



# Assessing Race in Clinical Research Models

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## Key Dates

RFA Posted:	December, 2022
Letter of Intent Pre-proposal (Required via email) Deadline:	January 23, 2023
American Heart Association Pre-proposal invitations:	January 31, 2023
Application Deadline (for invited participants only):	March 6, 2023
American Heart Association Peer Review:	March, 2023
Notification of Awards:	May, 2023
Award Start Date:	July 1, 2023

## Overview

Machine learning and artificial intelligence (AI) will likely continue to be integral in research-derived formulas that predict risk of disease or risk of complications. “Race correction” has been a common practice in the development of these research-derived formulas. The American Heart Association is committed to research that evaluates the role of race in algorithms and risk models and takes a close look at the downstream clinical implications of bias in algorithms on health disparities and mistrust in research.

The purpose of this Request for Proposal (RFP) announcement is to take a fresh look at risk prediction models and algorithms in the field of cardiovascular and stroke science that have been adjusted for race, and reevaluate based on potential downstream inequities in disease outcomes and treatments.

The field of cardiovascular and stroke science includes many algorithms and risk prediction models that are used to improve patient care, such as Framingham risk score<sup>1</sup>, Pooled Cohort Equations for atherosclerotic cardiovascular disease (ASCVD)<sup>2</sup>. Many of these models have been adjusted for race. Examples of topics that would be responsive to this RFP include (1) assessing the downstream effects of current risk prediction models on disease outcomes and treatments within populations that experience health disparities; (2) assessing potential bias in risk models and algorithms, correcting for the bias, and identifying factors for the bias; (3) developing statistical methods and advanced models that mitigate against the bias to support equitable care and treatment

- This RFP is targeted to early-trainees (pre-docs, post-docs, and fellows).
- Each early-trainee is required to have a letter of support from a mentor.
- 1-year awards for \$50,000 per year (including 10% indirect costs), with an additional amount of AWS credits to support data analysis on the AHA Precision Medicine Platform (up to \$50,000 dollars per year).

This RFP promotes analysis of relevant data sources and statistical methods to address the purpose of this RFP. Research supported by this RFP includes analysis of epidemiological studies, clinical trial data, de-identified electronic health record data, or other already accumulated datasets. This RFP does not support establishment of new cohorts or collection of new data on existing cohorts.

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1. D’Agostino RB, Vasan RS, Pencina MJ, Wolf PA, Cobain M, Massaro JM, Kannel WB. General cardiovascular risk profile for use in primary care: the Framingham Heart Study. *Circulation*. 2008;117(6):743–753.
  2. Goff DC Jr, Lloyd-Jones DM, Bennett G, et al.; American College of Cardiology/American Heart Association Task Force on Practice Guidelines . 2013 ACC/AHA guideline on the assessment of cardiovascular risk: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2014;129(25)(suppl 2):S49-S73.

## Who we're looking for

Our goal is to find trainees who are interested in this area of research that are paired with a mentor with experience in biostatistics, risk prediction models and bias.

## Before you apply

- For teams that are invited to submit a full application, the project lead must be an American Heart Association professional member.
  - Join or renew when preparing an application in Proposal Central, [online](#) or by phone at 301-223- 2307 or 800-787-8984.
  - Membership/Partnership processing takes 3 to 5 days; do not wait until the application deadline to renew or join.
- Projects can include collaborators from multiple areas of expertise; however, the project proposal must be submitted by a project lead representing an academic or non-profit organization based in the United States.
- Any member of the team can serve as the project lead. Projects may have co-investigators from other collaborating organizations. We strongly recommend that organizations identify only one project lead per project.
- Preference will be given to applicant organizations that are institutes of higher education, public entities, or nonprofits that are tax exempt under Section 501(c)(3) of the Internal Revenue Code and are not private foundations or Type III supporting organizations. Other types of nonprofit and for-profit organizations are also eligible to apply. The American Heart Association may require additional documentation.
- Awardees will be selected based on health impact and scientific merit.
- Projects will be considered that:
  - Are aligned with the American Heart Association's mission and goals
  - Provide a clear plan for bringing together datasets and experts across fields to take a fresh look at migraine.
- Organizations that are currently funded through other American Heart Association funding mechanisms can apply.
- Organizations can submit multiple proposals.

## How to apply: pre-proposal

1. Pre-proposal Letters of Intent **are mandatory** and are **due Jan 23, 2023, at 5 pm CT**. Email your Letter of Intent in a PDF Format to [datascience@heart.org](mailto:datascience@heart.org)
2. All Letters of Intent will be reviewed. Those responsive to the RFP will be invited to submit a full application.
3. Your letter of intent (2 page limit) should include the following information about the proposed project:
  - Project title
  - Name and contact of project lead and mentor
  - Data to be used
  - Planned approach and activities to achieve the goals

## How to apply: invited proposal

Applications must be submitted using [ProposalCENTRAL](#), the American Heart Association's online submission portal. **Deadline is March 6, 2023 at 5 pm CT.**

A review will take place with a diverse group of experts. Committee members will include data scientists and public health experts.

Only invited Applicants may submit a full proposal. Applications invited to submit a proposal are chosen from the Letters of Intent.

See *Details and requirements* for additional guidance.

**A plan of action** to use the research to establish a common language and standard set of metrics for measuring the impact of various social determinants of health on quality-of-life related risks and outcomes.

**A research plan that can be up to 6 pages (12-point font, single space, 1-inch margins on all sides):**

1. Operational plan with links to the data analysis plan (see below)
2. Rationale
3. Expertise (names, titles, affiliations, relevant expertise)
4. Methods/results section:
  - A clear description of the tools and types of analysis (as well as how bias will be quantified if relevant) to be performed in the workspace on the Precision Medicine Platform
  - An explanation of how the Precision Medicine Platform will be leveraged to share data and code within the team and to accelerate collaboration across research communities
  - A plan for interoperability of data with national or international standards
5. Expected outcomes and deliverables, a timeline, and project success milestones
6. A data analysis plan that includes a link to the Jupyter notebook created in a workspace on the Precision Medicine Platform. The submitted notebook should be in HTML format. In Jupyter, follow these steps:
  - a. In the File Menu, selecting *Download as > HTML (.html)*. The HTML file will download to a temporary downloads folder.
  - b. Re-upload the HTML file to the workspace by clicking the *upload* icon in JupyterLab or clicking the *Upload* button on the Jupyter Home tab.
  - c. In the workspace, save the notebook in the */mnt/workspace/Export\_Files* directory which will sync the notebook with the workspace portal.
  - d. The notebook will be listed within the Export files section on the workspace portal page. To the right of the notebook, click the box with the arrow that shows “Share for Grant Application” when you hover over it.
  - e. Sharing the notebook creates a static link that will be used by the peer review team.
7. Discussion of how the proposal is aligned with and will leverage:
  - The American Heart Association’s mission and goals (required)
  - The American Heart Association’s Precision Medicine Platform (required)
8. Works Cited (pages for Works Cited are not included in 6-page limitation)
9. NIH biosketches of trainee and mentor (not included in 6-page limitation)
10. Letter of support from the mentor explaining how the mentor will support the applicant.
11. Project technical summary to briefly describe the proposed work (not included in 6-page limitation)
12. Non-scientist summary to describe your work to people without science or medical backgrounds. Address the following: (not included in 6-page limitation)
  - Problem being addressed
  - Specific questions and how you will attempt to answer them
  - Potential impact of this work
13. Budget information including:
  - Salary and fringe benefits of the project lead, mentor, collaborating investigators, and other participating research staff or faculty.
  - Project-related expenses, such as salaries of technical personnel essential to the conduct of the project, travel, and publication costs in accordance with institutional and American Heart Association policies. Please note that the American Heart Association does not fund the costs of program implementation or operations beyond what is established in an approved budget.

- Maximum of 10% institutional indirect costs may be claimed on the award.
- *The awardee will be responsible for overseeing the total budget for the grant. If awarded, the project lead and the institution assume an obligation to expend grant funds for the research purposes set forth in the application and in accordance with all regulations and policies governing the grant programs of the American Heart Association.*

## Details and requirements

### Duration

Up to 1 year from date of funding, contingent upon milestones and timelines being met.

### Number of Awards

The American Heart Association anticipates awarding up to 10 grants for this RFP.

The American Heart Association reserves the right to determine the final number of awardees.

### Award Amount

- \$50,000/year (including 10% indirect costs).
- An additional Amazon Web Services (AWS) service credit (up to \$50,000) for use of the American Heart Association Precision Medicine Platform may be provided for computational time, use of AWS tools and infrastructure, and storage. Credit amount will be determined based on estimated need over duration of the grant.

### Precision Medicine Platform, research environment, trial workspace

Projects must be conducted via the American Heart Association's [Precision Medicine Platform](#), powered by Amazon Web Services.

Each team may be eligible to receive Amazon Web Services computational credits to cover the cost of cloud computing for a secure and private workspace on the American Heart Association's Precision Medicine Platform to enable investigators in each team to collaborate and analyze data securely.

Data analysis is enabled in secure workspaces by a web interface that allows researchers to code in various languages, including R and Python, and to use statistical software including but not limited to SAS and R studio. The most up-to-date machine learning and artificial intelligence software available from Amazon Web Services is also included. Researchers are also able to install their own tools.

The American Heart Association asks that the grantees also accelerate collaboration through the sharing of data and code as well as the coordination for interoperability of data to facilitate findability and sustainability. The American Heart Association fully supports the FAIR (Findable, Accessible, Interoperable and Reusable) guiding principles of data stewardship.

The Platform is HIPAA and FedRAMP compliant. Learn more about the [Platform's Security Information](#).

To learn more about the Precision Medicine Platform:

- [Overview](#)
  - [Full list of available analytical tools](#)
  - Videos:
    - [Learn more about the platform – video 1](#)
    - [Explore the capabilities of the platform – video 2](#)
1. [Register here](#) for a 60-day complimentary trial workspace to use during the application period
  2. Once registered, login and go to Data - Explore & Request and click Request Workspace (do not select any datasets).

3. Within the form, please include the following text for your Researcher Purpose:  
*Trial Workspace for Assessing Race in Clinical Research Models RFP.*

### **Final progress report**

Awardees must submit a final progress report progress. Progress reports may take the form of a required written report in addition to video conferencing, phone calls, and/or face-to-face visits. Reporting will be focused on achievement of stated milestones as indicated in the project timeline. The American Heart Association reserves the right to request additional updates, site visits, or reporting.

### **Public access**

The American Heart Association's public access policy requires that all journal articles resulting from American Heart Association funding be made freely available in PubMed Central and attributed to a specific American Heart Association award within 12 months of publication. It is the responsibility of the awardee to ensure journal articles are deposited into PubMed Central

### **Open Data**

Any factual data that is needed for independent verification of research results must be made freely and publicly available in a repository approved by the AHA within 12 months of the end of the funding period (and any no-cost extension). An exception to this is if the data sets were funded by NIH and they are stored on dbGaP.

For more information on the above policies, see the American Heart Association's [Open Science Policy](#) webpage.

### **Additional Requirements**

- The projects submitted can have no scientific or budgetary overlap with other work funded by the AHA or any other source.
- Any inventions, intellectual property, and patents resulting from this funding are governed by the AHA's [Patent, Intellectual Property and Technology Transfer Policy](#).
- The applicant/awardee and institution are responsible for compliance with all AHA research award policies and guidelines for the duration of any awards they may receive.
- Visit the Research Programs Awards Policies page for more information on this topic: [American Heart Association Policies Governing All Research Awards](#)

For questions and assistance: [datascience@heart.org](mailto:datascience@heart.org)