

AGREEMENT FOR C.A.R.E.S. PARTICIPATION  
BETWEEN  
EMORY UNIVERSITY, THROUGH ITS WOODRUFF HEALTH SCIENCES CENTER  
AND

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This Agreement for C.A.R.E.S. Participation (“Agreement”) is made and entered into this \_\_\_\_day of \_\_\_\_\_, 2014 (“Effective Date”), between Emory University, through its Woodruff Health Sciences Center (“Emory”) and \_\_\_\_\_ (hereafter “Data Contributor”).

WITNESSETH

WHEREAS, Emory has been authorized by the Centers for Disease Control and Prevention (“CDC”) to conduct certain public health activities by acting as a Public Health Authority, as defined in 45 CFR 164.501, pursuant to the Standards for Privacy of Individually Identifiable Health Information promulgated under the Health Insurance Portability and Accountability Act (HIPAA) [45 CFR Parts 160 and 164];

WHEREAS, under the HIPAA Standards, Covered Entities, such as hospitals and emergency medical services provider may disclose, without individual authorization, Protected Health Information to Public Health Authorities, “authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations and public health interventions...” [45 CFR 164,512(b)(i)];

WHEREAS, Emory has entered into a Memorandum of Understanding with the CDC to conduct the Cardiac Arrest Registry to Enhance Survival (CARES) Program (“Program”), which is authorized by sections 301(a) and 317(k)(2) of the Public Health Service Act;

WHEREAS, the purpose of CARES is to help local communities identify and track cases of cardiac arrest and identify opportunities for improvement in the treatment of out-of-hospital cardiac arrest (“OHCA”);

WHEREAS, Data Contributor wishes to enter into an arrangement with Emory to assist Data Contributor with its quality assessment and improvement activities relating to OHCA events, and as part of the arrangement, will provide certain data regarding OHCA patients treated by Data Contributor;

NOW THEREFORE, in consideration of the mutual covenants and premises herein contained, the parties agree as follows.

**Article 1. Incorporation of Recitals**

The above recital paragraphs are material to and incorporated into this Agreement as if fully restated in this paragraph.

**Article 2. Definitions**

2.1. Aggregated Registry Data

Aggregated Registry Data shall mean De-Identified Contributed Data when combined with De-Identified Contributed Data from other data contributors as set forth in Section 3.4.

2.2. Contributed Data

Contributed Data shall mean the data provided by Data Contributor to Emory pursuant to Sections 3.1 or 3.1.1. Contributed Data may include PHI.

2.3. Covered Entity

Covered Entity shall have the same meaning as found at 45 CFR 160.103.

- 2.4. De-Identified Contributed Data  
De-Identified Contributed Data shall mean Contributed Data which has been de-identified in accordance with the requirements of 45 CFR 164.514(b) as required by Section 3.4
- 2.5. Program  
Program shall mean the Cardiac Arrest Registry to Enhance Survival (CARES) Program which is the subject of that certain Memorandum of Understanding between Emory and the Centers For Disease Control dated the 5<sup>th</sup> day of August, 2014.
- 2.6. Protected Health Information / PHI  
Protected Health Information or PHI shall have the same meaning as found at 45 CFR 160.103.

**Article 3. Contributed Data**

Data Contributor agrees to participate in the Program and, as a participant, will provide certain data regarding OHCA patients to Emory for the purposes described in this Section (“Contributed Data”).

3.1. Hospitals

If Data Contributor is a hospital, the Contributed Data to be provided by Data Contributor will include the following essential data elements and may include the following supplemental elements for patients who suffered an OHCA event:

3.1.1. *Essential Data Elements*

- (1) Emergency department outcome;
- (2) Hospital outcome;
- (3) Disposition from hospital;
- (4) Hypothermia treatment if provided;
- (5) Neurological outcome at discharge from hospital;

3.1.2. *Supplemental Data Elements*

- (1) Was the final diagnosis acute myocardial infarction;
- (2) Was a coronary angiography performed;
- (3) Date and time of coronary angiography performed;
- (4) Was a cardiac stent placed;
- (5) Was a CABG performed;
- (6) Was an ICD placed and/or scheduled;
- (7) Additional Hypothermia module treatment fields;

3.2. Emergency Medical Services Agency

If Data Contributor is a provider of emergency medical services, the Contributed Data to be provided by Data Contributor will include the following essential data elements and may include the following supplemental elements for patients who suffered an OHCA event:

3.2.1. *Essential Data Elements:*

- (1) Address of Cardiac Arrest (town/city, State and zip code only);
- (2) Name, Age, Date of Birth, Gender, Race/Ethnicity of patient;
- (3) EMS Agency ID;
- (4) Date of Cardiac Arrest;
- (5) Call Number (and Booklet Number, where applicable);
- (6) ID of First Responder(s) Involved in Incident;
- (7) ID of Destination Hospital;
- (8) Witnessed Status of Arrest & Whether Arrest was Witnessed Prior to or After the Arrival of EMS;
- (9) Presumed Etiology of Arrest;
- (10) Indication of whether Resuscitation of Arrest was Initiated;

- (11) Generalized Identity of Who Initiated CPR (no names);
- (12) Type of Bystander CPR provided;
- (13) Whether Dispatcher CPR instructions were provided;
- (14) If an AED was Applied prior to EMS Arrival and Who First Applied the AED (no names, generalized ID);
- (15) Who First Defibrillated the Patient (no names, generalized ID);
- (16) First Arrest Rhythm of the Patient;
- (17) Whether ROSC was Sustained in the Pre-hospital setting;
- (18) Was Hypothermia care provided in the field; and
- (19) Knowledge of the End of the Event, if known.

3.2.2. *Supplemental Data Elements:*

- (1) Medical History;
- (2) Whether a 911 responder performed CPR;
- (3) Whether Return of Spontaneous Circulation (ROSC) Occurred in the Pre-hospital Setting;
- (4) EMS Interventions Including: Mechanical CPR device, Automated CPR feedback device and/or ITD used, Vascular Access, Drugs Administered, 12 Lead, and STEMI; and
- (5) Time Response Intervals.

3.3. Computer Aided Dispatch

If Data Contributor is a provider of Computer Aided Dispatch services, the Contributed Data to be provided by Data Contributor will include the following emergency medical services measures for patients who suffered an OHCA event:

Response Times

- (1) Time call received at dispatch center
- (2) Time First Responder dispatched
- (3) Time of First Responder en route
- (4) Time Ambulance dispatched
- (5) Time for Ambulance en route
- (6) Time First Responder arrived at scene
- (7) Time Ambulance arrived at scene
- (8) Time EMS arrived at patient side
- (9) Time Ambulance left scene
- (10) Time Ambulance arrived at ED
- (11) Whether No First Responder dispatched

3.4. De-Identification

Emory shall de-identify the Contributed Data provided by Data Contributor in accordance with the requirements of 45 CFR 164.514(b) (“De-Identified Contributed Data”) and shall aggregate such de-identified data with the data contributed by the other data contributors in the Program (“Aggregated Registry Data”). Emory shall take reasonable steps to insure that the Contributed Data provided by Data Contributor is no longer recoverable in an identifiable format after de-identification.

3.5. Use of Contributed Data and De-Identified Contributed Data

Contributed Data may be used solely for the purposes of creating the De-Identified Contributed Data as provided in Section 3.4.

3.6. Use of De-Identified Contributed Data and Aggregated Registry Data

Emory may use or disclose De-Identified Contributed Data and the Aggregated Registry Data as follows:

*3.6.1. The Program*

Emory will have the right to use and disclose the Aggregated Registry Data for public health activities and purposes in connection with the Program, including benchmarking and quality improvement activities of the Program. Emory shall share the Aggregated Registry Data in a way that will not separately identify Data Contributor or its Contributed Data.

*3.6.2. Data Contributor*

Emory shall provide Data Contributor with access to the Program software in order to generate benchmarking reports based on its Contributed Data. If Data Contributor is a hospital, Data Contributor shall also have access to Emergency Medical Services Agency data related only to OHCA patients transported to Data Contributor, and/or Aggregated Registry Data.

*3.6.3. Other Participants*

Emory will have the right to use and disclose the Aggregated Registry Data for public health activities and purposes of Data Contributor and other data contributors participating in the Program. Emory shall share the Aggregated Registry Data in a way that will not separately identify Data Contributor or its Contributed Data.

*3.6.4. Use for Research Purposes*

The parties agree that Emory may, from time to time, allow researchers unaffiliated with Emory ("Researchers") to apply to use, for research purposes, the Aggregated Registry Data. Any such release of Aggregated Registry Data to Researchers shall be subject to prior review and approval by the CARES Data Sharing Committee. Any research reports or publications shall not separately identify Data Contributor or its Contributed Data.

*3.6.5. With Approval*

Except as otherwise stated in this Agreement, Emory may only disclose the De-Identified Contributed Data to individuals or entities selected by Data Contributor with Data Contributor's prior written authorization.

**3.7. Protection of Contributed Data**

*3.7.1. Safeguards*

Emory agrees to use appropriate administrative, physical, and technical safeguards to protect the confidentiality, integrity, and availability of any Contributed Data in accordance with 45 CFR Sections 164.308 (Administrative Safeguards), 164.310 (Physical Safeguards), 164.312 (Technical Safeguards) and 164.316 (Policies And Procedures And Documentation Requirements).

*3.7.2. Mitigation*

Emory, at its sole expense, agrees to mitigate, to the extent practicable, any harmful effect that is known to Emory of a use or disclosure of PHI by Emory in violation of the requirements of this Agreement.

**Article 4. Term And Termination**

**4.1. Term**

The time of performance of this Agreement shall be for a one (1) year period, commencing upon the date of the last signing party, unless sooner terminated or extended as provided. The Agreement will be automatically renewed for additional one (1) year periods, unless terminated in accordance with this Section.

**4.2. Termination Without Cause**

Emory and Data Contributor each will have the right to terminate this Agreement without cause for any reason at any time upon providing no less than thirty (30) days' advance written notice to

the non-terminating Party. Termination will be effective upon the date stated in the notice of termination.

4.3. Termination for Breach

Either party shall have the right to terminate this Agreement upon breach by the other party of any material term of this Agreement, provided the breach continues for fifteen (15) days after receipt by the breaching party of written notice of such breach from the non-breaching party and the non-breaching party has not given written authorization for a longer time to cure such breach.

4.4. Effect of Termination

Emory shall retain the right to maintain all De-Identified Contributed Data and its incorporation into Aggregated Registry Data contributed prior to the date of termination and make such uses and disclosures of the Aggregated Registry Data (including the De-Identified Contributed Data of Data Contributed as incorporated therein) for those permitted purposes under this Agreement. To the extent that Emory maintains any Contributed Data from Data Contributor, the terms and provisions of this Agreement that protect Contributed Data shall survive termination of this Agreement and may only be used or disclosed for those permitted purposes under this Agreement.

**Article 5. Miscellaneous**

5.1. Notices

All notices or other writings required under this Agreement shall be considered as having been provided when sent by U.S. mail, first class, postage-prepaid or by certified mail, to the Parties at the following addresses:

**Emory:**

CARES Program  
Emory University  
Woodruff Health Sciences Center  
Mailstop 1599/001/1BQ  
1599 Clifton Road NE  
Atlanta, Georgia 30322  
Attention: Bryan McNally, MD, MPH

**Data Contributor:**

If either Party seeks to change where notices shall be sent, the Party desiring this change must provide the other Party with seven (7) days advance written notice of such change.

5.2. Independent Contractor Status

The Parties' relationship will be that of an independent contractor and nothing in this Agreement shall be construed to create a partnership, joint venture, or employer-employee relationship. Neither Party is an agent of the other Party and is not authorized to make any representation, contract or commitment on behalf of the other Party.

5.3. Third Party Beneficiaries

The Parties agree that they have not entered into this Agreement for the benefit of any third person(s) or entity, and it is their express intention that the Agreement is intended to be for their respective benefit only and not for the benefit of others who might otherwise be deemed to constitute third party beneficiaries hereof.

5.4. Publication

Data Contributor agrees that Emory may use Data Contributor's name along with a list of other Program participants on Emory's website and other materials listing Program participants. Any other press release, advertising, or other promotional written or oral statements to the public in connection with or alluding to the Program or the relationship between the parties created by this Agreement that has or contains any reference to Data Contributor, or the name of any

member of Data Contributor's staff, is prohibited without Data Contributor's prior written approval.

5.5. Indemnification

Each party agrees to indemnify, defend and hold harmless the other party, and the other party's Respective officers, employees and agents, against any loss, claim, damage or liability (including attorney's fees) ("Claim") arising out of the performance of this Agreement but only in proportion to and to the extent that such Claim is caused by or the result of the negligent or intentional acts or omissions of the indemnifying party, its officers, employees or agents.

5.6. Severability

The invalidity or unenforceability of any term or provision hereof shall not affect the validity or enforceability of any other term or provision hereof. No failure to exercise any right or demand performance of any obligation under the Agreement shall be deemed a waiver of such right or obligation.

5.7. Assignment

This Agreement shall be binding upon and inure to the benefit of each of the parties hereto and their successors and permitted assigns, provided, however, this Agreement may not be assigned by either party without the prior written approval of the other party.

5.8. Amendment

Any amendment to this Agreement must be in writing and signed by each party.

5.9. Waiver

No provision of this Agreement may be waived except by an agreement in writing signed by the parties. A waiver of any item or provision shall not be construed as a waiver of any other term or provision.

5.10. Counterparts

This Agreement may be executed in any number of counterparts with the same effect as if all of the parties had signed the same document. Such executions may be transmitted to the parties electronically or by facsimile and such electronic or facsimile execution and transmission shall have the full force and effect of an original signature. All fully executed counterparts, whether original executions, or electronic or facsimile executions, or a combination thereof, shall be construed together and shall constitute one and the same Agreement.

5.11. Authority

The undersigned hereby represent and acknowledge that they have read the foregoing Agreement, that they know its contents, and that they are executing this Agreement as a free and voluntary act and on behalf of the named parties. The undersigned further represent that they are duly authorized to execute this document on behalf of the named parties.

**IN WITNESS WHEREOF**, the Parties have executed this Agreement effective as of that Commencement Date first above written.

Emory University, Through Its  
Woodruff Health Sciences Center

Data Contributor

By: \_\_\_\_\_

By: \_\_\_\_\_

Name: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_