

BUSINESS ASSOCIATE AGREEMENT

**Emory University,
By and through its School of Medicine**

and

This Business Associate Agreement (this "Agreement") effective as of _____ (the "Effective Date"), is entered into by and among Emory University, by and through its School of Medicine, on behalf of themselves and their respective components as defined below (collectively and individually referred to as "Emory" or "Business Associate"), and _____ ("Covered Entity").

WHEREAS, Sections 261 through 264 of the federal Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, as amended by the federal Health Information Technology for Economic and Clinical Health Act ("HITECH Act"), which imposes new and modified obligations on Covered Entity and Business Associate through the HIPAA Security and Privacy Rule, 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, 162, 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

WHEREAS, in consideration of the parties' continuing obligations under this Agreement, compliance with the HIPAA Security and Privacy Rule and the Administrative Simplification provisions, 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 and implement appropriate safeguards for the security of Electronic Protected Health Information under all of the Underlying Contracts.

NOW THEREFORE, in consideration of the promises and mutual covenants and agreements of the parties as set forth herein, the receipt and sufficiency of which are hereby acknowledged, the parties agree to amend and restate their previous agreement as follows:

1. **DEFINITIONS**. For purposes of this Agreement:

- 1.1 "Access" shall mean the ability or the means necessary to read, write, modify, or communicate data/information or otherwise use any system resource.
- 1.2 "Administrative Safeguards" shall mean administrative actions, and policies and procedures, to manage the selection, development, implementation, and maintenance of security measures to protect Electronic Protected Health Information and to manage the conduct of the Business Associate's workforce in relation to the protection of that information.
- 1.3 "Availability" shall mean the property that data or information is accessible and useable upon demand by an authorized person.
- 1.4 "Breach" will have the meaning given for such term in the Breach Notification Rules.
- 1.5 "Breach Notification Rules" will mean Section 13402 of HITECH and the regulations implementing such provisions, currently Subpart D of Title 45 of the Code of Federal Regulations, as such regulations may be in effect from time to time.
- 1.6 "Confidentiality" shall mean the property that data or information is not made available or disclosed to unauthorized persons or processes.
- 1.7 "Electronic Protected Health Information" or "ePHI" shall mean Protected Health Information that is transmitted by electronic media or maintained in electronic media.
- 1.8 "HIPAA" shall mean the Health Insurance Portability and Accountability Act of 1996.
- 1.9 "HIPAA Regulations" shall mean the Privacy Rule and the Security Rule at 45 C.F.R. parts 160, 162 and 164.
- 1.10 "HITECH" will mean the Health Information Technology for Economic and Clinical Health Act, found in Title XIII of the American Recovery and Reinvestment Act of 2009, Public Law 111-005.
- 1.11 "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).
- 1.12 "Information System" shall mean an interconnected set of information resources under the same direct management control that shares common functionality. A system normally includes hardware, software, information, data, applications, communication, and people.
- 1.13 "Integrity" shall mean the property that data or information have not been altered or destroyed in an unauthorized manner.
- 1.14 "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).
- 1.15 "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.
- 1.16 "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 created or received

by Business Associate from or on behalf of Covered Entity, and includes Electronic Protected Health Information.

- 1.17 "Physical Safeguards" shall mean physical measures, policies, and procedures to protect Business Associate's electronic Information Systems and related buildings and equipment, from natural and environmental hazards, and unauthorized intrusion.
- 1.18 "Required By Law" shall have the same meaning as the term "required by law" in 45, C.F.R. § 164.103.
- 1.19 "Secretary" shall mean the Secretary of the Department of Health and Human Services or his designee.
- 1.20 "Security Safeguards" shall mean all of the Administrative, Physical, and Technical Safeguards in an Information System.
- 1.21 "Security Incident" shall mean the attempted or successful unauthorized Access, use, disclosure, modification, or destruction of Electronic Health Information or interference with system operations in an Information System.
- 1.22 "Technical Safeguards" shall mean the technology and the policy and procedures for its use that protect Electronic Protected Health Information and control Access to it.
- 1.23 "Unsecured PHI" will have the same meaning given for such term in the Breach Notification Rules.

Terms used, but not otherwise defined, in this Agreement shall have the same meaning as those terms in the HIPAA Regulations or the Breach Notification Rules, as applicable, and shall be deemed by the parties to change as terms within the HIPAA security and Privacy Rule may change..

2. OBLIGATIONS AND ACTIVITIES OF BUSINESS ASSOCIATE

- 2.1 Business Associate agrees to use and/or disclose the PHI only as permitted or required by this Agreement or as required by law. In connection with this Agreement, Business Associate agrees to use and disclose Protected Health Information and Electronic Protected Health Information (a) solely for the purposes of the CARES program as referenced herein and (b) as necessary for the proper management and administration of Business Associate or to carry out its legal responsibilities as set forth herein.
- 2.2 Business Associate agrees to use appropriate safeguards to maintain the security of the PHI and to prevent use or disclosure of PHI other than as provided for by this Agreement, which will in no event be any less than the means which Business Associate uses to protect its own confidential information. Business Associate agrees to implement Security Safeguards that reasonably and appropriately protect the Confidentiality, Integrity, and Availability of the ePHI that Business Associate creates, receives, maintains, or transmits on behalf of Covered Entity.
- 2.3 Business Associate agrees to promptly report to Covered Entity any use or disclosure of PHI that is not permitted by this Agreement or of any Security Incident of which Business Associate becomes aware.
- 2.4 Business Associate agrees to ensure that any agent, including an authorized subcontractor, that receives, uses, or has access to PHI in the performance of the Underlying Contracts agrees, in writing, to the same restrictions and conditions on the use and/or disclosure of such PHI that apply to Business Associate through this Agreement.

- 2.5 Business Associate agrees to ensure that any agent, including an authorized subcontractor, to whom it provides ePHI agrees to implement reasonable and appropriate Security Safeguards to protect it.
- 2.6 Business Associate agrees to document any disclosures of PHI by Business Associate or its agents or authorized subcontractors, 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 PHI in accordance with 45 C.F.R. § 164.528.
- 2.7 Business Associate agrees to provide to Covered Entity information collected in accordance with Section 2.6 of this Agreement within fifteen (15) days of a request by Covered Entity, as necessary to permit 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.
- 2.8 Business Associate agrees to make available PHI in a designated record set, within fifteen (15) days of Covered Entity's request, to Covered Entity or, as directed by Covered Entity, to an individual in order to meet the requirements under 45 C.F.R. § 164.524, relating to an individual's right to inspect and obtain a copy of PHI relating to such individual.
- 2.9 Business Associate agrees to make any amendment(s) to Protected Health Information in a designated record set as Covered Entity directs or agrees to pursuant to 45 C.F.R. § 164.526 within thirty (30) days of Covered Entity's request.
- 2.10 Except for a disclosure permitted under Section 3.1.d of this Agreement, if Business Associate believes it has a legal obligation to disclose any PHI, it will notify Covered Entity as soon as reasonably practical after it learns of such obligation, and in any event at least five (5) business days prior to the proposed release, as to the legal requirement pursuant to which it believes the PHI must be released. If Covered Entity objects to the release of such PHI, Business Associate will allow Covered Entity to exercise any legal rights or remedies Business Associate might have to object to the release of the PHI, and Business Associate agrees to provide such assistance to Covered Entity, at Covered Entity's expense, as Covered Entity may reasonably request in connection therewith.
- 2.11 Business Associate agrees to make its internal practices, policies and procedures, books and records relating to the use and disclosure of PHI available to the Secretary for purposes of determining Covered Entity's compliance with the HIPAA Regulations.
- 2.12 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.
- 2.13 Business Associate agrees to promptly report to Covered Entity any use or disclosure of PHI not provided for by this Agreement of which it becomes aware.
- 2.14 Business Associate acknowledges that, effective February 17, 2010, Sections 164.308, 164.310, 164.312, and 164.316 of Title 45, Code of Federal Regulations, will apply to Business Associate in the same manner that such sections apply to covered entities and are incorporated into this Agreement by reference. The additional requirements of HITECH that relate to security and to privacy that apply to covered entities also will apply to Business Associate and are incorporated into this Agreement by reference. Business Associate agrees to implement the technical safeguards provided in guidance issued annually by the Secretary for carrying out the obligations under the Code of Federal Regulation sections cited above (in this Section 2.14) and the security standards in Subpart C of Part 164 of Title 45 of the Code of Federal Regulations.
- 2.15 Effective February 17, 2010, Business Associate may use and disclose Protected Health Information that Business Associate obtains or creates only if such use or disclosure, respectively, complies with each applicable requirement of Section 164.504(e) of Title 45, Code of Federal Regulations. The additional requirements of Subtitle D of HITECH that relate to

privacy and that apply to covered entities also will apply to Business Associate and are incorporated into this Agreement by reference.

- 2.16 Business Associate acknowledges that, effective February 17, 2010, Section 164.504(e)(1)(ii) of Title 45, Code of Federal Regulations, will apply to Business Associate in the same manner that such section applies to covered entities, with respect to compliance with the standards in Sections 164.502(e) and 164.504(e) of Title 45, except that in applying such Section 164.504(e)(1)(ii) each reference to the business associate, with respect to a contract, shall be treated as a reference to the covered entity involved in such contract.
- 2.17 Effective September 17, 2009, Business Associate will comply with Section 13402 of the HITECH Act and the regulations implementing such provisions, currently Subpart D of Title 45 of the Code of Federal Regulations, as such regulations may be in effect from time to time (collectively, the "Breach Notification Rules").
- a. Except as provided in 45 C.F.R. § 164.412, Business Associate will give Covered Entity notice of any Breach of Unsecured Protected Health Information without unreasonable delay, but in no case later than thirty (30) days after the first day on which the Breach is known, or by the exercise of reasonable diligence would have been known, to the Business Associate.
 - b. The notice required by Section 2.17.a. above will be written in plain language and will include, to the extent possible or available, the following:
 - i. The identification of the individual whose Unsecured Protected Health Information has been, or is reasonably believed by the Business Associate to have been, accessed, acquired or disclosed during the Breach;
 - ii. A brief description of what happened, including the date of the Breach and the date of the discovery of the Breach;
 - iii. A description of the types of Unsecured Protected Health Information that were involved in the Breach (such as whether the full name, social security number, date of birth, home address, account number, diagnosis, disability code, or other types of information were involved);
 - iv. Any steps individuals who were subjects of the Breach should take to protect themselves from potential harm that may result from the Breach;
 - v. A brief description of what the Business Associate is doing to investigate the Breach, to mitigate the harm to individuals, and to protect against further Breaches; and
 - vi. Contact procedures for individuals to ask questions or learn additional information, including a toll free telephone number, an email address, Web site, or postal address.
- 2.18 Business Associate shall secure all Protected Health Information by a technology standard that renders Protected Health Information unusable, unreadable, or indecipherable to unauthorized individuals and is developed or endorsed by a standards developing organization that is accredited by the American National Standards Institute and is consistent with guidance issued by the Secretary specifying the technologies and methodologies that render Protected Health Information unusable, unreadable, or indecipherable to unauthorized individuals, including the use of standards developed under Section 3002(b)(2)(B)(vi) of the Public Health Service Act, as added by Section 13101 of HITECH. This Section 2.19 will become effective on the earlier of: (i) thirty (30) days after publication of interim final regulations by the Secretary of the United States Department of Health and Human Services to carry out Section 13402 of the HITECH Act or (ii) September 17, 2009.

3. PERMITTED USES AND DISCLOSURES BY BUSINESS ASSOCIATE

- 3.1 Business Associate may use and disclose PHI only as follows:

- a. Except as otherwise limited in this Agreement, Business Associate may use or disclose PHI as necessary to perform functions, activities, or services for Covered Entity as specified in the Underlying Contracts, provided that such use or disclosure 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. With respect to permitted disclosures under subsection 3.1.a above, unless otherwise specifically agreed to by the parties as set forth herein, Business Associate will not permit the disclosure of PHI to any person or entity other than such of its employees, agents or subcontractors who must have access to the PHI in order for Business Associate to perform its obligations under an Underlying Contract and who agree to keep such PHI confidential as required by this Agreement.
 - c. Except as otherwise limited in this Agreement, Business Associate may use PHI for the proper management and administration of the Business Associate or to carry out the legal responsibilities of the Business Associate.
 - d. Except as otherwise limited in this Agreement, Business Associate may disclose PHI in its possession to a third party for the purpose of its proper management and administration or to fulfill any legal responsibilities of Business Associate, provided that (1) the disclosure is required by law or (2) Business Associate has obtained reasonable written assurances from the third party to whom the information is disclosed that it will remain confidential and be used or further disclosed only as required by law or for the purpose for which it was disclosed to the third party (i.e., for the proper management and administration of Business Associate or to carry out the legal responsibilities of Business Associate) and the third party agrees to notify Business Associate of any instances of which it is aware in which the confidentiality of the PHI has been breached. Business Associate will notify Emory's Privacy Officer of any disclosure required by law at 1599 Clifton Rd., 4th Floor, Atlanta, GA 30322, of such disclosure within fifteen (15) days of the disclosure.
 - e. If the Business Associate provides data aggregation services for Covered Entity under the Underlying Contract, Business Associate may use and aggregate the PHI for purposes of providing the data aggregation services to Covered Entity. Use of PHI for any other data aggregation is not permitted.
 - f. Effective February 17, 2010, Business Associate may use and disclose PHI that Business Associate obtains or creates only if such use or disclosure, respectively, complies with each applicable requirement of Section 164.504(e) of Title 45, Code of Federal Regulations.
- 3.2 All other uses or disclosures of PHI not authorized by this Agreement are prohibited.
- 3.3 As between Covered Entity and Business Associate, Covered Entity holds all right, title and interest in and to the PHI, and Business Associate does not hold, and will not acquire by virtue of this Agreement or by virtue of providing any services or goods to Covered Entity, any right, title or interest in or to the PHI or any portion thereof. Except as otherwise specified in this Agreement or agreed to in writing by the parties, Business Associate will have no right to de-identify PHI for its own use or compile and/or distribute statistical analyses and reports utilizing aggregated data derived from the PHI or any other health and medical data obtained from Covered Entity.

4. OBLIGATIONS OF COVERED ENTITY

- 4.1 Covered Entity agrees to timely notify Business Associate of any changes or limitations to Covered Entity's privacy practices and any individual restrictions on the use or disclosure of PHI

applicable to or accepted by Covered Entity to the extent that such changes or restrictions may impact Business Associate's use and/or disclosure of any PHI.

5. **TERM AND TERMINATION**

- 5.1 **Term.** This Agreement shall be effective as of the Effective Date and shall continue in effect until terminated as provided in Section 5.2 or until all of the PHI 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 5.3 of this Agreement.
- 5.2 **Termination For Cause.** In the event Covered Entity determines that Business Associate has committed a material breach of this Agreement, Covered Entity may either: (i) provide an opportunity for Business Associate to cure the breach or end the violation, provided that Covered Entity may immediately terminate any Underlying Contracts that require the use of PHI or ePHI if Business Associate does not cure the breach or end the violation within the time frame specified by Covered Entity; (ii) immediately terminate any Underlying Contracts that require the use of PHI if Business Associate has breached a material term of this Agreement and Covered Entity determines in its sole discretion that a cure is not possible; or (iii) if neither termination nor cure is feasible, Covered Entity shall report the violation to the Secretary.
- 5.3. **Effect of Termination.** Upon the termination, for any reason, of this Agreement or an Underlying Contract that requires the use of PHI by Business Associate, Business Associate will promptly return to Covered Entity or, at Covered Entity's sole option, destroy any PHI in its possession or control, or in the possession or control of its agents or subcontractors, and will retain no copies of such PHI. If Business Associate and Covered Entity agree that the destruction or return of the PHI is not reasonably feasible, Business Associate will extend the protections contained in this Agreement to such PHI and limit any further uses and/or disclosures of such PHI to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such PHI. Except in the case of non-feasibility or as otherwise agreed to in writing, any right or license that Business Associate has to use the PHI will terminate immediately upon the termination of this Agreement or the Underlying Contract allowing its use.

6. **DATA USE FOR A LIMITED DATA SET**

6.1 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:

a) *Essential Elements*

- (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) *Supplemental Elements*

- (6) Was the final diagnosis acute myocardial infarction;
- (7)Coronary Angiography performed;
- (8)Was a cardiac stent placed;
- (9)CABG performed;
- (10)Was an ICD placed and/or scheduled.

6.2 Business Associate will have the right to use and disclose anonymized PHI provided to it by the Covered Entity for research, public health or health care operations purposes, as provided herein. The Limited Data Set will be used solely 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 Centers for Disease Control staff in the Chronic Disease Branch on a regular basis.

6.3 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.

7. INDEMNIFICATION.

Each party agrees to indemnify, defend and hold harmless each other party, and each other party's respective employees and agents, against any loss, claim, damage or liability ("Claim") if and to the extent proximately caused by a material breach of this Agreement by the other party. The party seeking indemnification shall furnish to the other prompt written notice of any such Claim of which the party seeking indemnification has actual knowledge, provided, however, that the failure to deliver such prompt notice shall not release the indemnifying party from any of its indemnity obligations hereunder except to the extent such obligations have increased as a result of such failure, and then only to the extent of such increase. The party seeking indemnification shall use good faith efforts to furnish the indemnifying party with reasonable and sufficient authority, information and assistance necessary to defend the Claim.

8. **RIGHT TO INJUNCTIVE RELIEF.** Business Associate expressly acknowledges and agrees that the breach, or threatened breach, by it of any provision of this Agreement may cause Covered Entity to be irreparably harmed and that Covered Entity may not have an adequate remedy at law. Therefore, Business Associate agrees that upon such breach, or threatened breach, Covered Entity will be entitled to seek injunctive relief to prevent Business Associate from commencing or continuing any action constituting such breach without having to post a bond or other security and without having to prove the inadequacy of any other available remedies. Nothing in this paragraph will be deemed to limit or abridge any other remedy available to Covered Entity at law or in equity.

9. MISCELLANEOUS

- 9.1 **Regulatory References.** A reference in this Agreement to a section in the HIPAA Regulations, HITECH, or the Breach Notification Rules means the section as in effect or as amended.
- 9.2 **Survival.** The respective rights and obligations of Business Associate under Section 5.3 of this Agreement will survive the termination of this Agreement.
- 9.3 **Other Confidentiality Obligations.** The parties acknowledge that this Agreement is intended to supplement any and all other confidentiality obligations that either party may have under this or any other agreement or applicable law.
- 9.4 **Underlying Contracts.** The terms of this Agreement will govern the use of PHI under any Underlying Contract. Except as specified herein, all other terms of an Underlying Contract will continue in full force and effect. In the event of any conflict among the provisions of this Agreement and the Underlying Contract, the provisions of this Agreement will control.
- 9.5 **Amendment.** This Agreement may only be modified, or any rights under it waived, by a written agreement executed by both parties. The parties agree to amend this Agreement from time to time as is necessary for Covered Entity to comply with the requirements of the HIPAA

IN WITNESS WHEREOF, each of the undersigned has caused this Agreement to be duly executed in its name and on its behalf.

EMORY UNIVERSITY

By: _____

By: _____

Print Name: _____

Print Name: _____

Print Title: _____

Print Title: _____

Date: _____

Date: _____