

2022 SFRN on the Science of Diversity in Clinical Trials

Key Dates

RFA Posted	Oct. 26, 2021
Required Pre-proposal Deadline	Dec. 7, 2021
Application Deadline	Jan. 27, 2022
AHA 2-phase Peer Review	Feb-March 2022
Notification of Awards	late-March 2022
Award Start Date	April 1, 2022

There are two (2) funding opportunities through this RFA:

1. Network Center
2. Training Center*

* Those submitting a Network Center application are also permitted to apply for the Training Center.

An institution may apply for one or both funding opportunities.

A Director may only be a director on ONE of the above, even if the institution is funded for both a Network Center and the Training Center.

Important Notes

- Proposals must be received no later than 3 p.m. Central Time on the deadline date. Early submission is encouraged.
- Potential applicants should review the Features of All AHA Awards on the [AHA Application Information](#) page for answers to commonly asked questions about eligibility and award details.

- Full proposals must be submitted electronically via [ProposalCentral](#). **ONLY applicants who have submitted a pre-proposal may submit a full proposal.**
- For full proposals: **Any individual who is applying as a Center Director, a Project PI or a Training Center Director must be an [AHA Professional Member](#).** Join or renew when preparing an application in Proposal Central, online, or by phone at 301-223-2307 or 800-787-8984. Membership processing takes 3-5 days; do not wait until the application deadline to renew or join. This requirement is not applicable for the pre-proposal stage.

Required Pre-Proposal (formerly known as Letter of Intent - LOI)

Each Center Director is required to send a pre-proposal to StrategicAwards@heart.org no later than Tuesday, December 7, 2021, at 3 pm Central Time.

The pre-proposal must include the following information:

- Name and institution of the Center Director and each Project PI;
- Network title, and title and performance site of each proposed project. If a Training Center application will be submitted, also include the name of the proposed Director;
- If the Center Director is not at an institution of higher learning focused on the education of Black/Hispanic/American Indian/non-White students, they must partner with an institution meets this requirement. (See "Study Populations - Additional Expectations and Opportunities" below.) The pre-proposal **must include a letter from a Senior Institutional Official** (e.g., Director, C-level Hospital administrator, Healthcare Center Director, etc.) **at that partnering institution** indicating they meet the partnering requirement. AHA staff will review for compliance. A non-complying institution will not be permitted to submit a full application.

OVERVIEW

Purpose

The American Heart Association (AHA) announces a Request for Applications (RFA) for a Strategically-Focused Research Network (SFRN) on the Science of Diversity in Clinical Trials (SDCT).

The United States is a recognized leader in fundamental biological and biomedical discovery.

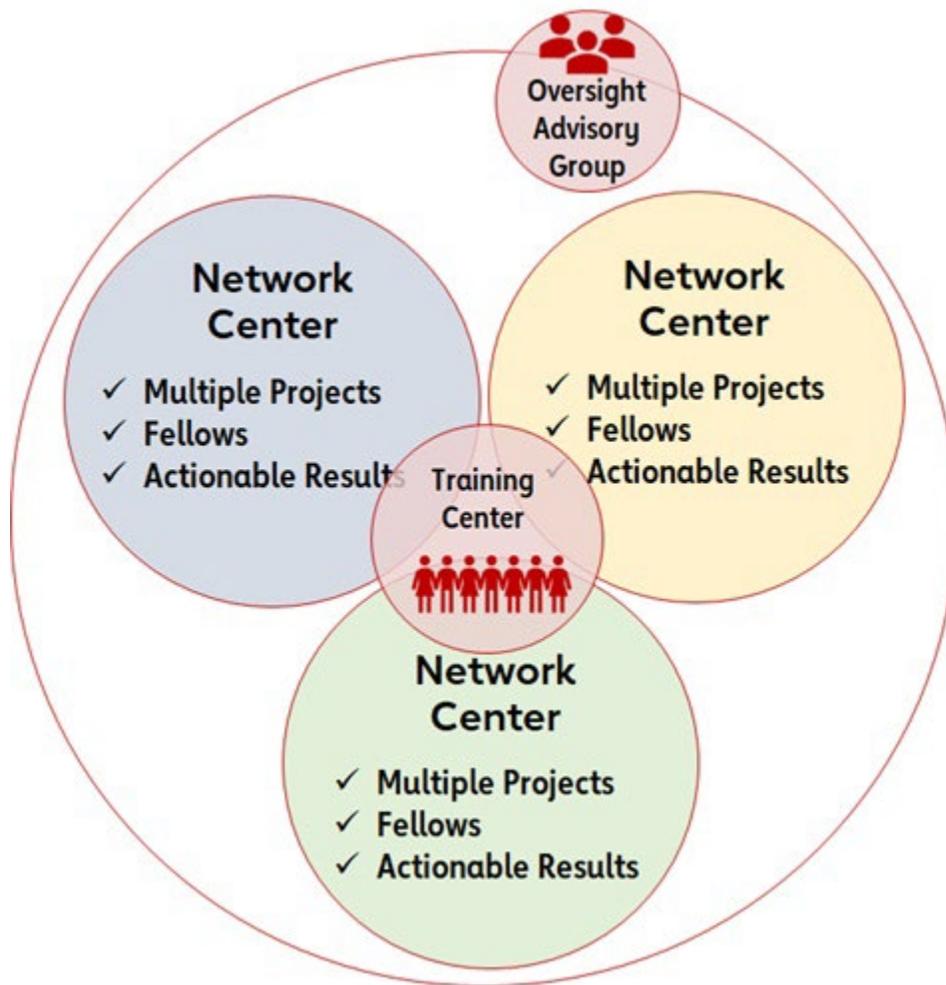
Despite this abundance of discovery science, the US has been considerably less effective in translating those discoveries to clinical practice. A particularly challenging problem is the fact that clinical trials, the seminal first step in delivery of new medicines and therapies, typically do not adequately include the diverse populations who live in our communities (Arevalo et al., *Contemp Clin Trial Comm* 4: 52, 2016; Clark et al., *Curr Prob Cardiol* 44:148, 2019; Knepper and McLeod, *Nature*, 557: 157, 2018; Taani et al, *Contemp Clin Trial Comm* 17: 100533, 2020). Because safety and effectiveness may vary in different populations, the lack of diversity in clinical trial enrollment compromises the health care that can be delivered to those who are excluded. Whereas this problem has been recognized for decades, little progress has been made in overcoming this critical deficiency.

Given that the U.S. Census Bureau estimates show that 50% of the US population will be other than non-Hispanic white by 2045, it is imperative that clinical trials reflect the needs of an increasingly diverse population. Moreover, whereas the challenges of diverse inclusion of trial participants is prominent in the United States, a lack of sufficient diversity is also consistently observed in internationally-conducted clinical trials (FDA 2019 Drug Trials Snapshots, <https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshots>). This is thus an issue with far-reaching implications for the health of the global population.

With the establishment of the SFRN on the Science of Diversity in Clinical Trials, the AHA will identify solutions underlying the inequitable participation of diverse individuals in clinical research, and the associated health inequities it creates. This initiative will be instrumental in achieving AHA's 2024 Impact Goal: to advance cardiovascular health for all, including identifying and removing barriers to health care access and quality by 2024.

Network Overview and Structure

GENERAL OVERVIEW – This SFRN on the Science of Diversity in Clinical Trials will consist of at least three centers, each of which will propose novel research strategies to engage individuals from under-represented groups in clinical trials such that their participation in clinical trials aligns with the diversity of our communities. Funded centers will be expected to collaborate on solving the core issues underlying this problem, many of which are delineated below.



NETWORK CENTERS – Each center application will include two or three research projects. Proposed projects will have a common fundamental theme that will assess an intervention or approach to addressing diversity in clinical trials. Projects may all be from a single institution, or they may be from multiple institutions. Each center project will be led by a Project Principal Investigator (PI) and must have the necessary research team, required infrastructure and ability to recruit and retain a diverse group of study participants.

At least 25% of key personnel of the research team must be from a group that is under-represented in science and medicine (Black/African-American; Hispanic/Latino; Native American or Alaska Native; Hawaiian or other Pacific Islander; LGBTQ+; women).

An overall Center Director will also be a key component of each center. Each Center Director will facilitate activities within his/her/their center and work closely with the other Network Center Directors to facilitate activities across the Network, including end-of-network deliverables.

TRAINING CENTER – The Training Center will incorporate a multidisciplinary approach to provide robust research experiences, training, and mentorship to create the next generation of clinical trialists. The Training Center will develop science curriculum and career development training opportunities while working closely with Center Fellows and their mentors to optimize their success. As detailed below, all SDCT Fellows will be from groups who are under-represented in science and medicine.

In addition to facilitating the training of SDCT Fellows, training materials will also be developed and made available to the broader scientific community and other stakeholders, thus leveraging the evidence-based approaches resulting from the Network’s findings and recommendations.

NOTE: AHA anticipates (and welcomes) applications for research focused on cardiovascular, stroke and brain health conditions. Because the goal of this funding mechanism is broad understanding of the science of diversity in clinical trials, applications proposing studies that are not directly cardiovascular, stroke or brain health are also welcome. Ultimately, successful applicants will be those proposing innovative approaches to address the critical deficiencies of inclusion in clinical trials and the ability to persuasively demonstrate the broad applicability of their results.

Oversight Advisory Committee

To facilitate success of this SDCT SFRN, an Oversight Advisory Committee (OAC) will be established. The OAC will be comprised of volunteers who are subject matter experts in the focus areas and will include representation from diverse groups historically excluded from clinical trials. Through the American Heart Association’s community impact platforms, unique opportunities may be established to engage underrepresented communities and beneficiaries of the Network’s work in the research, oversight, or dissemination, in forms to be determined as the planning continues to take shape.

Anticipated Outcomes

This funding mechanism will establish a collaborative, multi-center network with a specific focus on the science underlying barriers to diversity in clinical trials. The network’s philosophy will be to meet diverse groups where they are and work with them to overcome the long-established barriers to their participation in clinical trials. We envision centers will be housed at academic health centers or other institutions that share the commitment to this challenge and can build relationships with the diverse populations required for its understanding. The Network Centers will create, implement and make available to the broader scientific community a body of evidence-driven approaches that will help to overcome historical and modern barriers to participation of under-represented individuals in clinical trials. In addition, through the training of postdoctoral fellows, this mechanism will help to develop the next generation of clinical trialists who are experienced in working with diverse and under-served populations.

Longer term, AHA envisions this multi-center, collaborative SFRN will evolve into the AHA Clinical Network for Health Equity. This network will have as its focus continued development and evaluation of further novel approaches to enhancing and ensuring diversity in clinical trials. In addition to addressing the science of diverse enrollment, it will continue to serve as a training site for the next generation of clinical trialists, and it will serve as an educational leader in disseminating best practices. Finally, the AHA Clinical Network for Health Equity will serve as a major partner on trials for which diverse enrollment is particularly challenging. Indeed, whereas an intra-network, collaborative study is not planned at the onset of the SDCT SFRN, once the network is established we envision addition of collaborative clinical trials or projects across the network. These collaborative trials will leverage the knowledge gained during the initial network projects, and will have the ability to utilize all assets and capabilities of the network sites. These projects/studies are anticipated to come from an array of clinical needs, including but well beyond those related to cardiovascular disease, stroke and brain health.

Representative Approaches Responsive to this RFA

The intent of this initiative is to support a collaborative network of researchers whose collective efforts will lead to breakthroughs in understanding the science of diversity in clinical trials. Reasons underlying the deficiencies in clinical trial inclusiveness noted above are multiple and complex. Identified barriers to diversity in clinical trials include but are not limited to:

- Access to Medical Care for Screening and Referral
- Trust/Overcoming Fear
- Cultural/Language Differences
- Logistics/Participant Access to Sites and Requirements
- Participant Availability (e.g. Employment Flexibility)
- Technology Access and Literacy
- Leadership: Lacking Representation, Incentives
- Inadequate Planning for Inclusion
- Structural Racism in Processes and Systems

Recognizing that circumstances for all individuals are unique, there are at least two broad categories of under-represented individuals who are currently excluded from the clinical research enterprise: 1) those to whom the opportunities to participate in Clinical Trials do not reach or who are not approached to participate; and 2) those who are reachable, but who choose not to participate because the potential benefits to them (e.g., improved medical care, availability of medications) do not outweigh overcoming the “costs” (such as those noted above) associated with participating in a clinical trial. Proposals seeking to develop and assess studies that may provide solutions for one or both of these populations of participants are appropriate.

In addition, applicants are encouraged to propose recruitment and/or retention strategies in one or more of the three ecosystems in the patient journey to clinical trials: community settings, healthcare settings, and the clinical trial context. Funded centers may have access to a planned or existing clinical trial, partner with a not-for-profit organization or commercial business undertaking a clinical trial, or offer their own novel approaches to enable practical insights and accelerate the potential for immediate model adoption. A network may address a single topic using one or more study populations with possible inclusion of comparator study arms. Alternatively, a network may propose to address multiple topics that are closely aligned thematically. Regardless of the project approach, successful applications will clearly convey the ability to address one or more issues that underlie lack of inclusion of diverse participants in clinical trials.

We envision Centers will be housed at academic health centers or institutions and collaborating local health clinics or community partners that can build required relationships with diverse populations. Centers proposing collaboration with relevant domains of research outside of traditional biomedical science (e.g., social science related to structural racism, public health, behavioral economics, personal health behaviors, psychology theory and marketing) are anticipated to be competitive.

Study Population(s)

- All proposed projects must include study participants who are under-represented in clinical trials and/or underserved with regard to healthcare delivery. For the purposes of this RFA, eligible study populations include, but are not limited to:
 - Black or African-American
 - Hispanic or Latino
 - Asian
 - Tribal, Pacific Islanders, etc.
 - Age 65 or Older, especially the very elderly (over 75)
 - Those suffering from dementia and other major disabilities
 - Women
 - LGBTQ+ individuals
- The overall makeup of the study population for each project (and thus the overall center) must include a delineation of the targeted underrepresented groups.
- It will be important for applicants to design studies that incorporate both realistic recruitment goals and sufficient statistical power to ensure valid results.

Additional Expectations and Opportunities

- Center applications from investigators at academic institutions that primarily serve individuals from groups who are under-represented in science (e.g., Historically Black Colleges and Universities (HBCUs), Hispanic-Serving Institutions (HSIs) and similar institutions noted below) are strongly encouraged to apply.
- In keeping with AHA’s commitment to diversity and inclusion and in alignment with the goals of this initiative, Center applications not originating from institutions with the above focus must partner with an institution focused on educating or serving under-represented individuals and communities. Investigators from these partnering institutions must be included in a substantive manner (see Projects section below). Examples of potential institutional partners include:
 - An institution of higher learning focused on the education of Black/Hispanic/American Indian/non-White students, such as a(n):
 - HBCU or Predominantly Black Institution
 - HSI
 - Tribal College or University or Native American-Serving, Nontribal Institution
 - Alaskan Native- or Native Hawaiian/Pacific Islander-Serving Institution
 - Other majority-non-white institution of higher learning
 - A non-profit community hospital or other research/care institution that:
 - serves a majority non-white population OR
 - is located in a non-urban, non-suburban setting (area population <250,000) OR
 - serves an underrepresented population not listed above (e.g., a federally qualified health center (FQHC)) OR
 - serves an elderly population and/or those suffering from dementia

APPLICATION DETAILS

Network Center Application Details

Duration: Four (4) years

Number of Awards: AHA anticipates awarding at least three (3) Center grants to establish the SDCT SFRN. Awardees will be selected based on scientific merit and how each group aligns with AHA’s mission and goals.

Award Amount: The maximum budget amount a Center applicant may request is **\$4,300,000**. The AHA reserves the right to determine the final award amount for competitive projects based on need and potential impact.

Appropriate Budget Items:

- Salary and fringe benefits of the Center Director, Principal Investigators, three named fellows, collaborating investigator(s), and other participating research staff or faculty.
- 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.
- Centers may use award dollars to pay for travel to two required face-to-face (as feasible), network-wide meetings each year and other meetings where SFRN research is presented. One semiannual meeting will be in the Fall. A second semiannual meeting will be held in the Spring; it is anticipated awardee Centers will host both meetings on a rotating basis. The purpose of both meetings is to share results across the network and identify and act on potential collaborative opportunities. Additionally, there will be virtual meetings if face-to-face travel is not available. More information will be provided upon award and once travel options become clear.
- Maximum of 10% institutional indirect costs may be claimed on the award.

Sample Center Budget	Center Totals
<p>Projects: TWO or THREE projects for four years. Maximum of \$3.242M to be divided between/among the projects. It is not required to spend funds equally across projects or years.</p>	\$3,242,000
<p>Fellows Each center must train 3 postdoctoral fellows over the four-year grant period (one fellow in years 1-2; one fellow in years 2-3; one fellow in years 3-4). Up to \$65,000 per fellow per year: salary + health insurance/fringe. Fellows must maintain a minimum of 75% effort to research training.</p>	\$390,000
<p>Center Leadership A maximum of \$50,000 salary plus fringe/benefits per year to cover effort associated with directing the Center. Center Director (CD) must commit at least 20% effort for these efforts.</p>	\$250,000
<p>Center Travel Costs Covers travel for Center personnel to attend network meetings and other integration activities. \$7,000 per year must be allocated to Center Travel.</p>	\$28,000
<p>Direct Costs (Total) Research Dollars</p>	\$3,910,000

Indirect Costs AHA Policy allows for a maximum of 10% for indirect costs	\$390,000
Total	\$4,300,000

Note for Center Applicants: The Center Director will be responsible for overseeing the total budget for his/her/their grant. If awarded, the principal investigators 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.

Directors and Principal Investigators of projects of the Centers:

- Must possess an MD, PhD, DO, DVM or equivalent doctoral degree at time of application.
- Must have a faculty or staff appointment.
- May hold another AHA award simultaneously.
- Must demonstrate a 20% minimum effort requirement for the Director and a 10% minimum effort requirement for Principal Investigators (PI) of Center projects. These responsibilities are mutually exclusive.

Directors must have one of the following designations:

- U.S. citizen
- Permanent Resident
- Pending Permanent Resident (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 U.S., having filed an Application for Employment Form I-765)
- G-4 Visa – family member of employee of international organizations and NATO

Principal Investigators of proposed projects must have one of the following designations:

- U.S. citizen
- Permanent Resident
- Pending Permanent Resident (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 U.S., having filed an Application for Employment Form I-765)
- E-3 Visa – specialty occupation worker
- H1-B Visa – temporary worker in a specialty occupation
- 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

Named Fellows

AHA's aim is to help end historical structures and workplace cultures that advertently or inadvertently treat people inequitably based on race, ethnicity, gender, sexual orientation, age, ability, veteran status or other factors. Therefore, each fellow named to the SDCT SFRN must be from a racial or ethnic group that is under-represented in science (Black/African-American; Hispanic/Latino; Native American or Alaska Native; and/or Hawaiian or other Pacific Islander) or an LGBTQ+ person or a woman.

Each fellow must have one of the following designations:

- U.S. citizen
- Permanent Resident
- Pending Permanent Resident (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 U.S., having filed an Application for Employment Form I-765)
- E-3 Visa – specialty occupation worker
- H1-B Visa – temporary worker in a specialty occupation
- O-1 Visa – temporary worker with extraordinary abilities in the sciences
- TN Visa – NAFTA professional\
- J-1 Visa – exchange visitor
- F-1 Visa – student
- G-4 Visa – family member of employee of international organizations and NATO

*All awardees must meet the citizenship criteria throughout the duration of the award.

A named fellow may not hold another comparable fellowship award, although the institution may provide supplemental funding. Fellows may not hold a faculty or staff appointment, with the exception of MD or MD/PhD trainees who also maintain clinical responsibilities. These fellows may hold a title of instructor or similar due to their patient care responsibilities but must devote at least 75% effort to research training.

Training Center Application Details

Purpose - The goal of this program is to support postdoctoral fellows in effectively conducting clinical trials in an inclusive manner, while supporting their development as leaders. Additional training to support overall skills of trainees will also be a critical component of the Training Center. Examples of additional skills the training program may provide include:

- A strong foundation in research design, methods, and analytic techniques;

- Enhancement of trainees’ ability to conceptualize and think through research problems with increasing independence;
- Experience conducting research using state-of-the-art methods, and presenting and publishing their research findings;
- Interaction with members of the scientific community at appropriate scientific meetings and workshops;
- Increased understanding of the health-related sciences and the relationship of their research training to health and disease; and
- Opportunities for the development of professional skills, including those that support community engagement and leadership and establish a community for career-long support.

The Director of the proposed Training Center may also serve as a Project PI, but **cannot** also serve as a Network Center Director.

Award Details

Duration: 4 years

Award Amount: The maximum budget amount a Training Center applicant may request is **\$500,000**. The AHA reserves the right to determine the final award amount for competitive projects based on need and potential impact.

Appropriate Budget Items:

- Salary and fringe benefits of the Training Center Director and other participants with faculty or staff appointments.
- Project-related expenses, such as supplies, travel (to scientific meetings), and publication costs in accordance with institutional and AHA policies.
 - The Training Center Directors and fellows are expected to attend two face-to-face network meetings per year, in alignment with the other meetings for this Network. Awardees may use grant funds to pay for travel to face-to-face meetings and other meetings where relevant research is presented.
- Maximum of 10% institutional indirect costs may be claimed on the award.

Sample Training Center Budget	Center Totals
<p>Training Center Director One Director at the Training Center for four years A maximum \$50,000 salary plus fringe/benefits per year for Training Center Director. Training Director must commit at least 20% effort</p>	<p>\$250,000</p>

Training costs: to include data science training, career-oriented presentation skills training, other science curriculum & training opportunities for career development.	\$184,545
Center Travel Costs: Covers travel for Training Center Director to attend network meetings. Additionally, covers travel for special training opportunities for named fellows.	\$20,000
Direct Costs (Total)	\$454,545
Indirect Costs AHA Policy allows for a maximum of 10% for indirect costs	\$45,455
Total	\$500,000

Note for Centralized Training Center Applicants: The director will be responsible for overseeing the total budget for the grant. If awarded, the director and the institution assume an obligation to expend grant funds for the purposes set forth in the application and in accordance with all regulations and policies governing the grant programs of the AHA.

Number of Awards: The Science of Diversity in Clinical Trials SFRN will include one (1) Centralized Training Center grant*. This award will be selected based on scientific merit and how the proposal aligns with AHA’s mission and goals. The Centralized Training Center could be located at one of the funded Network Centers.

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

The Training Center Director must have one of the following designations:

- U.S. citizen
- Permanent Resident
- Pending Permanent Resident (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 U.S., having filed an Application for Employment Form I-765)
- G-4 Visa – family member of employee of international organizations and NATO

PEER REVIEW

General: Peer Review for the SDCT SFRN will be a two-phase process. Projects/Science from the Network Centers and the Training Center will be scored during Phase 1. Network Center and Training Center applications that advance past Phase 1 will undergo a separate Phase 2 review. This review will focus on the overall vision of the center, synergy and collaborative possibilities within a Network

Center (via the Center application) and across Centers, and the training plan and environment. Phase 2 will occur 3-4 weeks after Phase 1 review. Criteria for both phases of review follow.

Center Application Peer Review (Including Review of Individual Projects)

Phase 1 Review

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:

- **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 each applicant develop a plan for interoperability of data between Centers and with National or International Standards?

NOTE: 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(s):** Is the investigator(s) 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)? Project PIs must dedicate at least 10% to the project.
- **Significance:** Does this study address an important problem related to diversity in CTs? 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 additional science project(s)? i.e., does this project enhance the likelihood that the collective Center outcomes will exceed outcomes of the individual sum of its distinct components? For more information, [please see this page](#). **Only projects that demonstrate synergy will move forward to Phase 2.**
- **Lay Summary/Summary for Non-Scientists:** How well written is the lay summary in explaining to a non-scientist audience the research proposed and importance? Does the Lay Summary adequately explain the major health problem being addressed by this study? Does it provide specific questions and how the projects will address them? Does it provide information on the overall impact of this work and the potential advances in the field? **Does it relay how the proposal supports the mission of the AHA?**

Phase 2 Review

Each **NETWORK CENTER** moving beyond Phase I Review, will be scored on the following:

- **Synergy** – A clear vision of scientific direction is expected. A 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?
- **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 from all identified study populations to ensure robust results are achievable.

- **Training component** – Whereas much of the training of fellows will be coordinated and managed by the Training Center, individual Centers must also demonstrate the resources and capabilities needed to foster the success of their trainees. Successful applicants will demonstrate a postdoctoral training plan that includes clinical (M.D., D.O., PharmD) 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 Director** – Qualifications of the Director to provide scientific and administrative leadership for the Center; 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 advance the science of diversity in clinical trials.
- **Investigator Team** – Qualifications of each PI to provide scientific and administrative leadership for their respective projects; demonstrated commitment of each PI, and experience in the area(s) of studies proposed; qualifications of investigators, and co-investigators and the research team; training experience.
- **Diversity of the Research Team** – In keeping with AHA’s core values of diversity and inclusivity, AHA is committed to broadening the diversity of investigators supported by programmatic, multi-investigator initiatives it offers. As such, **at least 25% of key personnel of the research team must be from groups who are under-represented in science and medicine.** Applicants must be able to document the diverse composition of the proposed research team, and should comment on steps their institution(s) has taken/is taking to expand and support diverse investigators.
- **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.

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

Applicants are 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.

Training Center Peer Review

Training Center application scoring is based on the criteria below.

- **Training Director** - Does the Training Director have the scientific background, expertise, time commitment, and administrative and training experience to provide strong leadership, direction, management, and administration of the proposed research training program? Has the Training Director provided evidence of successfully training and facilitating advancement of post-doctoral fellows?
- **Training Program and Environment** - Are the research facilities and environment conducive to preparing trainees for successful careers in conducting clinical trials, particularly with under-represented study populations? Is the level of institutional commitment to the training program, including administrative and research training support, sufficient to ensure the success of the program? Does the program have a plan to collaborate with the Network Centers as well as incorporate the Center Fellows into the training program? Does the program provide appropriate inter- or multi-disciplinary research training opportunities? Are there planned activities and educational opportunities for the cohort of trainees that support skill development, cohesion and community building, and broader engagement? Is the proposed training program likely to ensure trainees will be prepared for research-intensive and/or research-related careers? Are effective mechanisms in place for obtaining feedback from current and former trainees? Is the program committed to participating in the AHA's rigorous evaluation plan to assess the quality and effectiveness of the training?
- **Trainee Pool and Recruitment Plan** - How will the applicant support the Network Centers in their recruitment of well-qualified post-doctoral trainees?

Applicants are 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.

Award Selection

Final funding decisions are subject to approval by the AHA.

RELEVANT POLICIES AND REQUIREMENTS

Institutional Eligibility/Location of Work

AHA awards are limited to U.S.-based non-profit institutions, including medical, osteopathic and dental schools, veterinary schools, schools of public health, pharmacy schools, nursing schools, universities and colleges, public and voluntary hospitals and others that can demonstrate the ability to conduct the proposed research. Applications will not be accepted for work with funding to be administered through any federal institution or work to be performed by a federal employee, except for Veterans Administrations employees.

The Centers are not transferable to other institutions. An institution may submit only one Center (and related Projects) application and only one Centralized Training Center application in response to this RFA. Individuals at the applicant institution who are not participating in their institution's center and project(s) application may participate in a separate institution's center application. Individuals other than the Center Director who are participating in their institution's center application, may participate in a separate institution's center application. The application may include individuals and/or projects at more than one institution provided there is evidence supporting the likelihood of a successful interaction among research and training personnel.

It is the responsibility of the submitting institution to ensure that only one proposal is submitted for the institution or to coordinate across several institutions to create a single application. The Center Director's institution will maintain fiscal responsibility for the entire award.

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 OAC reserves the right to request additional updates, site visits, or reporting.

Relevant AHA Policies

Preregistration: AHA requires preregistration for funded clinical trials and encourages preregistration for any studies that make an inferential claim from a sampled group or population, as well as studies that are reporting and testing hypotheses. After a project is

completed, protocols and preregistration analysis plans can be used in conjunction with the final study and analysis by researchers seeking to replicate, reproduce, and build upon findings. See AHA's preregistration information.

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 AHA 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](#).

Refer to the [AHA Award Policies](#) for information on all AHA award policies.

Notice of Potential Co-Funders

The AHA anticipates having one or more co-funders for this research initiative, including from industry. Representatives from these co-funders may listen to the discussion about applications, but they will not participate in the discussion and will not score applications. Additionally, there may be opportunity for a co-funder representative to participate as a member of the Oversight Advisory Committee. Regardless of level of participation, all AHA policies and procedures regarding non-disclosure and conflicts of interest will be scrupulously followed.

Application Submission

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

Other Features of this AHA research opportunity:

The AHA believes diversity and inclusion is an essential component to driving its mission and strongly encourages applications by women, underrepresented racial and ethnic groups in the sciences, military veterans, people with disabilities, members of the LGBTQ+ community, and those who have experienced varied and non-traditional career trajectories.