

## Award Announcement

### Key Dates

RFA Posted:	Sept 1, 2019
Letter of Intent Deadline (Required)	November 12, 2019
Application Deadline:	January 7, 2020
AHA Peer Review:	February/March 2020
Notification of Awards:	early Spring 2020
Award Start Date:	April 1, 2020

### Award Purpose

The American Heart Association's purpose in offering this Health Technologies & Innovation Strategically Focused Research Network (NETWORK) is to:

- 1) Research the role and value of innovative technology solutions to improve health outcomes, optimize costs, increase health engagement and patient/provider connectivity. It's anticipated that the NETWORK will serve to enhance research collaboration across disciplines and may further validate the value of existing health technology solutions or establish novel technology approaches – equally favorable endpoints.
- 2) Build a robust collaborative research team across the Network by providing the Network with structures and funds to conduct a high impact joint network research project (NETWORK PROJECT).
- 3) Incubate, nourish and explore, during the initial four-year award funding period, the creation of an enduring AHA Health Technology Research Collaborative (COLLABORATIVE) to endure subsequent to the four-year funding award. Potentially consisting of the four selected Centers, the COLLABORATIVE infrastructure may serve as an AHA research 'think tank' to assist with identifying, creating, testing and bringing to scale future innovative health technologies.

For this RFA:

"Health Technologies" are broadly defined and refer to the application and utilization of organized knowledge and skills, including but not limited to, systems, structures, procedures, software, algorithms, digital health content, hardware and devices developed to solve a health problem and/or improve quality-of-life. These technologies may be used by any stakeholder or set of stakeholders in the healthcare and health and well-being ecosystem, including but not limited to patient/public, providers, payers, regulators, quality monitors and industry.

"Network" refers to the research entity which is created by the Centers selected for this award. The Network and its Network oversight group provide opportunities for

collaboration and support to occur AMONG Centers throughout their 4 years of funding. These activities will enhance Network members' skills in 'research team science.'

"Network Project" refers to a high impact technology research project which will be collaboratively identified and executed by the Centers in the Network in conjunction with the Network Oversight Advisory Group (NOAG). This will be planned by Year 2 of the Network funding with implementation to follow. This budget is designed to provide sufficient funds to identify at least one highly impactful project, drive integration and collaboration, and produce significant findings.

The Network Oversight Advisory Group (NOAG) will consist of preeminent science, technology, business and other appropriate experts and leaders who will work with the NETWORK to assure specific aims for the NETWORK and the NETWORK PROJECT are achieved. As the NETWORK transitions to the COLLABORATIVE, there will be a Collaborative Oversight Advisory Group (COAG) via the Center for Health Technology and Innovation which will provide oversight and guidance.

"Health" is broadly defined and includes health across the continuum from well-being and prevention through disease to end-of-life, from individuals through populations; across the lifespan; and across gender, race, ethnicities and other relevant demographics, with an emphasis on under-represented racial and ethnic groups and across socioeconomic strata with an emphasis on lower Socio-economic Status (SES). Preference is given to aspects of health related to or anchored in cardiovascular, stroke or brain health. Brain health is inclusive across the dimensions of mild cognitive impairment, dementia and TIA and stroke.

## Summary Description of Network

- The NETWORK will consist of four Centers.
- The NETWORK stage will last for 4 years.
- Each Center will submit at least 1 research project in response to the Request for Applications (RFA), the total costs of which cannot exceed \$2.5 million over a 4-year period. One research project is required; however, applications will be accepted with up to three proposed projects.
- Within the first year of the award, the four Centers, with approval from the Network Oversight Advisory Group, jointly will determine a collaborative NETWORK PROJECT(s) not to exceed \$4 million dollars over 3-4 years that they will implement. The NETWORK PROJECT will be formulated by the 4 Centers after their selection into the NETWORK.
- Each Center will be evaluated and chosen on the strength of the science and technological aspects of its research project(s) and the Center's overall capabilities and history of strong collaboration and outcomes.

- All Centers are required to agree to AHA’s intellectual property (IP) guidelines for the NETWORK in order to submit their RFA. Note: Intellectual property guidelines for the NETWORK portion will follow AHA’s IP guidelines; work done in the COLLABORATIVE stage will be considered “work for hire” unless other terms are appropriate for a project.
- All Centers will be strongly encouraged to remain part of the COLLABORATIVE after the 4-year tenure of the NETWORK for at least an additional 5 years, unless exiting is mutually agreed to by AHA and the Center.

Applicants should focus on specific research questions in their project that could have an extraordinary impact, with an equity-first lens. The following hypothetical research projects are for purposes of illustration, and not to be considered an exhaustive list of areas to be explored:

- Development and testing of predictive analytics to facilitate clinical decision-making for the benefit and ease of patient and/or providers including but not limited to those utilizing machine learning, artificial intelligence, etc.;
- Creation of or improvement to health technologies (e.g. health applications, wearables/sensors, telehealth or telemedicine solutions, singly or in combination) to enable and/or enhance information-sharing and data sharing between patients and providers;
- Improvement and enhancement of clinical trial processes in using big data, machine learning, blockchain and/or other cutting-edge technologies;
- Best methods for consumer-friendly interfaces and health dashboards which enhance the consumer’s ability to be active partners in their own and their families’ care;
- Development, validation, or creation of health technologies and applications that can meaningfully impact and drive behavior change (evidence-based coaching, artificial intelligence, digital therapeutics and related);
- Improvement of or creation of new analytics and pathology detection capabilities, e.g. valves, biomarker phenotypes;
- Projects that address one or more of the above while also addressing the equity gap in care and access.

A Letter of Intent (LOI) will be required for this proposal. LOIs will be reviewed by the AHA and the NETWORK peer review group, and only innovative and clearly thought out projects will be asked to submit full applications.

## General Award Information

Duration: 4 years

Award Amount: The maximum budget amount an applicant may request is \$2.5 million. The AHA reserves the right to determine the final award amount for competitive projects based on need and potential impact.

Number of Awards: Four\* Centers will be selected from public institutions across the United States. Centers will be selected based on merit and collaboration.

\* The AHA reserves the right to determine the final number of awardees.

Subjects/Study Cohorts: All NETWORK studies and the NETWORK PROJECT must include under-represented racial and ethnic groups (UREGs) and women, congruent with AHA's mission. All Centers must address any rationale for the non-inclusion of UREGs in their subject populations.

Institutional Partnership Policy: Each Center applicant must partner with at least one non-research-intensive institution and its scientists and include them in a substantive manner in the scope of the center and project.

*What is a non-research-intensive institution?* To be considered non-research-intensive, an institution must meet the following:

- Only domestic accredited public or non-profit institutions of higher education are eligible. Federal government institutions are not eligible.
- The institution must grant baccalaureate or advanced degrees in the biomedical or behavioral sciences. For example, a four-year liberal arts college.
- To be eligible to apply for this AHA award, the applicant's institution may not have received more than \$6 million per year in NIH support in four of the last seven years.
- Letter from the institution's Provost indicating eligibility

NIH no longer maintains a list of ineligible institutions; therefore, there is no mechanism to verify if an institution does not qualify. Instead, an institution must meet all criteria above and submit a letter from the Dean of Research or Provost (or equivalent) stating as such.

Please refer to the [Organization Eligibility section](#) of the NIH Research Enhancement Award (R15) page: <https://grants.nih.gov/grants/funding/r15.htm> or more information. AHA follows NIH's guidelines.

#### Appropriate Budget Items:

- Salary and fringe benefits of the Center Director, Principal Investigator (who may also be the Center Director), Training Director, 3 named fellows, collaborating investigator(s), and other participants with faculty appointments.
- Project-related expenses, such supplies, equipment, travel, and publication costs in accordance with institutional and AHA policies
- Indirect costs in the amount of 10% of direct costs will be allocated to the prime award recipient. It is anticipated that the prime awardee institution will allocate appropriate indirect costs to any subrecipient institution receiving direct costs.

The awardee will be responsible for overseeing the total budget for his/her grant. If awarded, the principal investigator 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 AHA.

Award Assessment: During the NETWORK phase of the grant, each center will submit an annual written progress report. Additional reports may be required, and may be in a written, telephonic, video, or face-to-face format. Reporting will be focused on achievement of stated milestones as indicated in the project timeline. The NOAG reserves the right to request additional updates, site visits, or reporting. Reporting during the NETWORK PROJECT phase will be on a per-project basis.

Meetings: The awarded Centers will be expected to attend up to 8 face-to-face meeting (2 per year) for updates and progress to the NOAG. Other meetings may be scheduled based on performance and progress.

Application Submission: Applications must be submitted using the AHA's online submission portal available at [Grants@Heart](mailto:Grants@Heart). For explicit Application Instructions, visit the [AHA SFRN Webpage](#).

#### Peer Review:

##### Criteria:

Each Center will be assessed on three broad topic categories:

- 1) strength of the proposed center research PROJECT(s);
- 2) capacity of the CENTER to function effectively as part of the NETWORK, NETWORK PROJECT(s) and COLLABORATIVE; and
- 3) strength of the translational aspects of the proposed technology (i.e., technology review)

Specific assessment criteria for the center PROJECT(s) will include:

- Approach:
  - Are the conceptual framework, design, methods and analyses adequately developed, well-integrated, well-reasoned and feasible (as determined by preliminary data) and appropriate to the aims of the project?
  - Does the applicant acknowledge potential problem areas and consider alternative tactics?
  - Does the investigative team include a plan for inclusion of racially and ethnically diverse subjects?
  - Is the lay summary written such that lay individuals will fully understand what is being proposed, why it is being proposed, and what the impact will be?

*For all applications that include vertebrate animals or human subjects, applicants must explain how relevant biological variables, such as sex, 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.*

- Innovation:
  - Is the project original and innovative? For example: Does the project challenge existing paradigms and address an innovative hypothesis or critical barrier to progress in the field?
  - Does the project develop or employ novel concepts, approaches, methodologies, tools or technologies for this area?
- Investigative Team:
  - Is the investigative team 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)?
  - Describe how the proposed team reflects AHA's Core Values of diversity and inclusivity.
  - Describe the unique aspects the Center has which should be considered e.g. geography, technology, etc.
- Significance:
  - Does this study address an important problem broadly related to the mission of AHA?
  - If the aims of the application are achieved, how will scientific knowledge, clinical practice or consumer health practices be advanced?

- What will be the effect of these studies on the concepts, methods and technologies that drive this field?
- Environment:
  - Does the scientific environment in which the work will be done contribute to the probability of success?
  - Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements?
  - Is there evidence of institutional support?
- Impact:
  - How does the project relate to and support the mission of the AHA – *To be a relentless force for a world of longer, healthier lives?*
- Training component:
  - Each Center will provide a training program for fellows; training three (3) Center-funded postdoctoral fellows during the period of the award
  - Is a detailed plan for developing and implementing a postdoctoral training program that includes clinical (M.D.) or Ph.D. training in research in the field outlined by the RFA provided?
  - Are qualifications and characteristics of current and anticipated trainees, as well as a selection plan specified?
  - Are both didactic and practicum training opportunities, use of an individual development plan (IDP), and plans for assessing trainee progress at least annually described?
  - Additional expectations include plan for involving fellows in annual Center meetings and Center-to-Center visits, along with identifying opportunities for fellows to work with established investigators at other network Centers; ability to track trainees; conferences and meeting participation for trainees; documentation of a ready supply of fellows; and history of successful fellowship training for researchers in the appropriate research topic.

Successful applications will design studies that incorporate both realistic recruitment goals and sufficient statistical power to ensure valid results in clinical and/or population projects enrolling human subjects.

Additionally, because much research utilizing digital technology relies on traditional methods of scientific evaluation, priority will be given to researchers who plan to introduce new methodologies and evaluations to pave the way for a re-imagining of the digital clinical trial.

Specific assessment criteria of a Center as it applies to their joint activities, actions and contributions to the NETWORK, NETWORK PROJECT and COLLABORATIVE component.

- Collaboration:
  - Is there a demonstrable history of collaboration (e.g., letters from prior collaborators), as well as the ability and commitment to collaborate with other institutions and investigators within the applicant institution as well as within and beyond the awarded Network?
  - Are detailed processes for collaboration with other sites in addition to those within the proposed project delineated?
  - Evidence of formal training in leadership, with an emphasis on collaborative leadership, will be favorably reviewed.
- Interaction Plan within this Network and with other AHA Networks (if appropriate):
  - Is there a plan for and commitment to sharing knowledge and methods, providing a stimulating atmosphere for research collaborations, and providing networking opportunities for trainees?
  - Are strategies cited for communication and interaction among the Centers?
  - Centers proposing clinical projects must document that they have sufficient volume of patients to assure that robust studies may be conducted.
- Center Director:
  - Has the Center Director demonstrated an ability to lead others, and commitment to the success of the Center, NETWORK, NETWORK PROJECT and COLLABORATIVE?
  - Can he/she provide documented evidence of willingness to collaborate with beyond his/her institution to share ideas, science, etc. to progress the field of research as outlined in the RFA?
- Environment:
  - Is it evident that institutional commitment, resources and facilities to sustain the project, the NETWORK, NETWORK PROJECT, and COLLABORATIVE are available?
  - Is a letter from institutional leadership provided that assures the department and institution's support of the Center, along with confirmation that the Center Director will devote at least 20% effort towards the Center, NETWORK, NETWORK PROJECT, and COLLABORATIVE?
  - Other Center personnel may be appointed to assist the Director in the administration of the Center. However, the Director will be required to devote 20% effort to the Center. Is there evidence the center has the ability to scale up from early phase investigation to a larger, multi-site trial?

Specific assessment criteria of a Center's Project as it applies to the translational potential of the proposed technology will include: (this is a technical review)

- Proposed Product/Solution:
  - Does the application adequately describe the proposed product/solution, the setting in which it will be utilized, and the primary target population and/or indication for use?

- Has the expected benefit of the technology and its impact on current standard of care and/or new approaches to improved health been clearly delineated? Has evidence to support the benefit been presented?
- Market Size:
  - Have the applicants provided a reasonable and evidence-based approximation of the target market for the proposed technology, and the projected trends for that market?
  - Whereas a precise declaration of the ultimate price of the proposed product/technology is not required, has some reasonable estimate of the price been provided?
- Competitive Landscape:
  - Have the applicants provided a sufficient description of the competition (companies, products, etc) with which their technology will compete?
  - Have the applicants described competing approaches the target market might utilize, and the strengths and weaknesses of those competing technologies?
  - Have the applicants adequately presented how the proposed technology differentiates from other solutions for the problem?
- Intellectual Property (if applicable):
  - If applicable, have the applicants described the status of any intellectual property related to this proposal? For example, has the technology been disclosed to the lead institution's technology transfer office, and/or has a patent application(s) been filed?
  - If no patents have been or are anticipated to be filed, applicants should describe the type(s) of intellectual property to be generated.
- Regulatory Path:
  - Does the proposal describe the expected regulatory pathway for the technology? Have the applicants described potential regulatory risks, and how they may impact development of the technology? If one or more clinical trials are being proposed, does the proposal consider how they may impact the regulatory approach?
- Reimbursement Path (if applicable):
  - For some proposals (e.g., development of direct-to-consumer health and/or wellness aids), a reimbursement path may not be needed.
  - For those applicants who are proposing a product or service that is envisioned to be reimbursable, have the applicants defined similar products or services that are currently covered for the indication?
  - Have the applicants identified the relevant CPT/DRG/APC codes and the associated reimbursement rates? If no reimbursement code currently exists, how would the costs of the technology or service be covered?

## Process

Applicants are required to submit a Letter of Intent (LOI) for this proposal on or before Tuesday, November 12, 2019, at 5 p.m. CT. Letters of Intent must be submitted via [Grants@Heart](mailto:Grants@Heart).

Please note: Only applicants who submit a LOI and are INVITED to apply may submit a full application. AHA will contact applicants as soon as possible regarding their status after LOI review.

Peer Review – two phases of Peer Review, approximately 4-5 weeks apart.

- Phase I – There will be science review of the Center Project(s), a review of the Center and a technical review of the Center Project(s). The science peer review committee will conduct an expert study section review of the proposed project, and the Center's potential to contribute to a NETWORK PROJECT and the COLLABORATIVE. A Technical (or Technology) Review Panel will provide input and insights on the proposed center project(s), with a particular focus on the translational potential of the technology being proposed.

Centers with success in this Phase I of peer review will be invited to Phase II.

- Phase II – In a face to face review with the Peer Review Committee, invited applicant teams will present responses to the questions from Phase I peer review, provide further details on their proposed center project and their capabilities to be successful collaborative partners on the NETWORK PROJECT and the ultimate COLLABORATIVE in a Reverse Site Visit

For more information on Peer Review, including criteria and information on reverse site visits, see SFRN General Information page on the [AHA SFRN website](#).

*An applicant is prohibited from contacting AHA peer reviewers. This is a form of scientific misconduct and will result in removal of the application from funding consideration and institutional notification of misconduct.*

### Relevant 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 compliance with this policy.

**Open Data:** Any research data that is needed for independent verification of research results must be made freely and publicly available and placed in the AHA's Precision Medicine Platform (if it matches the type of data the PMP accepts) or in an AHA approved repository within 12 months of the end of the funding period (and any no-cost extension). Please see AHA's [Open Science Policy page](#).

The projects described can have no scientific or budgetary overlap with other funded work. Any inventions, intellectual property, and patents resulting from the initial funding of the NETWORK or the COLLABORATIVE by AHA are governed by the AHA 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. To review AHA policies, go to AHA's [Policies Governing All Research Awards](#).

Work funded via the COLLABORATIVE mechanism will be considered "work for hire" under contract with the AHA, with the resulting intellectual property and patent rights governed by the AHA COLLABORATIVE agreements, unless other terms are more appropriate for a project, such as a joint development or licensing agreement.

Award Selection and Other Policies: Final funding recommendations will be approved by the AHA.

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