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| **Proposal for a Scientific Manuscript using the**  **American Heart Association Quality Improvement Programs Registry** | | |
| **Date:** | | **Lead Author:** |
| **Lead Author Contact Information:** | | |
| **Co-Author Name(s):** | | |
| **Project Liason/Committee Approval:** | | |
| **Target:**   * **Scientific Conference:** * **Manuscript (Target Journal)**: | | |
| * **Database: please mark one.** | * AFib * CAD * Heart Failure * Resuscitation (adult, pediatric, neonatal) * Stroke | |
| **Working Title:** | | |
| **Goals/Objectives/ Research Question:** | | |

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| --- |
| **Hypothesis/Rationale:** |
| **Study Population (*specify admission diagnosis of interest, including inclusion and exclusion criteria*):** |
| Variables Utilized for Project: |
| **Primary Outcome/Endpoint:** |
| **Secondary Outcomes/ Endpoints:** |
| **Brief Description of Proposed Analyses:** |
| **Sample Tables (*please provide examples of the tables as you plan to present them in the space below)*:** |
| **Key References:** |
| **Lead Author Demographic Information:**  *This information is requested for internal purposes only, and will be kept in strict confidence. Your response is voluntary and bears no impact on the terms and conditions of the Agreement.* |
| **Gender:** ❑ Male ❑ Female ❑ Other |
| **Ethnicity:** ❑ White ❑ Native Hawaiian/Other Pacific Islander  ❑ Black/African American ❑ American Indian/Alaska Native  ❑ Hispanic/ Latino ❑ Other (Two or more)  ❑ Asian ❑ Other (Not specified) |
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**ACKNOWLEDGEMENT OF PROPRIETARY RIGHTS**

**AND NON-DISCLOSURE AND DATA USE AGREEMENT**

This Acknowledgement of Proprietary Rights and Non-Disclosure and Data Use Agreement (“Agreement”) is entered into between the American Heart Association, Inc., a New York not-for-profit corporation, having its principal offices at 7272 Greenville Avenue, Dallas, Texas 75231-4596 ("AHA") and \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (“Data Recipient”).

**RECITALS**

**WHEREAS,** AHA is a non-profit health organization with volunteers throughout the United States who are dedicated to the goal of building healthier lives free from cardiovascular diseases and stroke, through research, advocacy and the development of programs that improve patient access to high-quality health care;

**WHEREAS**, AHA owns and operates a variety of comprehensive quality improvement and accreditation programs, that include inpatient and outpatient for data collection and reporting on standardized, clinical cardiovascular processes, outcomes, procedures, and patient level variables (each a “Program”, and collectively referred to as “AHA Quality Improvement Programs”);

**WHEREAS**, each Program includes a registry (“Program Registry”) by which hospitals and other healthcare facilities enrolled in one or more Program (referred to as “Program Participant”) can submit data, including aggregate and de-identified data, and certain patient data in the form of a Limited Data Set, as defined under the Health Insurance Portability and Accountability Act of 1996, as amended, (“HIPAA”) regulation at 45 C.F.R. 164.514(e);

**WHEREAS**, the agreement between AHA and the Program Participant enrolled in AHA Quality Improvement Programs permits use and disclosure of the Limited Data Set for the purposes of quality improvement and technical support, and for certain Research, Public Health or Health Care Operations purposes, as defined under HIPAA; and

**WHEREAS**, Data Recipient has requested an opportunity to review aggregate and de-identified data, and/or the Limited Data Set, and also other confidential, proprietary, and/or copyrighted information (collectively referred to as “Protected Information”) housed in one or more Program Registry;

**WHEREAS,** this Protected Information sought by Data Recipient is maintained in the strictest of confidence and disclosed only pursuant to this Agreement protecting the proprietary nature and rights of the AHA as to the requested information and restricting the use of such information by Data Recipient.

**NOW THEREFORE,** in consideration of the mutual promises and conditions contained herein, and for other good and valuable consideration, the parties agree to the following:

**AGREEMENT**

In consideration of the foregoing recitals, which are incorporated herein, and the mutual covenants and agreements herein, the parties hereto agree as follows:

1. Acknowledgement of Proprietary Rights. Data Recipient acknowledges that all Protected Information (including the Limited Data Set) provided to Data Recipient under this Agreement is owned exclusively by the AHA and is protected by United States HIPAA regulations, copyright laws and international treaty provisions. The AHA shall, through its data analytic center, provide Data Recipient with one (1) numbered copy of the Protected Information pursuant to this Agreement. In addition, Data Recipient shall return the Protected Information to the AHA as provided in paragraph 4.

2. Obligations of Data Recipient. Data Recipient understands and agrees (a) the Protected Information constitutes confidential and proprietary information; (b) to maintain the Protected Information in strict confidence; (c) not to disclose, duplicate, or otherwise reproduce, directly or indirectly, the Protected Information in whole or in part, or any materials relating thereto; (d) not to use or disclose the Protected Information except as specifically outlined in the AHA approved research proposal; (e) immediately report to AHA any use or disclosure of the Protected Information not provided for by this Agreement of which it becomes aware; and (f) not identify or contact the individuals.

3. Minimum Necessary Information. Data Recipient agrees that it shall use appropriate safeguards to prevent use or disclosure of the Protected Information other than as permitted under this Agreement. Data Recipient represents and warrants that only persons in its employ or control, directly involved in the permitted use of the Protected Information, and with a need to know shall have access to the Protected Information and that persons having access to the Protected Information shall be subject to and comply with the requirements herein and refrain from any disclosure, duplication, or reproduction of the Protected Information. Data Recipient agrees to bind in writing and obtain the signature of all persons with access to the Protected Information to this Agreement, prior to disclosure.

4. Permitted Uses and Disclosures. The Protected Information shall only be used as provided in this Agreement, and as set forth in the AHA approved research proposal, subject to the following additional requirements: (i) AHA and/or AHA Quality Improvement Program shall be acknowledged in any publication related to the research proposal; and (ii) any use of the Protected Information beyond that authorized in this Agreement shall subject Data Recipient to legal and equitable remedies, including but not limited to injunctive relief and additional use charges as set by the AHA.

5. Breach Notification. Data Recipient agrees that if it fails to adhere to any of the provisions set forth in this Agreement and, as a result, the Protected Information or other confidential information is unlawfully accessed, used, or disclosed, the Data Recipient agrees to pay all costs associated with any notification to affected individuals that is required by law, and will also pay any and all fines and administrative penalties imposed for such unauthorized access, use or disclosure of confidential information or for delayed reporting. Unless otherwise agreed upon by the parties, if AHA notifies Data Recipient of a breach under this provision, Data Recipient shall be responsible for providing notification to comply with the Breach Notification requirements set forth in the HIPAA Regulations. Such notification shall be provided in a form mutually agreed upon by AHA and Program Participant.

6. No Commercial Use. Data Recipient agrees that it shall not attempt to commercially exploit the Protected Information in any manner and that it shall not disassemble, decompile, or otherwise reverse engineer the Protected Information.

7. Data Recipient Contact. The individual that will be responsible for maintaining the Protected Information on behalf of Data Recipient and contact information is as follows:

Name of Data Recipient Contact: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Position: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Fax: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ E-Mail: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

8. Term. Data Recipient’s authorization to possess and use the Protected Information shall terminate twelve (12) months from the date of this Agreement or upon the completion of the research proposal, whichever comes first, unless otherwise agreed in writing by the AHA. Upon termination, Data Recipient shall ensure that all electronic or copies of the Protected Information have been removed from any media using an overwrite program or otherwise destroyed.

9. Termination by AHA. AHA may terminate this Agreement by giving written notice of termination if Data Recipient: (1) breaches any of its obligations under this Agreement with respect to the Protected Information; or (2) materially breaches its obligations under this Agreement.

10. Entire Agreement. This Agreement contains the entire agreement between the parties with respect to the subject matter of this Agreement, and it supersedes all other prior and contemporary agreements, undertakings, and commitments between the parties with respect to the subject matter of this Agreement.

11. Governing Law. This Agreement is deemed to have been entered into in the State of Texas, and its interpretation, its construction, and the remedies for its enforcement or breach are to be applied pursuant to, and in accordance with, the laws of the State of Texas.

12. Program Registry Use. The Protected Information accessed in the Program Registry shall only be used to address the question stated in the AHA approved research proposal. Any subsequent inquiries must be submitted in a new proposal.

[Signature Page to Follow]

IN WITNESS WHEREOF, the parties have executed this Agreement to become effective as of last date below.

**DATA RECIPIENT:**

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

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

Institution: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

**AMERICAN HEART ASSOCIATION**

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

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

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