**NORTH CAROLINA**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**BUSINESS ASSOCIATE ADDENDUM**

This Agreement is made effective the \_\_\_ day of \_\_\_\_\_\_\_\_\_\_\_\_, 202\_\_, by and between \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (name of Division, Office or Institution) (“Covered Entity”) and \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (name of contractor) (“Business Associate”) (collectively the “Parties”).

1. **BACKGROUND**
   1. Covered Entity and Business Associate are parties to a contract entitled (identify contract) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (the “Contract”), whereby Business Associate agrees to perform certain services for or on behalf of Covered Entity.
   2. Covered Entity is an organizational unit of the North Carolina Department of Health and Human Services (the “Department”) that has been designated in whole or in part by the Department as a health care component for purposes of the HIPAA Privacy Rule.
   3. The relationship between Covered Entity and Business Associate is such that the Parties believe Business Associate is or may be a “business associate” within the meaning of the HIPAA Privacy Rule.
   4. The Parties enter into this Business Associate Addendum to the Contract with the intention of complying with the HIPAA Privacy Rule provision that a covered entity may disclose Protected Health Information to a business associate and may allow a business associate to create or receive protected heath information on its behalf, if the covered entity obtains satisfactory assurances that the business associate will appropriately safeguard the information.
2. **DEFINITIONS**

Unless some other meaning is clearly indicated by the context, the following terms shall have the following meaning in this Agreement:

* 1. “Electronic protected health information” or “ePHI” shall have the same meaning as the term “Electronic protected health information” in 45 C.F.R. § 160.103.
  2. “HIPAA” means the Administrative Simplification Provisions, Sections 261 through 264, of the federal Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, as modified and amended by 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, Public Law 111-5.
  3. “Individual” shall have the same meaning as the term “individual” in 45 C.F.R. § 160.103 and shall include a Person who qualifies as a personal representative in accordance with 45 C.F.R. § 164.502(g).
  4. “Person” shall have the same meaning as the term “person” in 45 C.F.R. § 160.103 and shall include a human being that is born alive, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.
  5. “Reproductive Health Care” shall have the same meaning as the term “reproductive health care” in 45 C.F.R. § 160.103 and shall include “health care”, as defined in 45 C.F.R. § 160.103, that affects the health of an Individual in all matters relating to the reproductive system and to its functions and processes. This definition shall not be construed to set forth a standard of care for or regulate what constitutes clinically appropriate Reproductive Health Care.
  6. “Privacy Rule” shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 C.F.R. Part 160 and Part 164.
  7. “Protected Health Information” or “PHI” shall have the same meaning as the term “Protected Health Information” in 45 C.F.R. § 160.103, limited to the information compiled, created, or received by Business Associate from or on behalf of Covered Entity.
  8. “Required By Law” shall have the same meaning as the term “required by law” in 45 C.F.R. § 164.103.
  9. “Secretary” shall mean the Secretary of the United States Department of Health and Human Services or the Person to whom the authority involved has been delegated.
  10. Unless otherwise defined in this Agreement, terms used herein shall have the same meaning as those terms have in the Privacy Rule.

1. **OBLIGATIONS OF BUSINESS ASSOCIATE**
   1. Business Associate agrees to not use or disclose PHI other than as permitted or required by this Agreement or as Required By Law.
   2. Business Associate agrees to use appropriate safeguards and comply, where applicable, with subpart C of 45 C.F.R. Part 164 with respect to ePHI, to prevent use or disclosure of the ePHI other than as provided for by this Agreement.
   3. Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of PHI by Business Associate in violation of the requirements of this Agreement.
   4. Business Associate agrees to report to Covered Entity any use or disclosure of the PHI not provided for by this Agreement of which it becomes aware, including breaches of unsecured PHI as required by 45 C.F.R. § 164.410.
   5. Business Associate agrees, in accordance with 45 C.F.R. § 164.502(e)(1) and § 164.308(b)(2), to ensure that any subcontractors that create, receive, maintain, or transmit PHI on behalf of Business Associate agree to the same restrictions and conditions that apply to Business Associate with respect to such information.
   6. Business Associate agrees to make available PHI as necessary to satisfy Covered Entity’s obligations in accordance with 45 C.F.R. § 164.524.
   7. Business Associate agrees to make available PHI for amendment and incorporate any amendment(s) to PHI in accordance with 45 C.F.R. § 164.526.
   8. Unless otherwise prohibited by law, Business Associate agrees to make internal practices, books, and records relating to the use and disclosure of PHI received from or created or received by Business Associate on behalf of, Covered Entity available to the Secretary for purposes of the Secretary determining Covered Entity's compliance with the Privacy Rule.
   9. Business Associate agrees to make available the information required to provide an accounting of disclosures of PHI in accordance with 45 C.F.R. § 164.528.
2. **PERMITTED USES AND DISCLOSURES**
   1. Except as otherwise limited in this Agreement or by other applicable law or agreement, if the Contract permits, Business Associate may use or disclose PHI to perform functions, activities, or services for, or on behalf of, Covered Entity as specified in the Contract, provided that such use or disclosure:
      1. would not violate the Privacy Rule if done by Covered Entity; or
      2. would not violate the minimum necessary policies and procedures of the Covered Entity.
   2. Except as otherwise limited in this Agreement or by other applicable law or agreements, if the Contract permits, Business Associate may disclose PHI for the proper management and administration of the Business Associate or to carry out the legal responsibilities of the Business Associate, provided that:
      1. the disclosures are Required By Law; and
      2. Business Associate obtains reasonable assurances from the Person to whom the information is disclosed that it will remain confidential and will be used or further disclosed only as Required By Law or for the purpose for which it was disclosed to the Person, and the Person notifies the Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached.
   3. Except as otherwise limited in this Agreement or by other applicable law or agreements, if the Contract permits, Business Associate may use PHI to provide data aggregation services to Covered Entity as permitted by 45 C.F.R. § 164.504(e)(2)(i)(B).
   4. Reproductive Health Care Disclosure Prohibited:
      1. Business Associate shall not disclose or respond to any request or demand for PHI that is actually or potentially related to Reproductive Health Care where the request or demand is for the purpose of health oversight activities, law enforcement activities, judicial or administrative proceedings, or disclosures to coroners and medical examiners.
      2. Business Associate agrees that it will not use, disclose, transmit, or otherwise provide PHI for the purpose(s) of identifying an individual, conducting a criminal, civil, or administrative investigation about an individual, or imposing criminal, civil, or administrative liability upon an individual, for the mere act of seeking, obtaining, providing or facilitating lawful Reproductive Health Care Services.
      3. Business Associate shall require that any request or demand for PHI actually or potentially related to Reproductive Health Care be accompanied by a signed attestation ensuring that the PHI sought is not for a prohibited purpose. The attestation must meet the requirements set forth in 45 C.F.R. § 164.509(c), and a separate attestation shall be required for each request. Business Associate shall retain a copy of the attestation and any supporting documentation in accordance with applicable law. Attestations that lack the required content or that contain extraneous material shall be considered invalid.
      4. Business Associate shall promptly notify Covered Entity of any requests for PHI related to Reproductive Health Care requiring attestation and provide any additional information as reasonably requested by Covered Entity. Any request or demand for such PHI must be forwarded to the Department for review, together with the signed attestation from the requesting party.
   5. Notwithstanding the foregoing provisions, Business Associate shall not use or disclose PHI if the use or disclosure would violate any term of the Contract or other applicable law or agreements.
3. **TERM AND TERMINATION**
   1. **Term**. This Agreement shall be effective as of the effective date stated above and shall terminate when the Contract terminates.
   2. **Termination for Cause**. Upon Covered Entity's knowledge of a material breach by Business Associate, Covered Entity may, at its option:
      1. Provide an opportunity for Business Associate to cure the breach or end the violation, and terminate this Agreement and services provided by Business Associate, to the extent permissible by law, if Business Associate does not cure the breach or end the violation within the time specified by Covered Entity;
      2. Immediately terminate this Agreement and services provided by Business Associate, to the extent permissible by law; or
      3. If neither termination nor cure is feasible, report the violation to the Secretary as provided in the Privacy Rule.
   3. **Effect of Termination**.
      1. Except as provided in paragraph (2) of this section or in the Contract or by other applicable law or agreements, upon termination of this Agreement and services provided by Business Associate, for any reason, Business Associate shall return or destroy all PHI received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity. This provision shall apply to PHI that is in the possession of subcontractors or agents of Business Associate. Business Associate shall retain no copies of the PHI.
      2. In the event that Business Associate determines that returning or destroying the PHI is not feasible, Business Associate shall provide Covered Entity notification of the conditions that make return or destruction not feasible. Business Associate shall extend the protections of this Agreement 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.
4. **GENERAL TERMS AND CONDITIONS**
   1. This Agreement amends and is part of the Contract.
   2. Except as provided in this Agreement, all terms and conditions of the Contract shall remain in force and shall apply to this Agreement as if set forth fully herein.
   3. In the event of a conflict in terms between this Agreement and the Contract, the interpretation that is in accordance with the Privacy Rule shall prevail. In the event that a conflict then remains, the Contract terms shall prevail so long as they are in accordance with the Privacy Rule.
   4. A breach of this Agreement by Business Associate shall be considered sufficient basis for Covered Entity to terminate the Contract for cause.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PLEASE PRINT NAME

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

SIGNATURE Date