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Arrhythmias and Sudden Cardiac Death

Strategically Focused Research Network

Key Dates

RFA Posted:	Sept 28, 2018
Letter of Intent Deadline:	Dec 4, 2018
Application Deadline:	Feb 7, 2019
AHA Peer Review:	Spring 2019
Notification of Awards:	June 2019
Award Start Date:	July 1, 2019

Award Objectives and Characteristics Announcement

The American Heart Association announces a Request for Applications for the Arrhythmias and Sudden Cardiac Death Strategically Focused Research Network.

Purpose

A leading priority of the AHA is to fund research that increases an understanding of the etiology, pathophysiology, treatment and prevention of cardiovascular diseases and stroke. The intent of this initiative is to support a collaboration of basic, clinical and population researchers from different disciplines whose collective efforts will lead to new approaches to study arrhythmias and sudden cardiac death (SCD).

This Strategically Focused Research Network provides the AHA with a mechanism to advance the understanding of the causes, pathophysiology, risk factors, epidemiology, prevention and treatment of arrhythmias and SCD. Applicants are requested to focus on areas that could have an extraordinary impact on cardiovascular disease and stroke outcomes.

Topics of Interest

Specific Questions to be Answered by this Grant Opportunity

The intent of this initiative is to support a collaboration of basic, clinical and population researchers from different disciplines whose collective efforts will lead to new approaches to study arrhythmia and SCD. Population studies are inclusive of projects ranging from cohort studies to translational work involving community interventions.

Each Center must have three (3) research projects in at least two (2) of these three (3) disciplines: basic, clinical, and population science. All projects must focus on arrhythmias and SCD research.



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Note: Centers are highly encouraged, where applicable, to align with AHA initiatives focusing on arrhythmias or SCD and/or AHA initiatives addressing the use of digital technology to improve health outcomes, for example solutions developed in collaboration with the [Center for Health Technology & Innovation](#).

Researchers are encouraged to use AHA metrics as their research outcomes measures, health metric scores, or improving health metric scores. Researchers are encouraged to address interventions where efficacy can be measured via AHA mission metrics.

The following are illustrative descriptions of overarching themes that could be addressed by a Center. Successful applications will provide strong evidence of synergy among the proposed projects and will address at least one of the issues below or an alternate issue of equal importance.

Basic Mechanistic Pathways

There is an interest in gaining further insight into the key mechanistic factors associated with arrhythmia disorders and SCD.

Prevention, Risk Factors and Diagnosis

Prevention of arrhythmias and SCD are key initiatives in improving cardiovascular outcomes. It will be important to better identify and understand some of the key therapeutic targets for primordial, primary and secondary prevention.

Some key questions surround the identification of risk factors for arrhythmia and SCD and how they differ across the life span. New prediction models are also needed to better identify those at risk and determine preventative therapies.

New strategies are needed to improve the diagnosis of arrhythmias. These may include newer biomarkers, imaging modalities and wearable monitors which may play a key role in improving the identification and risk stratification of those at risk for arrhythmias and SCD.

Genetics/Genomics

A more in-depth understanding of the role of molecular and genetic testing (genotyping, polygenic risk scores) in primary prevention of arrhythmias and SCD is needed. In addition, the impact of inherited genetic conditions across the lifespan and how they influence the level of risk in different populations is a key area of interest.

Treatment/Intervention

Some key questions surround the use of cardiac implantable electronic devices (CIEDs) and the shared decision-making process regarding implantation. New strategies are also needed for the treatment of non-shockable rhythms. In addition, more insight is needed into how to better utilize pharmacotherapy and CIEDs in older patients.

Outcomes, Quality of Care

There are questions of importance which center around the impact of pre-hospital and post cardiac arrest care on outcomes, especially neurologic recovery. A focus of research may include determining best practices for cardiac arrest training and how these could be implemented nationwide to improve post arrest morbidity and mortality. There is also an



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interest in partnering with other groups and organizations to collaborate and share data to advance the understanding of the causes, pathophysiology, risk factors, epidemiology, prevention and treatment of arrhythmias and SCD.

Award Details

Duration: 4 years with the opportunity for up to a 12-month No-Cost Extension.

Award Amount: The maximum budget amount a Center applicant may request is \$3,709,200. The AHA reserves the right to determine the final award amount for competitive projects based on need and potential impact.

Number of Awards: The Arrhythmias and SCD Strategically Focused Research Network will be comprised of four (4) Center grants*. Awards will be selected based on merit.

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

Subjects/Study Cohorts: All Network studies must include under-represented minorities, which is congruent with AHA's mission. All Centers must address any rationale for the non-use of underrepresented minorities in their subject populations.

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

What is a non-research-intensive institution? To be considered a 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 each of four of the last seven years.

The following is a list of institutions, and their relevant components (defined above), that are currently financially ineligible. NIH updates this list annually in April. An application from an institution that becomes ineligible after the application is submitted will remain under review and in consideration for funding. [List of Ineligible Institutions \(PDF\)](#)

Appropriate Budget Items:

- Salary and fringe benefits of the Center Director, Training Director, Principal Investigators, three named fellows, 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 in accordance with institutional and AHA policies.



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- 10% institutional indirect costs may be claimed by one (1) institution.
- It is expected that each Center will earmark a percentage of their award (% of direct costs) to use toward collaborative efforts according to the schedule below.

Year	% of Direct Costs for Center
1	5% (\$42,150)
2	7% (\$59,010)
3	7% (\$59,010)
4	10% (\$84,300)

*These percentages are the minimum. It is expected that the percentages may be higher.

Collaborative efforts must be detailed in each annual scientific progress report. Money can be set aside as a specific budget line item, or line items may be earmarked or tagged as collaborative expenses (for example, travel funds can be considered collaborative efforts).

Examples of collaboration include but are not limited to:

- Sending fellow or PI to another center in Network to learn a technique/skill
- Collaborating with Network investigator, on new or tangential project or publication
- Hosting Network fellows for relevant symposium

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 American Heart Association.

Interim Assessment: Awardees must report progress on a minimum annual (once per year) basis. Progress 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 Oversight Advisory Committee reserves the right to request additional updates, site visits, or reporting.

Peer Review Criteria

Each **PROJECT** within a Center application will be scored individually according to the criteria below.

Projects – Potential impact of the project on research in the field of the designated research topic; strengths of applicant investigators (qualifications, expertise and productivity); potential for collaboration or synergy of projects; scientific content; background; preliminary studies; detailed specific aims; approach detail; analytical plan; sample size; data management; significance; innovation; individual project scientific merit; and total project coordination (within and among projects). Projects will be rated on the following areas:



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- **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? *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?
- **Investigator:** 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)?
- **Significance:** Does this study address an important problem broadly related to cardiovascular disease or stroke? If the aims of the application are achieved, how will scientific knowledge or clinical practice 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?*
- **Synergy:** How does this project enhance the Center and the two additional science projects? How does this project allow the Center and two additional science projects to out-perform were it to be a standalone project? ***Only projects that demonstrate synergy will move forward to Phase II.***

CENTER application scoring is based on the criteria below.

- **Synergy** – A clear vision of scientific direction is expected. A Strategically Focused Research Center should be viewed as a group of interrelated research projects, each of which is not only individually scientifically meritorious, but also complements the other projects and contributes to an integrating theme. Describe the rationale for the total program. Explain the strategy of achieving the objectives of the overall program and how each individual project relates to the strategy. Describe the synergies and interactions among projects and their investigators. Is there evidence of synergy among the projects and training component of the Center?



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- **Collaboration** – History of collaboration, as well as the ability and commitment to collaborate with other institutions, investigators and within the applicant institution as well as within the awarded Network. Defined and detailed process for collaboration with other sites in addition to within and among the proposed projects; plans to actively participate in a collaborative network. Evidence of formal training in leadership skills with an emphasis on collaborative leadership will be favorably reviewed. What collaborations do you envision between investigators working on individual projects?
- **Interaction Plan within and among this Network and other AHA Networks** (if appropriate) – Plan for and commitment to sharing knowledge and methods, providing a stimulating atmosphere for research collaborations, and providing networking opportunities for trainees. Cited strategies 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.
- **Training component** – 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; qualifications and characteristics of current and anticipated trainees; didactic and practicum training opportunities; plan for the selection of prospective fellows and how funded fellows' ongoing progress will be guided via an individual development plan (IDP) and evaluated at least annually. 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.
- **Center Team** – Qualifications of the Director to provide scientific and administrative leadership for the Center; experience and commitment of the nominated Director; quality of research team; qualifications of investigators and co-investigators; experience in the field of study outlined by the RFA; training experience.
- **Center Director** – Demonstrated ability to lead others, along with experience and commitment to the success of the Center, the projects contained within, and the Network. Documented evidence of willingness to collaborate with others outside their institution to share ideas, science, etc. to progress the field of research as outlined in the RFA.
- **Investigator team** – Qualifications of each PI to provide scientific and administrative leadership for their respective projects; demonstrated commitment of each PI, and experience with studies in the field outlined by the RFA; quality of interdisciplinary research team; qualifications of co- investigators; training experience.
- **Environment** – Institutional commitment, resources and facilities to sustain the Center; institutional resources available to complete the project; analytical resources available to the project; letter from Center Director's Department Head assuring the department and institution's support of the Center along with confirmation that the Center Director will



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devote at least 20% effort towards the Center. 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.

Process:

Peer Review of Submitted Applications

Two phases of face-to-face Peer Review of Submitted Applications take place and are typically held approximately 4-5 weeks apart.

- Phase I includes a written review of the science/projects
- Phase II includes a reverse site visit of a limited set of the applicants for reviewers to ask questions, listen to the teams describe their projects and identify degree of synergism between projects.

For more information on Peer Review of submitted applications, 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 Policies:

Public Access: The AHA requires that all journal articles resulting from AHA funding be made freely available in PubMed Central within twelve (12) months of publication. It is 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 twelve (12) months of the end of the funding period (and any no-cost extension).

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

Other: The projects described can have no scientific or budgetary overlap with other funded work. Any inventions, intellectual property, and patents resulting from this funding are governed by the AHA Patent, Intellectual Property and Technology Transfer Policy. The applicant/awardee and institution are responsible for compliance with all American Heart Association 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: [AHA Policies Governing All Research Awards](#)



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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 website](#).

Application Submission

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