

American Heart Association Grand Challenge: Precision Health and Precision Medicine

Key Dates

RFA Posted:	February 2019
Application Deadline:	July 31, 2019
AHA Peer Review:	Summer 2019
Notification of Awards:	Fall, 2019
Award Start Date:	December 1, 2019

Purpose

To explore modern experimental techniques (in all fields) coupled with robust data sources, to make significant advances in understanding and/or deployment of precision health and precision medicine practices. Data source examples include, but are not limited to: images, electronic health records, (pan)omic-related data, endophenotypes, community engagement data (including social determinants of health), wearable devices, and smart phone and/or other sensor-related technology. Investigators at all career levels and across all disciplines are eligible to apply.

Success for the awardee(s) and/or collaborative team is identified as creating novel approaches to inform, prevent, identify, treat, or create solutions that make an extraordinary impact on precision medicine and data science.

A successful proposal will include:

- Specific Aims, Impact, Significance and Innovation, a Hypothesis and Approach as outlined below in the Application Submission section,
- Expected Outcomes and Deliverables, a Timeline, and Milestones.
- Information on the data to be analyzed and how the [Precision Medicine Platform's](#) infrastructure will be used for the proposed work,
- Establishment of a complimentary secure workspace on the Precision Medicine Platform prior to the deadline by providing application ID, uploading data, and generating preliminary data with a link to the grant application.

Example topics for applicants include, but are not limited to:

- predicting behavioral and lifestyle choices from data sources and deployment of trial interventions;
- creating technology advances in pan-omic pipelines at scale;
- establishing advances in analytics, systems biology, endophenotypes, analysis and visualization tools, interconnectivity between research datasets, and clinical practices leading to better quality of care and access to information for clinicians everywhere;
- solutions to Health disparities, resilience, readmissions with the goal of better management of a condition, or overall improvement in health outcomes for all groups;

Award Characteristics

Duration: Four years. All work must be completed within this timeframe. No-cost extensions will not be permitted.

Award Amount:

- \$250,000/year, including 10% institutional indirect costs (\$1,000,000 total award amount)
- The Institute Executive Committee reserves the right to determine the final award amount for competitive projects based on need and potential impact.

Number of Awards: Two

Appropriate Budget Items:

- Salary and fringe benefits of the Principal Investigator, collaborating investigator(s), and other participants with faculty appointments.
- Project-related expenses, such as salaries of technical personnel essential to the conduct of the project, supplies, equipment, travel, and publication costs are unrestricted in accordance with institutional and AHA policies.
- 10% institutional indirect costs from award funds.

Precision Medicine Platform: Applicants must use the workspace on the [Precision Medicine Platform](#) (PMP) to store and perform analyses on the data, and may be asked to provide feedback periodically on the use of the platform. The PMP is both [HIPAA](#) and [FedRAMP](#) compliant. Datasets will reside in a secure, walled-off workspace for which only the applicant has access. It is possible to grant collaborators access to the workspace, but it is the applicant's responsibility to ensure they have the appropriate data access approvals when adding them. All data access approval notices and/or current review status are necessary at the time of application review.

Resources:

- Learn more about the platform [here](#).
- Explore the capabilities of the platform [here](#).
- A demo workspace may be requested by providing your application ID prior to the application deadline. This is valid only for applicants of the Data Grant Portfolio 3.0 at this time.

Interim Assessment: Awardees must report progress on a semi-annual (twice a year) basis. Progress reporting may take the form of written reports, phone calls, and/or face-to-face visits. The focus will be on achievement of stated milestones as indicated in the project timeline.

Final Assessment: Upon completion, the awardee will be evaluated on successful completion of the experiments outlined in the specific aims and stated milestones as well as research outputs in the form of abstracts and publications. Final assessment may be in the form of written reports, phone calls, and/or face-to-face meetings.

Application Submission

Applications must be submitted using the AHA's online submission portal, [Grants@Heart](#), and will include the following documents:

1. [Research Proposal](#) (5-page limit including figures and tables, not including literature cited)
Include the following sections and information:
 - **Specific Aims**
 - **Impact, Significance, and Innovation**
 - **Hypothesis and Approach**

- including information on the dataset(s):
 - a link to the preliminary data in the [Precision Medicine Platform](#) (e.g., a quick statistical review of the data using a [Jupyter Notebook](#))
 - description of the tools to be used in the workspace to analyze and visualize the data
- **Expected Outcomes and Deliverables**
- **Timeline and Milestones**

Note: For all applications that include vertebrate animals or human subjects, applicants must explain how relevant biological variables, such as sex or age, are factored into the research design, analysis and reporting. Furthermore, strong justification from the scientific literature, preliminary data, or other relevant considerations must be provided for applications proposing to study only one sex or a specific age group.

Format:

- Only Portable Document Format (PDF) files will be accepted.
- Document must be single-spaced.
- No more than 15 characters per inch (cpi) or an average of no more than 15 characters per inch (includes symbols, punctuation and spaces).
- No less than ¾" margins allowed.
- 60 lines per page are the maximum allowed (The average number of lines per page using the font and point size below will be approximately 50-55 lines)
- Arial Font style, 12-point font size for Windows users; Helvetica Font style, 12-point font size for Macintosh users
- Figures, charts, tables, graphics and legends may be smaller in size but must be clear and legible
- 5-page limit

2. Literature Cited (no page limit)

List all literature citations for your Research Plan.

Citation references should be limited to relevant and current literature; be concise and select only those references cited in the Research Plan. Standard abbreviations are acceptable with two exceptions: full titles and full paging must be provided. Use of [EndNote](#), [Mendeley](#), [RefWorks](#) or similar programs is encouraged.

Each reference must list:

- Authors in the same order as they appear on the paper (list all or up to 15)
- Title
- Name of the book or journal
- Volume number
- Page numbers
- Year of publication

3. BioSketch (5-page limit)

Use of the [NIH General biographical](#) sketch is required for AHA programs.

4. [Data Access Approval Letters](#) (no page limit)

Include letters declaring approval of access from Data Owners or Data Access Committees for all datasets proposed in your work. If you are the owner of the data, please state so in this section. All data

access approval notices are necessary at the time of application review.

5. [Budget Justification Form](#) (2-page limit)

The Budget Justification form requests minimal narrative explanation of expenses proposed for the project. See Award Characteristics section above for appropriate budget items.

Peer Review Criteria

Applicants should never contact reviewers regarding their applications. Discussing scientific content of an application or attempting to influence review outcome will constitute a conflict of interest in the review. Reviewers must notify the AHA if contacted by an applicant.

Reviewers will comment on the following criteria, which should be fully addressed in the proposal.

Impact, Significance, and Innovation: Does the project develop or employ novel concepts, approaches, methodologies, tools or technologies to address the question? If the project is completed will it add to the knowledge around cardiovascular diseases and/or stroke or will the project create tools to enhance the sharing of resources for the research community? Can the work be done using the workspace in the Precision Medicine Platform? How does the proposed work enhance the global mission of achieving maximum impact in equitable health and wellbeing?

Hypothesis and Approach: Is the hypothesis testable? Does the approach include enough detailed information on the datasets? Is a link to the preliminary data on the Precision Medicine Platform provided? Is a description of the tools to be used in the workspace to analyze and visualize the data (with a link to a [Jupyter Notebook](#), if possible) provided?

Investigator(s): Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)?

Access: Does the investigator have the necessary access to the data in the proposed work?

Note: As applicants have 5 pages for the application, reviewers are aware of this and will be instructed to focus on innovation.

Eligibility

These grants are open to all scientists- there is no field of study restriction. Knowledge of biology and/or computer science may be helpful. Collaboration with other scientists (in any field) is optional. Applicants are to provide proposals that adhere to the above broad objectives, while specifically addressing the outlined goals.

Faculty/staff members must be conducting independent research at time of application. At application, the principal investigator must hold an M.D., Ph.D., D.O. or equivalent terminal doctoral degree and must meet institutional requirements for grant submission. Applicant must demonstrate ability to complete the project proposal with the allotted time and money made available by the grant.

Other than the requirement that the Principal Investigator be independent, eligibility for AHA Institute for Precision Cardiovascular Medicine Data Grants are not restricted by experience level or seniority. While no minimum percent effort is specified, the principal investigator must demonstrate that adequate time will be

devoted to ensuring successful completion of the proposed project. Percentage of effort must be documented for each named collaborating investigator.

The AHA Institute for Precision Cardiovascular Medicine research awards are limited to non-profit or public institutions, such as: medical, osteopathic, and dental schools, veterinary schools, schools of public health, pharmacy schools, nursing schools, universities and colleges, public and voluntary hospitals, and other non-profit institutions that can demonstrate the ability to conduct the proposed research. For Institute awards only, applications will be accepted from federal employees and Veterans Administration employees.

At the time of application, the principal investigator must have one of the following designations:

- U.S. citizen
- Permanent resident
- Pending permanent resident. Applicants must have applied for permanent residency and have filed form I-485 with the U.S. Citizenship and Immigration Services and have received authorization to legally remain in the United States (having filed an Application for Employment Form I-765).
- E-3 Visa - specialty occupation worker
- H1-B Visa - temporary worker in a specialty occupation
- J-1 Visa - exchange visitor
- O-1 Visa - temporary worker with extraordinary abilities in the sciences
- TN Visa - NAFTA Professional
- G-4 Visa - family member of employee of international organizations and NATO
- Hold a faculty position at a foreign University which meets foreign equivalency determinants for a non-profit in the United States.

Awardee must meet AHA citizenship criteria and research status if at a foreign university throughout the duration of the award. Applicants are not required to reside in the U.S. for any period of time before applying for AHA funding.

Relevant Policies

AHA Open Science Policies:

Public Access: The AHA requires that all journal articles resulting from AHA funding be made freely available in PubMed Central within 12 months of publication. It will be the responsibility of the author to ensure this occurs.

Open Data: Any research data that is needed for independent verification of research results must be made freely and publicly available in an AHA approved repository within 12 months of the end of the funding period (and any no-cost extension, when applicable). For more information, see the [Open Data Policy](#).

Awardees will be encouraged to deposit data resulting from the project in the AHA's Precision Medicine Platform. Restrictions may apply to data governance as set forth by the data owner. For more information visit each respective website: [Precision Medicine Platform](#) and the [Institute for Precision Cardiovascular Medicine](#). The Platform is HIPAA compliant and FedRAMP certified. Please visit the website for any forms or certification documents.

Any inventions, intellectual property, and patents resulting from this funding are governed by the [AHA Patent, Intellectual Property and Technology Transfer Policy](#).

Federally Funded Data Policies (United States):

Applicants must gain approvals from the appropriate governing body of the dataset owner. There are no restrictions on datasets that can be used, other than being related to cardiovascular health. If the applicant intends to apply using **NHLBI funded data**, they may do so in accordance with NIH and NHLBI data access and data sharing policies.

1. Request controlled access to data through dbGaP/BioLINCC with approval from the study's Executive Committee or the study's described vetting process.
2. Store and access the approved specified dataset within a secure cloud framework - using AWS (the [Precision Medicine Platform](#))– following [NIH Guidance](#)
3. Develop the tools, algorithms and other work products outlined within the Data Grant type for which the applicant is applying.
4. Access to any BioLINCC or dbGaP - derived data must follow the respective BioLINCC or dbGaP data use agreements, including the outlined prohibition that states that the data cannot be deposited in another resource or transferred to unapproved third parties.
5. Controlled access and data use policies of the NHLBI are different from the open data policy below. Upon conclusion of the project, the data will not remain on the secure cloud framework. According to the NHLBI-funded studies' data access and data sharing policies as well as terms of the NHLBI-funded studies' data use agreement, the source data will either be destroyed or returned to its source.
6. AHA, AWS, and grant awardees will not retain any rights to the source data.
7. Any new data, such as harmonized data, resulting during these awards from developing or applying the tools and algorithms may not be deposited in open access repositories; rather, NIH, NHLBI and NHLBI-funded studies policies must be followed.

Any further access to data used from these NHLBI-funded studies would need to be continuously regulated through BioLINCC and dbGaP. Controlled access and Data Use policies and practices must be adhered to and maintained throughout the duration of the project, including the standard provisions of data destruction and disposition terms consistent with those policies.

The projects described can have no scientific or budgetary overlap with other funded work. Awards are not intended to supplement or duplicate currently funded work. Rather, it is expected that submitted applications will describe projects that are clearly distinct from ongoing research activities in the applicant's laboratory. Minor variations from existing research projects are not sufficient to constitute independent and distinct projects. Additional policies may be applied in the award agreement, if awarded.

Awards are transferable to other institutions. The grantees will maintain fiscal responsibility for the entire award.

The appropriate Institutional Officer must approve and submit the proposal in AHA's online grants management system, Grants@Heart.

Award Selection and Other Policies

Final funding recommendations will be approved by the AHA Institute Executive Committee. Awardees selected who reside and conduct research in countries outside of the United States of America may be subject to an additional cost for legal equivalency determination review. This cost will be deducted from the award amount one time.

Awardees will be required to attend the American Heart Association Research Leader's Academy and will be encouraged to attend the annual Institute for Precision Cardiovascular Medicine event at Scientific Sessions.

For all other relevant policies and Frequently Asked Questions, please see the [Application Information website](#).

Required Documents for Artificial Intelligence and Machine Learning Grant Applications

The Applicant (PI) is required to submit certain documents, which vary with each award program. In addition, other individuals (called Third Parties) associated with the application will provide supporting documents.

Toggle between the **Applicant** and **Third-Party Personnel** tabs below to view a complete list.

Instructions are contained in the [Application Instructions \(PDF\)](#) for items below that are not hyperlinked. All required documents must be uploaded to **Grants@Heart** by the applicant before the application can be submitted to the Grants Officer. The Grants Officer is responsible for sign-off and submitting the application to AHA.

Applicant

- Proposal (5 pages)
- Literature Cited (no page limit)
- [Biographical Sketch/Bibliography](#) (5 pages)
- [Data Access Approval Letter\(s\)](#) (no page limit)
- [Budget Justification Form](#) (2 pages)
- [Vertebrate Animal Subjects, if applicable \(no page limit\)](#)
- Human Subjects Research Form (no page limit)

Third Party

- [Collaborating Investigator's Biographical Sketch/Bibliography \(5 pages\)](#)
- [Collaborating Investigator's Letter \(5 pages\)](#)
- [Consultant's Letter \(5 pages\)](#)