

August 30, 2019

TO: Mayor Jerry L. Demings -AND-Board of County Commissioners

- THRU: Yolanda G. Martinez, EdPhD., PhD., Director
- FROM: Christian C. Zuver, M.D., Medical Director EMS Office of the Medical Director Contact: (407) 836-7611
- SUBJECT: Agreement for Cardiac Arrest Registry to Enhance Survival (CARES) Program between Orange County, Florida and Emory University Consent Agenda – September 10, 2019

Each year, approximately 350,000 persons in the United States experience an out-ofhospital cardiac arrest (OHCA) or sudden death; approximately 90% of persons who experience an OHCA die. Despite decades of research, median reported rates of survival to hospital discharge are poor (10.4%) and have remained virtually unchanged for the past 30 years. Without a uniform and reliable method of data collection, communities cannot measure the effectiveness of their response systems, nor can they assess the impact of interventions designed to improve OHCA survival.

The Cardiac Arrest Registry to Enhance Survival (C.A.R.E.S) is an international cardiac arrest registry developed by the Centers for Disease Control and Prevention (CDC) and Emory University. The overall goals are to save more lives from OHCA and provide a HIPAA compliant process for assessing patient outcomes in OHCA.

The EMS Office of the Medical Director requests approval and execution of the agreement between the Emory University and Orange County for participation in C.A.R.E.S. The agreement will allow Orange County to participate in this international cardiac arrest registry for the purpose of identifying and tracking cases of cardiac arrest and identifying opportunities for improvement in the treatment of OHCA.

- ACTION REQUESTED: Approval and execution of Agreement for C.A.R.E.S. Participation between Emory University, through its Woodruff Health Sciences Center and Orange County, Florida and authorization for the Mayor or designee to sign future amendments to this Agreement. The agreement period is one year, commencing upon the date of the last signing party. The Agreement will be automatically renewed for additional one-year periods. There is no cost to the County. (EMS Office of the Medical Director)
- C: Danny Banks, Deputy County Administrator Sawsan Mohiuddin, Assistant County Attorney

BCC Mtg. Date: September 10, 2019

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

This Agreement for C.A.R.E.S. Participation ("Agreement") is made and entered into this day of <u>July 31st</u>, **2019** ("Effective Date"), between Emory University, through its Woodruff Health Sciences Center ("Emory") and Orange County, Florida, a charter county and political subdivision of the State of Florida(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. Preliminary Matters

1.1. 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. <u>Contributed Data</u>

Contributed Data shall mean the data provided by Data Contributor to Emory pursuant to Sections 3.1, 3.1.1 or 3.3. 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. <u>De-Identified Contributed Data</u>

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^{th} 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;

Page 2 of 13

(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. <u>Emergency Medical Services Agency</u>

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.

Page 3 of 13

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:

- (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. <u>Use of Contributed Data and De -Identified Contributed Data</u> 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 Page 4 of 13 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. Data Contributor will also have access to data supplied by other data contributors but only for OHCA patients which they have in common, 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. Uses and Disclosures of Contributed Data

Page 5 of 13

Emory will not, and shall ensure that its directors, officers, employees, and agents do not, use or further disclose Contributed Data received from Data Contributor other than as permitted or required by this Agreement or as may otherwise be required by law applicable to Emory.

3.7.2. Required Safeguards To Protect Contributed Data

Emory agrees to use appropriate administrative, physical, and technical safeguards to protect the confidentiality, integrity, and availability of any electronic 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).

3.7.3. 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 Contributed Data by Emory in violation of the requirements of this Agreement.

3.7.4. Ownership of Contributed Data

Under no circumstances shall Emory be deemed in any respect to be the owner of any Contributed Data used or disclosed by or to Emory pursuant to the terms of this Agreement. Emory acknowledges that all rights, title, and interest in and to any Contributed Data furnished to Emory rests solely and exclusively with the Data Contributor.

3.7.5. Reporting of Improper Use and Disclosures of Contributed Data

Emory will report to Data Contributor, as soon as reasonably practical, any use or disclosure of Contributed Data not provided for by this Agreement of which Emory becomes aware.

3.7.6. Reporting of Breaches of Unsecured Contributed Data

Emory shall report to Data Contributor, as soon as reasonably practical, a breach of Unsecured Contributed Data, of which it reasonably becomes aware. For purposes of this Section Unsecured Contributed Data shall mean Contributed Data that has not been rendered unusable, unreadable, or indecipherable to unauthorized individuals and is consistent with guidance issued by the Secretary of Health and Human Services, as modified from time to time, 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, in accordance with Section 13402(b) of HITECH.

3.7.7. Agreements with Third Parties

Emory will ensure that any agent or subcontractor to whom Emory provides Contributed Data created by, received from, maintained for or transmitted to Emory on behalf of Data Contributor agrees to the same restrictions, terms, conditions, and requirements that apply to Emory with respect to such information, including without limitation compliance with Sections (b) and (c) hereof.

3.7.8. Creation of Contractual Liability

While the parties have contractually adopted portions of HIPAA for purposes of defining privacy and security obligations of Emory under this Agreement, the parties specifically disclaim an intent or agreement to become subject to regulatory oversight and liability as applicable to Covered Entities and Business Associates under HIPAA or to define Contributed Data in any manner that would make it Protected Health Information under HIPAA.

3.7.9. Auditing Standards

Emory represents and warrants that the data center wherein the Contributed Data is received and housed has undergone, and will yearly undergo during the term of this Agreement, an (i) SSAE-16 Type 2 audit demonstrating the accuracy of the controls and the implementation and effectiveness of the controls over the preceding twelve months; and (ii) a SOC2 Type 2 audit demonstrating the effectiveness of the security, availability, processing integrity, confidentiality and privacy controls of the data center.

Article 4. Fees

NOTE: This section ONLY applies in the following circumstances:

- 1. Data Contributor is an Emergency Medical Services Agency AND
- 2. There is no State Coordinator in the State in which Data Contributor operates.

In order to determine whether a State Coordinator exists in your state, please consult:

http://mycares.net/

If Data Contributor desires to act as the State Coordinator, please contact:

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

4.1. Data Contributor Fees

If Data Contributor is an Emergency Medical Services Agency and there is no State Coordinator in the state in which Data Contributor provides emergency medical services, then and in that event Data Contributor shall pay to Emory an annual Data Contributor Fee based on the following:

Population Coverage Annual Fee	
< 300.000	\$1.000.00
300.001 - 750.000	\$2.500.00
750.001 +	\$5,000.00

4.2. Loss of State Coordinator

Should any entity that is acting as a State Coordinator terminate their status as a State Coordinator and not be replaced during the calendar year, then and in that event Data Contributor shall owe the Data Contributor Fee for the following calendar year.

4.3. <u>Change in Data Contributor Fees</u>

Changes in the amount or frequency of the Data Contributor Fee will not be made more often than yearly and will become effective following at least sixty (60) days prior notice to Data Contributor. Any such changes shall not exceed the greater of three percent (3%) or the increase of the Consumer Price Index – All Urban Consumers (CPI-U).

4.4. Payment

Data Contributor shall receive an invoice for the Data Contributor Fee, which generally shall be due and owing during the month of January. Each Participant shall pay all Data Contributor Fees within thirty (30) days following the documented date of e-mailing of invoice by Emory or their designee sent to the State Coordinator's e-mail address as provided to Emory by State Coordinator.

4.5. Late Charges

Data Contributor Fees not paid to Emory within fifteen (15) days following

notice of late payment are subject to a late charge of five percent (5%) of the amount owed and interest thereafter at the rate of one and one-half percent $(1\frac{1}{2}\%)$ per month on the outstanding balance, or the highest amount permitted by law, whichever is lower.

4.6. <u>Suspension of Service</u>

Failure to pay Data Contributor Fees within thirty (30) days following the written notice under Section 4.5 may result in suspension or termination of the State Coordinator's access to the Aggregate Registry Data.

4.7. <u>Taxes</u>

All Data Contributor Fees shall be exclusive of federal, state, municipal, or other government excise, sales, use, occupational, or similar taxes existing as of the date of this Agreement or enacted in the future. A Data Contributor shall pay any tax that Emory may be required to collect or pay, now or at any time in the future, and that are imposed upon the delivery of the services under this Agreement.

Article 5. Term And Termination

5.1. <u>Term</u>

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.

5.2. <u>Termination Without Cause</u>

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.

5.3. <u>Termination for Breach</u>

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.

5.4. 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. Upon termination of this Agreement, Emory shall promptly return or destroy, except to the extent infeasible, all Contributed Data to Data Contributor. To the extent determined that the return or destruction is infeasible and 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 Emory shall limit further uses and disclosures of such Contributed Data to only those purposes that make return or destruction of Contributed Data infeasible..

Article 6. Miscellaneous

6.1. Intentionally left blank

6.2. <u>Notices</u>

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:

Remainder of Page Intentionally Left Blank

Emory: CARES Program Emory University Woodruff Health Sciences Center Mailstop 1599/001/1BQ 1599 Clifton Road NE Atlanta, Georgia 30322 Attn: Allison Crouch, MBA, MPH Data Contributor: Orange County Board of County Commissioners Attn: Medical Director Orange County EMS System 2002-A East Michigan Street Orlando, Florids 32806 With copy to: County Administrator P.O. Box 1393 Orlando, Florida 32802

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.

6.3. 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.

6.4. 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.

6.5. <u>Publication</u>

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.

6.6. <u>Indemnification</u>

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 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 or the failure of the indemnifying party or its officers, employees or agents to comply with this Agreement or applicable laws, rules and regulations.

6.7. <u>Severability</u>

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.

6.8. <u>Assignment</u>

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.

6.9. <u>Amendment</u>

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

6.10. <u>Waiver</u>

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.

6.11. 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.

6.12. <u>Authority</u>

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

By: Bryan McNally, MD, MPH

Name: Bryan McNally, MD, MPH

Title: Executive Director CARES

Date: July 31st, 2019



Data Contributor ORANGE COUNTY, FLORIDA

By: Board of County Commissioners WWW. Brick By:

Jerry L. Demings Orange County Mayor

Date: 10 540 19

ATTEST: Phil Diamond, CPA, County Comptroller, as Clerk of the Board of County Commissioners

By:

Deputy Clerk

Katie Smith

Printed Name

s:\smohiuddin\agreements\cares site agreement.docx

Page 13 of 13