



ACKNOWLEDGEMENT OF PROPRIETARY RIGHTS AND NON-DISCLOSURE AGREEMENT

This Acknowledgement of Proprietary Rights and Non-Disclosure and 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 enter Institution name (“Institution”) on behalf of its faculty member, enter Investigator name (“Investigator”). Institution and Investigator shall collectively be referred to as (“Data Recipient”). This Agreement addresses terms and conditions for the following project (“Authorized Purpose”) described below:

Authorized Purpose

Project Module: COVID-19 CVD Registry – *Powered by Get With The Guidelines®*

Brief Project Description: enter Project Description

RECITALS

WHEREAS, AHA is a non-profit health organization with volunteers throughout the United States who are dedicated to being a relentless force for a world of longer, healthy lives 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 aggregate and de-identified data, and certain 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 aggregate and de-identified data and/or Limited Data Set for the purposes of quality improvement and technical support, and for 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, 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 and subsequently stored on AHA’s Precision Medicine Platform (“PMP”), which is AHA’s cloud-based technology platform providing data access and analysis solutions for the research community.

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. Protected Information. “Protected Information” refers to aggregate and de-identified data, Limited Data Set, and also other confidential, proprietary, and/or copyrighted information provided by AHA or on behalf of AHA.

2. Acknowledgement of Proprietary Rights. Data Recipient acknowledges that all Protected Information 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 and only for use directly related to the Authorized Purpose. In addition, Data Recipient shall destroy the Protected Information to the AHA as provided in paragraph 9. No additional license or rights are provided to Data Recipient under this Agreement.

3. 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 it directly relates to the Authorized Purpose and set forth in the AHA approved Authorized Purpose; (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 to whom the Protected Information pertains.

4. 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, unless such persons are already legally obligated to maintain the confidentiality of AHA’s Protected Information pursuant to a prior existing agreement with Data Recipient.

5. Permitted Uses and Disclosures. The Protected Information shall only be used as provided in the Authorized Purpose of this Agreement, and as set forth in the AHA approved research proposal, subject to the following additional requirements: (i) AHA, the Precision Medicine Platform, and/or AHA Quality Improvement Program shall be acknowledged in any publication related to the research proposal; (ii) Data Recipient further agrees and attests that the Protected Information shall not be used for any other purpose or project as it directly relates to the Authorized Purpose, and that any additional or subsequent use of this Protected Information shall require prior written approval from AHA; (iii) 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. In addition to the foregoing, AHA may maintain a public ongoing list of approved research proposals.

6. Breach Notification. In accordance with Section 2(e), Data Recipient agrees to immediately report to AHA if it, or any party to whom Data Recipient has disclosed the Protected Information, 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. Data Recipient agrees to pay all costs associated with any notification to affected parties that is required by law or AHA, 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. Such notification shall be provided in a form provided by AHA.

7. Fees. As consideration for the provision of Protected Information and access to the Precision Medicine Platform, Data Recipient shall pay to AHA the fees generally set forth on Attachment A, and finalized in a separate invoice to be issued on a monthly basis. Upon execution of this Agreement, AHA shall send the first invoice to Data Recipient. If the investigator chooses to collaborate with the AHA Data Analysis Team to conduct analysis on the PMP a separate monthly invoice will be generated based on hours and specified rate (See Attachment A). Payment in full is due within 30 days of receipt of each invoice.

8. 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.

9. 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: enter Data Recipient name

Title: enter Title

Address: enter Address

Phone: enter Phone

E-Mail: enter E-mail

10. Term. Data Recipient's authorization to possess and use the Protected Information, and access to the PMP, shall terminate upon one (1) year from the effective date of this Agreement or completion of the Authorized Purpose, whichever comes first, unless otherwise agreed in writing by the AHA. Upon termination or expiration of the Agreement, Data Recipient shall destroy Protected Information and provide AHA with written confirmation of such destruction. Data Recipient may retain one (1) copy of the Protected Information for archival purposes and monitoring its continued confidentiality obligations under this Agreement.

11. Termination by AHA. AHA may immediately terminate this Agreement by giving written notice of termination to Data Recipient.

12. No Assignment. Data Recipient may not assign this Agreement without prior written consent of AHA.

13. 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. Except as otherwise defined herein, any and all capitalized terms in this Agreement shall have the definitions set forth in HIPAA.

14. Governing Law. This Agreement and all adversarial proceedings arising out of this Agreement, shall be governed by the substantive laws of the State of Texas, without reference to its conflict of laws provisions. However, if Program Participant is a governmental entity or state institution, this Agreement shall be interpreted and construed under the substantive laws of the state in which the Institution resides without respect to its conflict of law principles.

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

INSTITUTION:

Signature: _____

Name: enter Institution signer name

Title: enter Institution signer title

Date: _____

INVESTIGATOR

Signature: _____

Name: enter Investigator name

Title: enter Investigator title

Date: _____

AMERICAN HEART ASSOCIATION

Signature: _____

Name: enter AHA signer name

Title: enter AHA signer title

Date: _____

ATTACHMENT A

INSTITUTIONAL PMP PRICING PLAN

- ☐ **Investigator-led Data on AHA's Precision Medicine Platform (PMP)**
- The access cost of a secure workspace on the PMP is \$2K per month.
 - Each participating institutional site is eligible for a one-time credit of \$2K for up to 2 manuscripts. The \$2K credit is equivalent to 1 month of access to a workspace on the PMP.
 - Thereafter, the investigator will be invoiced directly for continued workspace fees of \$2k per month.
 - Each workspace owner will name an analytic team on the manuscript proposal, which will be provisioned with the PMP workspace and appropriate dataset.
 - Software available for basic statistical analysis = Python and R. Individuals may also bring their web-based SAS license and use machine learning and AI tools as well as the many other visualization and software programs within the PMP workspaces.
- ☐ **Collaborate with AHA Data Analysis Team to Conduct Analysis on the PMP**
- The AHA Data Analysis Team will work with the authors to estimate the number of hours per project. The authors will need to be available for questions and discussion as part of the estimation process. This information will also help inform the author of the expected length of time a PMP workspace will be needed, to enable a cost projection.
 - The AHA Data Analysis Team includes 2 PhDs with significant study design, epidemiology and computer science capabilities, 2 data scientists with an MS, one with an MPH in Biostats and Epidemiology, and one bioinformaticist.

- Typical analyses will range from 50 – 250 hours depending on the complexity of the analyses.
- Rates are \$125 per hour in addition to the monthly PMP usage fees as noted above.
*Prioritization of manuscripts may depend on workflow
- The investigator will be invoiced directly for analytical hours accrued per month.
- See following page for more detail regarding AHA Data Analysis Team.

☐ **Ad Hoc Support with AHA Data Analytics**

- The AHA Data Science Team are available on an ad hoc basis to provide technical and analytic support for Self Service authors.
- Rates are \$175 per hour.

Collaborate with AHA Data Analysis Team to Conduct Analysis on the PMP

Obligations of AHA Data Analysis Team

AHA Data Analysis team will hold an initial call with the principal investigators (PI), and/or their appropriate research staff to assess and understand the statistical needs of the project. Topics to be discussed during the initial consultation call include but are not limited to: overview of expectations and accountability, description of project, research hypothesis, feasibility, primary and secondary objectives, definitions of exposure variables, end points, and cut off values, discussion of statistical techniques and methodologies, overview of desired and format of output including charts, graphs, tables etc, and estimation of hours and cost.

Within a week of the consultation call, the Data Analysis team will send a Statistical Analysis Plan (SAP) to the PI and their appropriate research staff detailing the planned analysis and agreed upon project deliverables with a time frame. Any changes to the planned analyses should be made prior to formal written approval of the SAP. Suggested changes must be within the scope of the approved proposal. The PI and their appropriate research staff will provide written approval of the Statistical Analysis Plan. Work on the project only will start after the contract has been agreed upon and signed by all necessary parties.

The Data Analysis team will provide the PI and their appropriate research staff with regular status updates and communicate any statistical issues that may arise. A finalized Statistical Analysis Report within the prespecified time frame will be delivered via email to the PI. The Data Analysis team performing the analysis will be co-authors on the publication(s) to acknowledge the intellectual contribution to the work. The Data Analysis team will be given at least 1 week to review any final drafts of an abstract or publication prior to submission or resubmission to ensure study and statistical integrity.