

American Heart Association and Amazon Web Services 4.0 Data Grant Portfolio: Artificial Intelligence and Machine Learning Clinical Training Grants

Key Dates

RFA Posted: Application Deadline: AHA Peer Review: Notification of Awards: Award Start Date: February 2019 July 26, 2019 Summer 2019 Fall, 2019 December 1, 2019

Purpose

To cross-train post-doctoral researchers in testing and refining artificial intelligence and machine learning algorithms using learning health care system data and/or multiple longitudinal data sources to improve our understanding of all data related to precision medicine. Data source examples include but are not limited to: images, electronic health records, genetics and omic-related data, community engagement data (including social determinants of health), wearable devices, smart phone and other sensor related technology. Applicants are encouraged to use multiple sources of data, or longitudinal data to continue to refine algorithms.

Success for the applicant is identified as the trainee gaining experience, knowledge, and proficiency in novel data science tools and techniques which can be translated into clinical practice and clinical research. After the conclusion of the award, the awardee is expected to begin integrating lessons learned into the clinical setting which will ultimately help patients suffering from cardiovascular and brain health conditions.

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. Finally, a successful proposal will
 include information on the data to be analyzed, and how the <u>Precision Medicine Platform 's</u>
 infrastructure will be used for the proposed work,
- Establishing a complimentary secure workspace on the Precision Medicine Platform prior to the deadline by providing your application ID, uploading data, and generating preliminary data with a link to the grant application. The link may include a Jupyter notebook.

Example topics for applicants include but are not limited to:

- identifying machine learning approaches for classification of images from multiple data sources;
- predicting behavioral and lifestyle choices from data sources;
- predicting income level, educational level from data sources;
- new pipelines to enable more effective and efficient workflows for analyzing data in the cloud.



Target Audience

The training grant is open to clinicians, and candidates who recently graduated from a medical school program (or working towards an M.D., D.O., or RN Ph.D). Please see additional Eligibility requirements below on page 6.

Award Characteristics

<u>Duration</u>: Two years. All work must be completed within this timeframe. No-cost extensions will not be permitted.

Award Amount:

- \$50,000/year (\$100,000 cash total)
- An additional Amazon Web Services (AWS) service credit for use on the AHA <u>Precision Medicine</u> <u>Platform</u> will be provided for computational time, use of AWS tools and infrastructure, and storage up to \$50,000/year.
- 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: Four

Appropriate Budget Items:

• Salary and fringe benefits of the trainee, cloud computing support, travel and health insurance. Fringe benefits for training grants are defined as \$1,000 for health insurance each year for the trainee. Additional fringe benefits are not allowed for this award type but may be substituted from base salary, with approval.

AWS service credits may be applied toward computational time, storage and utilization of the AWS infrastructure through the <u>Precision Medicine Platform</u>. The credits are not intended for use outside of the platform.

The sponsor will be responsible for overseeing the total budget for the trainee. The sponsor and the institution assume an obligation to expend award funds for the research purposes set forth in the application and in accordance with all regulations and policies governing the grant programs of the AHA.

<u>Precision Medicine Platform</u>: Applicants must use the workspace on the <u>Precision Medicine Platform</u> (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 <u>HIPAA</u> and <u>FedRAMP</u> 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 <u>here</u>.
- Explore the capabilities of the platform here.
- A demo workspace may be requested for X amount of time by providing your application ID, this is valid only for applicants of the Data Grant Portfolio 3.0 at this time.



<u>Interim Assessment</u>: 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. Reporting will be focused on achievement of stated milestones as indicated in the project timeline.

<u>Final Assessment</u>: Upon completion, the awardee will be evaluated on the successful completion of the experiments outlined in the specific aims and stated milestones as well as abstracts and publications produced. 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, <u>Grants@Heart</u>. The application requires the following documents.

Trainee Applicant Documents (1/3rd of peer review score)

- 1. Trainee Biosketch (5-page limit)
 - Use of the <u>NIH Fellowship Biographical</u> sketch is required for AHA programs. The Trainee is to include his/her training and career goals in Section 1: Personal Statement. The AHA may request a transcript of the trainee's academic record.
- Three Reference Reports (4-pages each) Reports must be uploaded by August 12th, 2019. Those asked to provide references will be linked to the <u>Referent Information Page</u> for instructions. Referent will complete the <u>Reference Report (.doc)</u> and will upload it through <u>Grants@Heart</u>.

Sponsor Applicant Documents (1/3rd of peer review score)

Please see Sponsor Information page for instructions.

- <u>Sponsor's Biosketch/Bibliography</u> (5-page limit) The sponsor is required to use the <u>NIH General biographical</u> sketch format.
- 2. <u>Sponsor's Past/Current Trainees (</u>3-page limit) The sponsor is required to list all past and current trainees.
- 3. Sponsor's Training Plan (3-page limit)

The sponsor is required to clarify the role that the applicant played in the development of the proposal, the relationship of the proposed project to ongoing research in the sponsor's laboratory, and how the project will contribute toward the training and career development of the applicant. The sponsor will detail the time he/she will spend with the trainee and how this time will be spent. While no minimum percent effort is specified, the sponsor must demonstrate that adequate time will be devoted to assuring successful completion of the proposed project. Any additional research support for the trainee must come from the sponsor's laboratory.



The trainee's career goals, as stated in Part A - Personal Statement of the trainee's biographical sketch and the sponsor's training plan must be complementary to one another and focused specifically on the individual. A standardized training plan will not be viewed favorably.

4. <u>Sponsor's Research Project Environment</u> (no page limit) Similar to the PHS SF424 (R&R) Facilities & Other Resources form used by the NIH, this document contains details about the facilities to be used for the conduct of the proposed research._

Collaborative Documents (1/3rd of peer review score)

These documents may be completed by both the trainee and the sponsor. The trainee applicant will upload these documents in <u>Grants@Heart</u>.

1. <u>Research Proposal</u> (5-page limit including figures and tables, not including literature cited)

A trainee must have primary responsibility for the writing and the preparation of the application, understanding the Sponsor will play a significant part in providing guidance to the applicant. Include the following sections and information:

- Specific Aims
- Impact, Significance and Innovation
- Hypothesis and Approach
 - includes information on the dataset(s),
 - a link to the preliminary data in the <u>Precision Medicine Platform</u> (e.g. a quick statistical review of the data using a <u>Jupyter Notebook</u>)(A demo workspace may be requested by providing your application ID prior to the grant deadline)
 - Description of the tools to be used in the workspace to analyze and visualize the data on the Precision Medicine Platform.
- 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 ³/₄" 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



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- 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 <u>EndNote</u>, <u>Mendeley</u>, <u>RefWorks</u> 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. 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 review.

4. Budget Justification Form (2-page limit)

This section justifies each section of the budget. See Award Characteristics 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. To judge the merit of the application, reviewers will comment on the following three criteria, each of which will account for one-third of the overall score.

Criterion 1 - Evaluation of the Trainee (1/3rd of the score)

- 1. Referencing the Trainee's reference reports and biographical sketch, does the trainee have potential to impact research in cardiovascular diseases and stroke?
- 2. Are the trainee's career plans specified in the biographical sketch?
- 3. Does the trainee have prior research experience and/or publications or other training that may significantly impact success?
- 4. What is the sponsor's assessment of the applicant?



Criterion 2 - Sponsor/Training Plan and Environment and Evaluation of the Program (1/3rd of the score)

Additional research support for the proposed project MUST come from the sponsor's laboratory. The sponsor should clarify the role the applicant played in the development of the proposal, the relationship of the proposed project to ongoing research in the sponsor's laboratory, and how the project will contribute toward the training and career development of the applicant.

Sponsor/Training Plan

- 1. Is the sponsor an independent investigator?
- 2. Does the sponsor or a mentor listed in the application have the experience to direct the proposed research training, as evidenced by a track record regarding productivity, cloud computing, coding, funding and prior trainees?
- 3. Does the sponsor have adequate current funding to support the trainee's project? Is the funded project related to precision medicine?
- 4. Does the sponsor demonstrate familiarity with the applicant's career and developmental goals?
- 5. Does the sponsor allow adequate time to spend with applicant?
- 6. What does the sponsor expect of the fellow? Are clear metrics outlined for the fellow?
- 7. Does the sponsor provide a comprehensive training plan that supports the applicant's progress towards his/her research career goals?

Evaluation of the Environment and Institutional Commitment to the Program

- 1. Does the scientific environment in which the work will be done contribute to the probability of success for the training experience?
- 2. What is the level of evidence of institutional commitment?

Criterion 3 - Evaluation of the Research Proposal (1/3rd of the score)

- 1. Is the proposed project the right balance of challenge, impact, and feasibility in relation to the candidate's experience and training?
- 2. Does the proposed research project summary include:
 - o the candidate's role on the project?
 - Specific aims?
 - Impact, Significance and innovation?
 - Hypothesis and Approach?
 - Expected Outcomes and Deliverables?
 - Timelines and Milestones?
- 3. Impact: How does this project address the mission of the AHA: "Achieving maximum impact in equitable health and wellbeing?"
- 4. Does the proposed project likely enhance career development for the trainee?

Notes:

*A trainee may not have had adequate time to generate preliminary data. Applicants may present preliminary data generated by the sponsor. The assessment of preliminary data, whether generated by the sponsor or the applicant, should be put into perspective so that bold new ideas and risk taking by beginning investigators are encouraged rather than stymied. The overall opportunity as a training



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experience for the applicant will be considered by the reviewers, who may also provide feedback on the research proposal.

Trainee Eligibility

The applicant must be enrolled or have recently completed a clinical training program and demonstrate the ability to complete the project proposal within the allotted time and money made available by the training grant.

- This training grant is open to recent graduates of M.D., D.O., or RN Ph.D. programs who successfully achieved the degree.
- At the time of award activation, the candidate may have no more than five years of postdoctoral research training or experience (excluding clinical training).
- This training grant is not intended for individuals of faculty rank.

Exceptions:

- M.D. or M.D./Ph.D. with clinical responsibilities who needs instructor or similar title to see patients, but who devote at least 80% full-time to research training.
- R.N./Ph.D. with faculty appointment. Fellow will be expected to devote his/her time to research or activities directly related to the development into an independent researcher. All other eligibility criteria apply.

Citizenship

A trainee working at a U.S. based institution must have one of the following designations:

- U.S. citizen.
- Permanent resident.
- Pending permanent resident (any resident who has an approved I-765 form and has submitted an I-485 application with the United States Citizenship and Immigration Services).
- E-3 Visa specialty occupation worker.
- F1 Visa student.
- 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 North American Free Trade Agreement (NAFTA) professional.
- G-4 Visa family member of employee of international organizations and NATO

For awards to non-U.S. based institutions, trainees must meet appropriate designations or approval to conduct research and receive funding. The foreign University will also need to meet foreign equivalency determinants for a non-profit in the United States.

Trainee must meet American Heart Association citizenship criteria and research status if at a non-U.S. based institution throughout the duration of the award. Applicants are not required to reside in the U.S. for any period of time before applying for American Heart Association funding. If the trainee loses student status at the awarded Institution, the Institution, trainee and sponsor must forfeit the award.

An awarded trainee must maintain one of the designations listed above throughout the duration of the award.



Note: This award is ineligible for transfer.

Sponsor Eligibility

It is imperative that the trainee receive counsel and direction from a sponsor who is an established investigator invested in the progress of the project. A single sponsor may have no more than two AHA-supported trainees (or fellows) (predoctoral or postdoctoral) at any time.

At the time of application, the sponsor 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 non-U.S. based institution which meets foreign equivalency determinants for a non-profit in the United States.

Sponsor 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.

A trainee must have primary responsibility for the writing and the preparation of the application, understanding the Sponsor will play a significant part in providing guidance to the applicant.

AHA does not require but strongly encourages institutions to develop and use Individual Development Plans (IDPs) for AHA training programs. IDPs provide a structure for the identification and achievement of career goals.

Relevant Policies

AHA Open Science Policies:

<u>Public Access</u>: 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.

<u>Open Data:</u> 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, where applicable). For more information, see the <u>Open Data Policy</u>.

Awardees will be encouraged to deposit data resulting from the project in the AHA's <u>Precision Medicine</u> <u>Platform</u>. Restrictions may apply to data governance as set forth by the data owner. The AHA Precision Medicine Platform is creating a community of tools and resources for all cardiovascular disease and stroke



researchers. For more information visit each respective website: <u>Precision Medicine Platform</u> and the <u>Institute</u> <u>for Precision Cardiovascular Medicine</u>. 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 <u>AHA Patent</u>, <u>Intellectual Property and Technology Transfer Policy</u>.

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 <u>Precision Medicine Platform</u>) – following <u>NIH Guidance</u>
- 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 NHLBIfunded 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.

This award is not eligible for transfer to other institutions. The sponsor 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, <u>Grants@Heart</u>.



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 Methodology Training Grant Applications

The Trainee 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 <u>Application Instructions (PDF)</u> 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 (Trainee)

- Research Plan (5 pages)
- Biographical Sketch/Bibliography (5 pages)
- Academic Record (no page limit)
- Literature Cited (no page limit)
- Publications or Abstracts (3 count)
- Vertebrate Animal Subjects, if applicable (no page limit)

Third Party Personnel

- Sponsor's Biographical Sketch/Bibliography (5 pages)
- Sponsor's Past/Current Trainees (3 pages)
- Sponsor's Training Plan (3 pages)
- Sponsor's Research Project Environment (no page limit)
- Collaborating Investigator's Biosketch/Bibliography (5 pages)
- Collaborating Investigator's Letter (5 pages)
- Consultant's Letter (5 pages)
- Reference Report (3 count, 4 pages each)