

# American Heart Association

## *Atrial Fibrillation*

### Strategically Focused Research Network

#### Key Dates

RFA Posted:	Sept 29, 2017
Letter of Intent Deadline:	Nov 30, 2017
Application Deadline:	Jan 31, 2018
Peer Review of submitted applications:	Spring 2018
Notification of Awards:	June 2018
Award Start Date:	July 1, 2018

#### Award Objectives and Characteristics Announcement

The American Heart Association (AHA) announces a Request for Applications for the [Atrial Fibrillation Strategically Focused Research Network](#).

Unique to this Strategically Focused Research Network, special project funding is also available through a collaboration between the Patient-Centered Outcomes Research Institute (PCORI) and the AHA. The PCORI/AHA funding initiative seeks to use comparative effectiveness research focused on **Decision-making and Choices to Inform Dialogue and Empower A-Fib Patients (DECIDE)**. The rationale is to enrich the overall scientific and community deliverables of the Network by testing and delivering a specific set of Shared Decision-Making Tools to help patients with atrial fibrillation and their clinicians engage in a meaningful conversation and collectively arrive at the best individual choice for the use of oral anticoagulants.

#### Purpose

Atrial Fibrillation (AFib) is an irregular heartbeat that can lead to stroke and other heart-related complications. In atrial fibrillation, the upper chambers of the heart (the atria) beat rapidly and irregularly instead of beating effectively to move blood into the ventricles. This irregular rhythm, and the underlying atrial myopathy, can lead to the development of atrial thrombi and emboli to the brain, resulting in a range of health issues, which include stroke and heart failure.

An estimated 6.1 million or more Americans were living with AFib as of 2010, making it the most common heart abnormality in the U.S. That number is expected to rise to 12.1 million by 2030. The risk of AFib increases with age, and is the most common heart arrhythmia in persons over the age of 65.

AFib can be caused by many distinct disorders, including those like hypertension or valvular heart disease that lead to chronically increased left atrial pressure. AFib is the most common complication after heart surgery, and can be seen with other conditions such as inflammation of the heart muscle or the tissue surrounding the heart (myocarditis or pericarditis, respectively), excessive thyroid hormone, or acute or chronic lung disease. Genetic

markers of susceptibility to AFib have also been identified. In some cases, multiple potential causes of AFib are present, and in others, the cause cannot be determined.

This Strategically Focused Research Network provides the AHA with a mechanism to enhance the understanding of the causes, biology, pathophysiology and epidemiology of Atrial Fibrillation, and to develop more effective ways to prevent and treat it with an ultimate improvement in patient outcomes. Testing effective methods for such improvement in outcomes will be provided by special funding from PCORI and the AHA. In brief, there is a large proportion of individuals with AFib who are not prescribed appropriate long-term oral anticoagulation (OAC) therapy, despite the fact that OAC is understood to reduce the risk of stroke associated with AFib by >60% [1, 2, 3]. The DECIDE Center will support the creation or adaptation of decision tools, validate them, and directly compare and evaluate shared decision-making tools and approaches in patients with atrial fibrillation and their clinicians, using comparative effectiveness research to address this important gap in evidence-based therapy.

**Specific Questions to be Answered by AHA Center Grant Applicants (See the next section for the “Specific Questions to be Answered by PCORI-AHA DECIDE Center Applicants” if you are applying for that initiative only.)**

Applicants are requested to focus on one specific impact question below that could have an extraordinary impact on cardiovascular disease and stroke. An institution may apply for an AHA Center and the PCORI-AHA DECIDE Center, although separate teams are required, and the DECIDE team should follow the directions in the “Specific Questions to be Answered by PCORI-AHA DECIDE Center Applicants” section below.

Each AHA Center, except the DECIDE 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 Atrial Fibrillation research.

Note: Centers are highly encouraged, where applicable, to align with AHA initiatives which address Atrial Fibrillation (e.g. AHA’s [my AFib experience](#)).

**Topics of Interest**

The following is an illustrative list of overarching themes that could be addressed by an AHA 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**

- How does AFib lead to cardiomyopathy? Is it a rate-related phenomenon? Is irregularity of rhythm itself in the absence of rapid rates enough to cause cardiomyopathy? What demographic, clinical, genetic, and arrhythmia characteristics predispose to the development of cardiomyopathy in the setting of a persistent atrial arrhythmia?
- What are the underlying associations between genetic, genomic, proteomic and metabolomic determinants and risk for AFib?
- Can we develop new AFib animal models with “human” electrophysiological features to define and test novel AFib therapeutics?
- What is the underlying mechanism of AFib and how can we optimize the development of antiarrhythmic drug(s) and/or catheter-based or surgical therapy such as ablation?

### Comorbidities

- What are the mechanisms by which aging results in AFib?
- AFib is associated with dementia. What mechanisms account for the association between AFib and dementia?
- What are the factors associated with progression of atrial fibrillation?
- What are the mechanisms by which HFPEF triggers AFib?
- What is the interaction between exercise and risk of AFib and where is the line between long-term exercise training and a rise in risk for AFib? What innovative tools can be implemented to measure the interaction?
- Are there specific dietary components – such as foods that contain magnesium, potassium, macronutrients, omega-3 fatty acids, alcohol, caffeine, etc. – which may modulate (increase or decrease) triggers of atrial fibrillation?

### Social Determinants/Quality of Care

- How can we improve patient and caregiver decision-making to convey information about options to reduce risk of stroke? For example, is there new and innovative technology or effective decision-making tools to improve risk and manage atrial fibrillation?
- How can we improve patient and caregiver decision making to convey information about options to reduce risk of stroke for older adults with executive cognitive decline (which is predictable with AFib) that still enable meaningful decision-making capacity?
- What tools could we implement for health care providers and patients to diagnose and manage atrial fibrillation?
- What tools could we implement to decrease the rate of perioperative atrial fibrillation, the most common and costly complication after cardiac surgery, that takes advantage of already known mechanisms to decrease the rate?
- What impact do race, socio-economic status, and accessibility of care have on outcomes in AFib patients?

## Specific Questions to be Answered by PCORI-AHA DECIDE Applicants

AHA and PCORI are collaborating to support the creation or adaptation and testing of decision aids to be used as part of a process of shared decision-making among patients, clinicians, and caregivers to help determine whether oral anticoagulation (OAC) should be used and which OAC best aligns with a given patient's goals and preferences. An institution may apply for an AHA Center and/or the PCORI-AHA DECIDE Center, although separate teams are required for each funding opportunity.

### Topic of Interest

Several factors must be taken into account by clinicians prescribing OACs and by their patients considering OACs for the prevention of stroke in patients with AFib, including the risk of stroke and the risk of bleeding. [4] Warfarin, a vitamin K antagonist that inhibits the body's synthesis of clotting factors, has been the mainstay of OAC treatment for many decades, but it requires close monitoring. Since 2010, four novel OACs (NOAC), also called "direct-acting oral anticoagulants," have become available that do not require close monitoring with frequent blood draws and are generally associated with lower bleeding risk; however, they are much more expensive than warfarin, are cleared by the kidneys to significant degrees (ranging from 35% to 80%, and

therefore require caution in patients with impaired renal function),[5] and are not as easily reversed in the case of bleeding.

Helping clinicians and patients understand the importance of anticoagulants, as well as the risks and benefits of OAC choices, may encourage shared decision-making between clinicians and patients and improve rates of prescription and adherence. A recent systematic review suggests that there is a paucity of tools available to help patients with AFib become appropriately informed and to help clinicians engage in shared decision-making regarding the use of OACs.[6] The best approaches for the use of such tools, once developed, would also require a study of their effectiveness in improving outcomes.

As part of the research plan for this proposal, the applicant should:

1. Consult with patients, clinicians, and other relevant stakeholders to determine relevant questions and outcomes around decision making for the use of OACs for AFib. A stakeholder advisory panel comprising relevant stakeholders should be part of the development and ongoing conduct of any proposed research project.
2. Conduct an environmental scan of existing decision aids available and update the current published and gray literature on the state of decision aids available to inform choice of OAC for patients with AFib. The literature must evaluate current knowledge about heterogeneity of treatment effect for relevant patient subgroups for the effectiveness of different anticoagulant medications. Including appropriately diverse patient subgroups is essential.
3. Develop or, preferably, adapt an existing decision tool and implementation program. Provide rationale for the development vs. adaptation decision. If adapting an existing instrument, provide data on prior validation and testing work for the aid. For new development or adaptation, provide a theoretical framework and explicit plan for development of the decision aid. In both cases, include plans for ensuring that the aid is consistent with best practices and quality criteria as specified by the International Patient Decision Aid Standards (IPDAS) Collaboration. Innovative approaches to informing patients and helping them to choose options consistent with their preferences are encouraged. Descriptions of tools must include the following features:
  - a. Incorporates the risks of stroke and bleeding and takes into account other relevant factors, including convenience, the need for monitoring, and the potential for benefits and harms, including side effects, of all OACs;
  - b. Includes a tool for patients and caregivers to prepare for conversations with healthcare providers, presenting the information in lay language that takes into account variability in health literacy and numeracy, as well as helps to clarify patient values for the potential benefits and harms involved;
  - c. Considers elderly patients and those with co-morbidities;
  - d. Assists patients in determining whether to use OACs and, if so, which OAC to use;
  - e. Includes a tool for clinicians to assist with engaging their patients in shared decision-making, to determine whether to prescribe an OAC and, if so, which OAC to recommend;
  - f. Incorporates programs or methods to educate clinicians and improve adherence to guideline-based practice in prescribing OACs to patients with AFib.

4. Test and validate the tool and implementation program to measure the following:
  - a. Outcomes of understandability, knowledge, decision conflict, satisfaction with decision, shared decision making, and care concordant with patient preferences.
  - b. Prescription of an OAC, including which OAC is prescribed.
  - c. Adherence to an OAC.
  - d. Clinical outcomes, including stroke and bleeding outcomes.

\*\*Testing and validating the tool within clinical cohorts of the four Centers in the AFib Strategically Focused Research Network is highly encouraged.

5. Conduct a comparison with other educational or shared decision-making interventions, for any of the following:
  - a. Comparing with one or more other decision aids or tools;
  - b. Comparing a patient-facing decision aid with a clinician education strategy; and/or
  - c. Comparing use of a self-administered decision aid (used to prepare patients in advance of the clinician visit) vs. an encounter decision aid (used at the time of the visit).

Applicants should include a broadly-representative population and include vulnerable populations, such as ethnic minorities and individuals with low literacy. The population should also include a broad range of stroke and bleeding risk. A range of both ages and levels of comorbid illness should be represented. While applicants may develop a decision aid de novo, or preferably adapt an existing aid, it is expected that the majority of the time and budget will be aimed at establishing comparative effectiveness rather than developing and validating the intervention. Adaptation of existing tools should address updating the tool to include the current range of therapeutic options and a range of health literacy and relevant cultural differences in the US population.

The population(s) in which the tool is developed and/or tested should be well-described and defended in the application. Testing and validating the tool within clinical cohorts of the four Centers in the AFib Strategically Focused Research Network is highly encouraged. Consideration should be given to conducting a multisite comparative effectiveness study, with preference towards incorporating other sites that are part of the AHA Strategically Focused Research Network on AFib into the study. Thus, in-depth early discussion and collaboration of scientific teams applying for an AHA Center and the DECIDE Center may be helpful in laying the foundation to prepare competitive awards.

Intellectual property issues of the tool must be addressed in the application. Please note that the resulting tool must be placed in the public domain.

## Award Details

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

Award Amount: The maximum budget amount an AHA Center applicant may request is \$3,709,200. The maximum budget amount the PCORI – AHA/ASA Collaborative: **Decision-making and Choices to Inform**

Dialogue and Empower A-Fib Patients (DECIDE) Center applicant may request is \$5,000,000. The AHA reserves the right to determine the final award amount for competitive projects based on need and potential impact.

Number of Awards: The Atrial Fibrillation Strategically Focused Research Network will be comprised of four (4) AHA Center grants and one (1) PCORI – AHA/ASA Collaborative: **Decision-making and Choices to Inform Dialogue and Empower A-Fib Patients (DECIDE) Center** grant. 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.

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.
- PCORI requires that findings from the research projects it supports undergo peer review of its findings and make the findings publicly available, per its published guidelines. Applicants should plan to request support for this peer review process during the timeline of the study. The link to the PCORI peer review process can be found [here](#).
- 10% institutional indirect costs may be claimed by one (1) institution.
- It is expected that each AHA Center and the DECIDE Center will earmark a percentage of their award (% of direct costs) to use toward collaborative efforts according to the schedule below. For the DECIDE Center, it is expected that the completion of the development and validation, and subsequent initiation of the comparative effectiveness trial, will happen no later than in year 2 of the project. Therefore, the estimated minimum costs for collaboration are increased in year 2 in the expectation of collaboration with other sites for the effectiveness evaluation.

Year	% of Direct Costs for AHA Center	% of Direct Costs for PCORI-AHA DECIDE Center
1	5% (\$42,150)	5% (\$62,500)
2	7% (\$59,010)	10% (\$125,000)*
3	7% (\$59,010)	10% (\$125,000)*
4	10% (\$84,300)	10% (\$125,000)*

\*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:

- testing of tools designed by the DECIDE study team in the clinical cohorts within the AHA Centers in the Strategically Focused Research Network (Centers proposing clinical projects must document that

they have a sufficient volume of patients to assure that robust studies may be conducted in interaction with the DECIDE Center and other AHA Centers.)

- sending fellow or PI to another center in Network, including the DECIDE Center, to learn a technique/skill
- collaborating with Network investigator, including the DECIDE Center, 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 an AHA Center (not the DECIDE 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:

- **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 *build healthier lives, free of cardiovascular diseases and stroke* and its commitment to work for health equity for *all Americans*?
- **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 2.**

AHA **CENTER** application scoring is based on the criteria below.

- I. **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?
- II. **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 a sufficient volume of patients to assure that robust studies may be conducted in interaction with the DECIDE Center and other AHA Centers.

- III. **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.

- IV. **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.
- V. **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.
- VI. **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.
- VII. **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 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.

The **DECIDE Center** application scoring is based on the criteria below.

- I. **Potential for the study to fill critical gaps in evidence** – The application should address the following questions: Does the application convincingly describe the clinical burden? Does the application identify a critical gap in current knowledge as noted in systematic reviews, guideline development efforts, or previous research prioritizations? Does the application identify a critical gap in current knowledge, evidenced by inconsistency in clinical practice and decision-making? Would research findings from the study have the potential to fill these evidence gaps?
- II. **Potential for the study findings to be adopted into clinical practice and improve delivery of care** – The application should describe how evidence generated from this study could be adopted into clinical practice and delivery of care by others. The application should address the following questions: Does the application identify who will make the decision (i.e., the decision maker) or use (i.e., the end-user) the study findings (not the intervention) this study produces, such as local and national stakeholders? Does the application identify potential end-users of study findings – such as local and national stakeholders – and describe strategies to engage these end-users? Does the application provide information that supports a demand for this kind of a study from end-users? Would this study’s research findings have the potential to inform decision-making for key stakeholders? If so, provide an example. How likely is it that positive findings could be reproduced by others, resulting in improvements in practice and patient outcomes? Identify the potential barriers that could hinder adoption of the intervention by others. Does the application describe a plan for how study findings will be disseminated beyond publication in peer review journals and national conferences?
- III. **Scientific merit (Research design, analysis, and outcomes)** – The application should show sufficient technical merit in the research design to ensure that the study goals will be met. The application should also address the following questions: Does the application describe a clear conceptual framework anchored

in background literature which informs the design, key variables, and relationship between interventions and outcomes being tested? Does the Research Plan describe rigorous methods that demonstrate adherence to the [PCORI Methodology Standards](#)? Is the overall study design justified? Are the patient population and study setting appropriate for the proposed research question? Does the application provide justification that the outcome measures are validated and appropriate for the population? Are each of the comparators (e.g., active intervention arm and comparator arm) described clearly and well-justified? If “usual care” is one of the arms, is it adequately justified and will it be sufficiently measured? Are the sample sizes and power estimates appropriate? Is the study design (e.g., cluster randomized design, randomized controlled trial, or observational study) accounted for, and is the anticipated effect size adequately justified? Is the study plan feasible? Is the project timeline realistic, including specific scientific and engagement milestones? Is the strategy for recruiting participants feasible? Are assumptions about participant attrition realistic, and are plans to address patient or site attrition adequate?

- IV. **Investigator(s) and environment** – This criterion should assess the appropriateness (e.g., qualifications and experience) of the investigator(s)/team and the environment’s capacity (e.g., resources, facilities, and equipment) to support the proposed project. It should not be an assessment of the institution’s quality. The application should also address the following questions: How well-qualified are the PIs, collaborators, and other researchers to conduct the proposed activities? Is there evidence of sufficient clinical or statistical expertise (if applicable)? Does the investigator or co-investigator have demonstrated experience conducting projects of a similar size, scope, and complexity? If the project is collaborative or dual-PI, do the investigators have complementary and integrated expertise? Are the leadership, governance, and organizational structures appropriate for the project?

**Center Team** – How well-qualified is the Director to provide scientific and administrative leadership for the Center? How much experience and commitment does the nominated Director have? What is the quality of the research team? Do the investigators and co-investigators have the experience in the field of study outlined by the RFA? Do they have the training experience?

**Center Director** – How well-qualified is the Center Director in demonstrating leadership? As well as demonstrating experience and commitment to the success of the Center, the projects contained within, and the Network? What is the documented evidence of the willingness of the Center Director to collaborate with others outside their institution to share ideas, science, etc. to progress the field of research as outlined in the RFA?

**Dual-PI Option Only** – Does the Leadership Plan adequately describe and justify PI roles and areas of responsibility? Is the level of effort for each team member appropriate for successfully conducting the proposed work? Does the application describe adequate availability of and access to facilities and resources (including patient populations, samples, and collaborative arrangements) to carry out the proposed research? Is the institutional support appropriate for the proposed research?

- V. **Patient-centeredness** – The application should demonstrate that the study focuses on improving patient-centered outcomes and employs a patient-centered research design (i.e., a design informed or endorsed by patients). (Note: The study can be patient-centered even if the end-user is not the patient, as long as patients will benefit from the information.) The application should also address the following questions: Does the application include a thorough description about which outcomes (both benefits and harms) are important

to patients, and are those outcomes included in the study plan? Does the application provide information that indicates that closing the evidence gap is important to patients and other stakeholders? Are the interventions being compared in the study available to patients now, and are they the best options for comparison (including whether they would be chosen by patients and their healthcare providers for managing the condition being studied)?

VI. **Patient and stakeholder engagement** – The application should demonstrate the engagement of relevant patients and other stakeholders (e.g., patients, caregivers, clinicians, policy makers, hospitals and health systems, payers [insurance], purchasers [business], industry, researchers, and training institutions) in the conduct of the study. Quality of engagement should be evaluated based on scope, form, and frequency of patient and stakeholder involvement throughout the research process. The application should also address the following questions: Does the application provide a well-justified description of how the research team incorporates stakeholder involvement? Does the study include the right individuals (e.g., researchers, patients, caregivers, clinicians, policy makers, and other healthcare system stakeholders) to ensure that the projects will be carried out successfully? Does the application show evidence of active engagement among scientists, patients, and other stakeholders throughout the research process (e.g., formulating questions, identifying outcomes, monitoring study, disseminating, and implementing)? Is the frequency and level of patient and stakeholder involvement sufficient to support the study goals? Is the proposed Engagement Plan appropriate and tailored to the study? Are the roles and the decision-making authority of all study partners described clearly? Are the organizational structure and resources appropriate to engage patients and stakeholders throughout the project?

VII. **Collaboration** – The application should demonstrate a 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. Applicants should define and detail the process for collaboration with other sites in addition to within and among the proposed projects; along with 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.

**Interaction Plan within and among this Network and other AHA Networks:** If appropriate, the applicant should plan for and commit to sharing knowledge and methods, as well as providing a stimulating atmosphere for research collaborations, and providing networking opportunities for trainees. Applicants should cite strategies for communication and interaction among the Centers.

VIII. **Training component** – The application should provide a plan that includes qualifications and characteristics of 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. The application should also include a plan for involving fellows in annual Center meetings and potential Center-to-Center visits, along with identifying potential opportunities for fellows to work with established investigators at other network Centers, ability to track trainees, and conferences and meeting participation for trainees.

**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 or designated PCORI 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 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 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 and PCORI's [policy and process](#) for Peer Review (of research findings).

Institutional Partnership Policy: Each AHA 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. This is not a requirement of DECIDE Center applicants.

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](#)

### **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.

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## References

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