

**BUSINESS ASSOCIATE AGREEMENT
AND
DATA USE AGREEMENT FOR LIMITED DATA SET**

This Business Associate and Data Use Agreement for a Limited Data Set (“Agreement”) is entered into by and between Emory University, through its School of Medicine (“Business Associate”) and _____ (“Covered Entity”) on the ___ day of _____, 200__ (“Effective Date”).

WHEREAS, Sections 261 through 264 of the federal Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, known as “the Administrative Simplification provisions,” direct the Department of Health and Human Services to develop standards to protect the security, confidentiality and integrity of health information; and

WHEREAS, pursuant to the Administrative Simplification provisions, the Secretary of Health and Human Services has issued regulations at the 45 C.F.R. Parts 160 and 164 (the “HIPAA Security and Privacy Rule”); and

WHEREAS, Business Associate is working collaboratively with the Centers for Disease Control and Prevention (the “CDC”), the American Heart Association, and emergency medical systems and hospitals across the United States to generate data to create the Cardiac Arrest Registry to Enhance Survival (“CARES”), a surveillance registry to improve the treatment of out-of-hospital cardiac arrest (“OHCA”). The goal of CARES is to develop a registry for nationwide use to help local emergency medical systems administrators and medical directors to help local communities identify and track cases of OHCA and identify opportunities for improvement in the treatment of OHCA events.

WHEREAS, Covered Entity wishes to enter into an arrangement with Business Associate to assist Covered Entity with its quality assessment and improvement activities relating to OHCA events, and as part of the arrangement, will provide Business Associate with certain Protected Health Information (as such term is defined below) regarding OHCA patients treated by Covered Entity.

WHEREAS, Business Associate, as a recipient of health information from Covered Entity, is a “business associate” of Covered Entity under the HIPAA Security and Privacy Rules, the parties wish to enter into or have entered into an arrangement whereby Business Associate will create a Limited Data Set (as such term is defined below) of certain Protected Health Information received from Covered Entity in connection with Covered Entity’s participation in CARES; and

THEREFORE, in consideration of the parties’ continuing obligations under this Agreement, compliance with the HIPAA Security and Privacy Rule, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree to the provisions of this Agreement in order to address the requirements of the HIPAA Security and Privacy Rule and to protect the interests of both parties.

1. Definitions

Terms used, but not otherwise defined, in this Agreement shall have the same meaning as those terms in the HIPAA Security and Privacy Rule.

- a. "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 accordance with 45 C.F.R. § 164.502(g).
- b. "Limited Data Set" means Protected Health Information that excludes certain direct identifiers of the Individual or of relatives, employers, or household members of the Individual, as further defined in 45 C.F.R. § 164.514(e).
- c. "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.
- d. "Protected Health Information" shall have the same meaning as the term "protected health information" in 45 C.F.R. § 160.103, limited to the information created or received by Business Associate from or on behalf of Covered Entity.
- e. "Required By Law" shall have the same meaning as the term "required by law" in 45 C.F.R. § 164.103.
- f. "Secretary" shall mean the Secretary of the Department of Health and Human Services or his designee.
- g. "Security Incident" means the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an information system.
- h. "Electronic Protected Health Information" means Protected Health Information which is transmitted by Electronic Media (as defined in the HIPAA Security and Privacy Rule) or maintained in Electronic Media.

2. Obligations and Activities of Business Associate

- a. Business Associate agrees to not use or disclose Protected Health Information other than as permitted or required by this Agreement or as Required By Law.
- b. Business Associate agrees to use appropriate safeguards to prevent use or disclosure of the Protected Health Information other than as provided for by this Agreement. Business Associate will implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of any Electronic Protected Health Information that it creates, receives, maintains, or transmits on behalf of Covered Entity as required by the HIPAA Security and Privacy Rule.

- c. Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of Protected Health Information by Business Associate in violation of the requirements of this Agreement.
- d. Business Associate agrees to report to Covered Entity any use or disclosure of the Protected Health Information not provided for by this Agreement of which it becomes aware.
- e. Business Associate agrees to ensure that any agent, including a subcontractor, to whom it provides Protected Health Information received from, or created or received by Business Associate on behalf of Covered Entity, agrees to the same restrictions and conditions that apply through this Agreement to Business Associate with respect to such information. Business Associate further agrees to ensure that any agent, including a subcontractor, to whom it provides such Electronic Protected Health Information agrees to implement reasonable and appropriate safeguards to protect it.
- f. Business Associate agrees to provide access to Protected Health Information in a Designated Record Set, if any, maintained by Business Associate, at the request of Covered Entity and in the time and manner agreed upon by the parties, to Covered Entity in order to meet the requirements under 45 C.F.R. § 164.524.
- g. Business Associate agrees to make any amendment(s) to Protected Health Information in a Designated Record Set, if any, maintained by Business Associate that the Covered Entity directs or agrees to pursuant to 45 C.F.R. § 164.526 at the request of Covered Entity, and in the time and manner agreed upon by the parties.
- h. Business Associate agrees to make internal practices, books, records, policies and procedures and Protected Health Information, relating to the use and disclosure of Protected Health Information received from, or created or received by Business Associate on behalf of, Covered Entity available to the Secretary, in a time and manner designated by the Secretary, for purposes of the Secretary determining Covered Entity's compliance with the HIPAA Security and Privacy Rule. The Secretary shall have the right to audit Business Associate's records and practices related to use and disclosure of Protected Health Information to ensure Covered Entity's compliance with the terms of the HIPAA Security and Privacy Rule.
- i. Business Associate agrees to document such disclosures of Protected Health Information and information related to such disclosures as would be required for Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 C.F.R. § 164.528.
- j. Business Associate agrees to provide to Covered Entity, in a time and manner agreed upon by the parties, information collected in accordance with Section 2(i) of this Agreement, to permit Covered Entity to respond to a request by an Individual for an

accounting of disclosures of Protected Health Information in accordance with 45 C.F.R. § 164.528.

- k. Business Associate shall report to Covered Entity any use or disclosure of Protected Health Information which is not in compliance with the terms of this Agreement of which it becomes aware.
- l. Business Associate shall report to Covered Entity any Security Incident of which it becomes aware.

3. Permitted Uses and Disclosures by Business Associate

- a. Except as otherwise limited in this Agreement, Business Associate may use or disclose Protected Health Information on behalf of, or to provide services to, Covered Entity for the following purposes, if such use or disclosure of Protected Health Information would not violate the Privacy Rule if done by Covered Entity: the creation of a Limited Data Set, as provided in the data use provisions set forth in Section 5 (Data Use) of this Agreement, which Limited Data Set will be used in connection with the CARES registry, a public health surveillance activity that is being conducted for public health, public research, and health care operations purposes.
- b. Except as otherwise limited in this Agreement, Business Associate may use Protected Health Information for the proper management and administration of the Business Associate or to carry out the legal responsibilities of the Business Associate.
- c. Except as otherwise limited in this Agreement, Business Associate may disclose Protected Health Information for the proper management and administration of the Business Associate, provided that disclosures are Required By Law, or Business Associate obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and used or further disclosed only as Required By Law or for the purpose for which it was disclosed to the person, and the person notifies the Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached.
- d. Except as otherwise limited in this Agreement, Business Associate may use Protected Health Information to provide Data Aggregation services to Covered Entity as permitted by 45 C.F.R. § 164.504(e)(2)(i)(B).

4. Obligations of Covered Entity

- a. Covered Entity shall notify Business Associate of any limitation(s) in its notice of privacy practices of Covered Entity in accordance with 45 C.F.R. § 164.520, to the extent that such limitation(s) may affect Business Associate's use or disclosure of Protected Health Information.

- b. Covered Entity shall notify Business Associate of any changes in, or revocation of, permission by Individual to use or disclose Protected Health Information, to the extent that such changes may affect Business Associate's use or disclosure of Protected Health Information.
- c. Covered Entity shall notify Business Associate of any restriction to the use or disclosure of Protected Health Information that Covered Entity has agreed to in accordance with 45 C.F.R. § 164.522, to the extent that such restriction may affect Business Associate's use or disclosure of Protected Health Information.

5. Data Use for a Limited Data Set

- a. Covered Entity agrees to participate in the CARES surveillance registry described in the cover letter attached to this Agreement, and as a participant, will provide certain PHI regarding OHCA patients to the Business Associate for the purposes described in this Section. The PHI to be provided by Covered Entity will include the following hospital outcome measures for patients who suffered an out-of-hospital cardiac arrest (“OHCA”) event:
 - (1) Emergency department outcome;
 - (2) Hospital outcome;
 - (3) Disposition from hospital;
 - (4) Hypothermia treatment if provided; and
 - (5) Neurological outcome at discharge from hospital.
- b. Business Associate will have the right to use and disclose PHI provided to it by the Covered Entity for research, public health or health care operations purposes, as provided in Section 3.a above. The Limited Data Set will be used in connection with the CARES surveillance registry, which is created for the health care operations and public health activity purposes further described in the attached cover letter to this Agreement. Without limiting the foregoing, the Limited Data Set will be available to and may be used by Business Associate, Covered Entity and other local emergency medical system administrators, medical directors, and 911 systems personnel, as well as epidemiologist and researchers studying OHCA events in an effort to better understand methods to improve survival from these events. The Limited Data Set also will be provided to the CDC staff in the Chronic Disease Branch on a regular basis.
- c. Business Associate will not use or further disclose the information contained in the Limited Data Set other than as permitted by this Agreement or as Required By Law.
- d. Business Associate will use appropriate safeguards to prevent the use or disclosure of the information contained in the Limited Data Set other than as permitted in this Agreement.
- e. Business Associate will not attempt to identify the Individuals to whom the information contained in the Limited Data Set pertains, or attempt to contact such Individuals.

- f. Business Associate will report to Covered Entity any use or disclosure of the information contained in the Limited Data Set not provided for in this Agreement of which Recipient becomes aware. Business Associate will take reasonable steps to limit any further such use or disclosure.
- g. Business Associate will ensure that any of its agents or subcontractors to whom it provides the Limited Data Set agrees in writing to the same restrictions and conditions that apply to Business Associate under this Agreement.

6. Term and Termination

- a. Unless otherwise terminated by applicable law or regulation, the Term of this Agreement shall be effective as of the above Effective Date, and will remain in effect until all of the Protected Health Information provided by Covered Entity to Business Associate, or created or received by Business Associate on behalf of Covered Entity (including information contained in Limited Data Sets), is destroyed or returned to Covered Entity, or, if it is not feasible to return or destroy such Protected Health Information or would be in violation of applicable law, protections are extended to such information, in accordance with the termination provisions in Section 6.c. of this Agreement.
- b. In the event of a material breach of this Agreement by Business Associate, Covered Entity shall either:
 - (1) Provide an opportunity for Business Associate to cure the breach or end the violation and terminate this Agreement if Business Associate does not cure the breach or end the violation within the time specified by Covered Entity;
 - (2) Immediately terminate this Agreement if Business Associate has breached a material term of this Agreement and cure is not possible; or
 - (3) If neither termination nor cure is feasible, Covered Entity shall report the violation to the Secretary.
- c. Effect of Termination
 - (1) Except as provided in paragraph (2) of this Section 6.c., upon termination of this Agreement, for any reason, Business Associate shall return or destroy all Protected Health Information received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity. This provision shall apply to Protected Health Information that is in the possession of subcontractors or agents of Business Associate. Business Associate shall retain no copies of the Protected Health Information.
 - (2) In the event that Business Associate determines that returning or destroying the Protected Health Information is not feasible or would be in violation of applicable law, Business Associate shall provide to Covered Entity notification of the conditions that make return or destruction infeasible. If the return or destruction of the Protected Health Information is not feasible, Business Associate shall extend the protections of this Agreement to such Protected Health Information and limit

further uses and disclosures of such Protected Health Information to those purposes that make the return or destruction not feasible, for so long as Business Associate maintains such Protected Health Information.

7. Miscellaneous

- a. A reference in this Agreement to a section in the HIPAA Security and Privacy Rule means the section as in effect or as amended.
- b. The parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for Covered Entity to comply with the requirements of the HIPAA Security and Privacy Rule and the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191.
- c. The respective rights and obligations of the parties under Section 6.c. of this Agreement shall survive the termination of this Agreement.
- d. Any ambiguity in this Agreement shall be resolved to permit Covered Entity to comply with the HIPPA Security and Privacy Rule.
- e. The Secretary of Health and Human Services shall have the right to audit Business Associate's records and practices related to use and disclosure of Protected Health Information to ensure Covered Entity's compliance with the terms of the HIPAA Security and Privacy Rule.
- f. In the event that any provision of this Agreement is held by a court of competent jurisdiction to be invalid or unenforceable, the remainder of the provisions of this Agreement will remain in full force and effect. In addition, in the event a party believes in good faith that any provision of this Agreement fails to comply with the then-current requirements of the HIPAA Security and Privacy Rule, such party shall notify the other party in writing. For a period of up to thirty days following such notice, the parties shall address in good faith such concern and amend the terms of this Agreement, if necessary, to bring it into compliance. If, after such thirty-day period, the Agreement fails to comply with the HIPAA Security and Privacy Rule, then either party has the right to terminate this Agreement upon written notice to the other party.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the day and year written above.

COVERED ENTITY:

BUSINESS ASSOCIATE:

Emory University, through its School of Medicine

By: _____

By: _____

Title: _____

Title: _____