Service Agreement, if Business Associate does not cure the breach or end the violation within the time specified by Covered Entity; or

b. Immediately terminate this Agreement whether it is in the form of a standalone Agreement or an Addendum to a Service Agreement if Business Associate has breached a material term of this Agreement and cure is not possible.

3. **Effect of Termination:** Upon termination of this Agreement for any reason, Business Associate agrees to return or destroy all PHI received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity, maintained by Business Associate in any form. If Business Associate determines that the return or destruction of PHI is not feasible, Business Associate shall inform Covered Entity in writing of the reason thereof, and shall agree to extend the protections of this Agreement to such PHI and limit further uses and disclosures of the PHI to those purposes that make the return or destruction of the PHI not feasible for so long as Business Associate retains the PHI.

F. **Miscellaneous:**

1. **Indemnification:** To the extent permitted by law, Business Associate agrees to indemnify and hold harmless Covered Entity from and against all claims, demands, liabilities, judgements or causes of action of any nature for any relief, elements of recovery or damages recognized by law (including, without limitation, attorney’s fees, defense costs, and equitable relief), for any damage or loss incurred by Covered Entity arising out of, resulting from, or attributable to any acts or omissions or other conduct of Business Associate or its agents in connection with the performance of Business Associate’s or its agents’ duties under this Agreement. This indemnity shall apply even if Covered Entity is alleged to be solely or jointly negligent or otherwise solely or jointly at fault; provided, however, that a trier of fact finds Covered Entity not to be solely or jointly negligent or otherwise solely or jointly at fault. This indemnity shall not be construed to limit Covered Entity’s rights, if any, to common law indemnity.

Covered Entity shall have the option, at its sole discretion, to employ attorneys selected by it to defend any such action, the costs and expenses of which shall be the responsibility of the Business Associate. Covered Entity shall provide Business Associate with timely notice of the existence of such proceedings and
such information, documents and other cooperation as reasonably necessary to assist Business Associate in establishing a defense to such action.

These indemnities shall survive termination of this Agreement, and Covered Entity reserves the right at its option and expense, to participate in the defense of any suit or proceeding through counsel of its own choosing.

2. **Mitigation:** If Business Associate violates this Agreement or the HIPAA Rules/Regulations, Business Associate agrees to mitigate, to the fullest extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of PHI in violation of the requirements of this Agreement.

3. **Survival:** The respective rights and obligations of Business Associate under this Agreement shall survive the termination of this Agreement.

4. **Notices:** Any notices pertaining to this Agreement shall be given in writing and shall be deemed duly given when personally delivered to a Party or Party’s authorized representative as listed below or sent by means of a reputable overnight carrier, or sent by means of certified mail, return receipt requested, postage prepaid. A notice sent by certified mail shall be deemed given on the date of receipt or refusal of receipt. All notices shall be addressed to the appropriate Party as follows:

   If to Covered Entity:
   
   Entity Name  
   Address  
   City, State Zip  
   Attn: Name  

   If to Business Associate:
   
   Company Name  
   Address  
   City, State Zip  
   Attn: Name  
   Phone Number  

5. **Amendments:** This Agreement may not be changed or modified in any manner except by an instrument in writing signed by a duly authorized officer of each of the Parties hereto. The Parties, however, agree to amend this Agreement from time to time as necessary, in order to allow Covered Entity to comply with the requirements of the HIPAA Rules/Regulations.
6. **Choice of Law:** This Agreement and the rights and the obligations of the Parties hereunder shall be governed by and construed under the laws of [___________] (state) without regard to applicable conflict of laws principles.

7. **Assignment of Rights and Delegation of Duties:** This Agreement is binding upon and inures to the benefit of the Parties hereto and their respective successors and permitted assigns. However, neither Party may assign any of its rights or delegate any of its obligations under this Agreement without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed. Notwithstanding any provisions to the contrary, however, Covered Entity retains the right to assign or delegate any of its rights or obligations hereunder to any of its wholly owned subsidiaries, affiliates or successor companies. Assignments made in violation of this provision are null and void.

8. **Nature of Agreement:** Nothing in this Agreement shall be construed to create (i) a partnership, joint venture or other joint business relationship between the Parties or any of their affiliates, (ii) any fiduciary duty owed by one Party to another Party or any of its affiliates, or (iii) a relationship of employer and employee between Parties.

9. **No Waiver:** Failure or delay on the part of either Party to exercise any right, power, privilege or remedy hereunder shall not constitute a waiver thereof. No provision of this Agreement may be waived by either Party except by a writing signed by an authorized representative of the Party making the waiver.

10. **Equitable Relief:** Any disclosure of misappropriation of PHI by Business Associate in violation of this Agreement will cause Covered Entity irreparable harm, the amount of which may be difficult to ascertain. Business Associate therefore agrees that Covered Entity shall have the right to apply to a court of competent jurisdiction for specific performance and/or an order restraining and enjoining Business Associate from any such further disclosure or breach, and for such other relief as Covered Entity shall deem appropriate. Such rights are in addition to any other remedies available to Covered Entity at law or in equity. Business Associate expressly waives the defense that a remedy in damages will be adequate, and further waives any requirement in an action for specific performance or injunction for the posting of a bond by Covered Entity.
11. **Severability:** The provisions of this Agreement shall be severable, and if any provision of this Agreement shall be held or declared to be illegal, invalid or unenforceable, the remainder of this Agreement shall continue in full force and effect as though such illegal, invalid or unenforceable provision had not been contained herein.

12. **No Third Party Beneficiaries:** Nothing in this Agreement shall be considered or construed as conferring any right or benefit on a person not party to this Agreement nor imposing any obligations on either Party hereto to persons not a party to this Agreement.

13. **Headings:** The descriptive headings of the articles, sections, subsections, exhibits and schedules of this Agreement are inserted for convenience only, do not constitute a part of this Agreement and shall not affect in any way the meaning or interpretation of this Agreement.

14. **Entire Agreement:** This Agreement, together with all Exhibits, Riders and amendments, if applicable, which are fully completed and signed by authorized persons on behalf of both Parties from time to time while this Agreement is in effect, constitutes the entire Agreement between the Parties hereto with respect to the subject matter hereof and supersedes all previous written or oral understandings, agreements, negotiations, commitments, and any other writing and communication by or between the Parties with respect to the subject matter hereof. In the event of any inconsistencies between any provisions of this Agreement in any provisions of the Exhibits, Riders, or amendments, the provisions of this Agreement shall control.

15. **Interpretation:** Any ambiguity in this Agreement shall be resolved in favor of a meaning that permits Covered Entity to comply with the HIPAA Rules/Regulations and any applicable state confidentiality laws. The provisions of this Agreement shall prevail over the provisions of any other agreement that exists between the Parties that may conflict with, or appear inconsistent with, any provision of this Agreement or the HIPAA Rules/Regulations.

16. **Regulatory References:** A citation in this Agreement to the Code of Federal Regulations shall mean the cited section as that section may be amended from time to time.

17. This Agreement may be executed in two (2) counterparts, each of which shall be deemed an original.
Agreed to:

**Business Associate**

By: ______________________
   (Authorized Signature)

Name: _____________________
   (Print or Type)

Title: ______________________

Date: ______________________

**Covered Entity**

By: ______________________
   (Authorized Signature)

Name: _____________________
   (Print or Type)

Title: ______________________

Date: ______________________