

American Heart Association

Health Equity Research Network (HERN)

On Disparities in Maternal-Infant Health Outcomes

Key Dates

RFA Posted: Pre-Proposal Deadline (via email): Application Deadline: AHA 2-Phase Peer Review: Notification of Awards: Award Start Date: February 1, 2022 March 8, 2022, by 3 p.m. Central April 21, 2022, by 3 p.m. Central late-May and mid-June 2022 late June 2022 July 1, 2022

Membership Requirement

As a reminder, each **applicant for an AHA research award must be a current 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 may take 3-5 days; **do not wait until the application deadline to renew or join**.

Pre-Proposal

Each Coordinating Center PI is **required** to send a pre-proposal via email to <u>strategicawards@heart.org</u> with the following information:

- Names and institutions of the Coordinating Center PI and each Project PI
- Network title and title of each proposed project

Please follow this link to a template for the pre-proposal (Word).

Diversity and Inclusion

The AHA strongly supports diversity and inclusion and 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.

Purpose

The American Heart Association (AHA) announces a Request for Applications (RFA) for the Health Equity Research Network (HERN) on Disparities in Maternal-Infant Health Outcomes.

The United States has the highest maternal mortality rate among industrialized countries, and cardiovascular disease is the leading cause of pregnancy-related mortality in the U.S. (Mehta et al., Circulation, 144:e251, 2021). Major racial disparities exist in maternal health outcomes. Black women experience pregnancy-related death at a rate 2.5 times higher than White women and 3.5 times higher than Hispanic women, and American Indian/Alaska Native women experience pregnancy-related death more than twice as often as White women (Hoyert, NCHS Health E-Stats, 2021). While educational attainment is often a health protective factor, research suggests this may not be the case with maternal mortality. College educated Black women are still at higher risk than White and Hispanic women with less than a high school diploma, and Black college-educated women are five times as likely to die than White college-educated women (Petersen et al., Morbidity and Mortality Weekly Report, 68(35), 2019; Bond et al., Circ Cardiovasc Qual Outcomes, 14:e007643, 2021).

Structural racism in the healthcare system can impact how Black women are treated during pregnancy and postpartum care (Taylor, Journal of Law, Medicine & Ethics, 48(3), 2020) and the chronic stress associated with racism has been shown to be tied to cardiovascular disease (Churchwell, et al., Circulation, 142: e454, 2020). Research has begun to explore how social determinants of health (SDOH) impact individuals' risk of cardiovascular disease, and suggests adverse SDOH are linked to higher CVD risk factors (Jilani, et al., Curr Atheroscler Rep, 23(9): 55, 2021; Mannoh, et al., Curr Opin Cardiol, 36(5): 572, 2021), bur further research is needed to understand this connection. Geographic disparities also exist, with women living in rural communities experiencing higher mortality rates than women living in urban communities (Harrington, et al., Circulation, 141:e615, 2020).

Racial disparities exist for infant mortality rates as well, with Black babies having an infant mortality rate of 10.8 deaths per 1,000 live births compared to 4.6 deaths for White babies (Ely & Dirscoll, National Vital Statistics Reports, 69(7), 2020). Racism and other chronic stressors also impact birth outcomes, often leading to low birthweight or preterm birth (Braveman, et al., PLoS One, 12: e0186151, 2017), which are the leading causes of infant mortality and often lead to long-term cognitive developmental health issues (Farooqi, et al., PLoS One, 11:e0151819, 2016; Taylor, Semin Perinatol, 40: 529, 2016). Interestingly, new research suggests that when Black newborns are cared for by a Black physician as compared to a White physician, the rate of infant mortality is cut in half (Greenwood, et al., PNAS, 117(35): 21194, 2020). Additional research is needed to more fully understand how structural racism and racial disparities manifest and can be addressed with regard to maternal and infant morbidity and mortality.

According to the World Health Organization (WHO), maternal death is defined as "the annual number of female deaths from any cause related to or aggravated by pregnancy or its management (excluding accidental or incidental causes) during pregnancy and childbirth or within 42 days or termination of pregnancy, irrespective of the duration and site of the pregnancy"

(https://www.who.int/data/gho/indicator-metadata-registry/imrdetails/4622). A broader definition of pregnancy-related death by the Centers for Disease Control (CDC) includes up to 100 days postpartum (https://www.cdc.gov/reproductivehealth/index.html). Causes of death vary by when they occur, with hemorrhage and cardiovascular conditions most common while mothers are pregnant, infection most common at birth and within 42 days of giving birth, and cardiomyopathy and mental health conditions most common up to a year after birth (CDC Foundation, 2018, http://reviewtoaction.org/Report_from_Nine_MMRCs).

The AHA's recently published statement on maternal health (Mehta et al., Circulation, 144: e251, 2021) outlined a number of policy recommendations for improving maternal health outcomes, several of which

focus specifically on disparities in outcomes. In addition to implementation of new policies, additional research is needed to better understand factors underlying these disparities, such as SDOH, structural racism, and the related chronic stress in maternal and infant health outcomes, resulting in improved health equity.

Defining additional opportunities for improvements in delivery of care are also needed. For example, cardio-obstetrics is a multidisciplinary field that takes a team approach to addressing cardiovascular disease during pregnancy and can help prevent maternal mortality (Mehta, et al., Circulation, 141, 2020). As an additional example, research suggests doula care is beneficial for improving maternal health outcomes (Bohren, et al., Chochrane Database Syst Rev., 7(7): CD003766, 2017), and in particular, race and/or cultural concordance between doulas and birthing mothers is beneficial in building a trusting relationship and helping to mitigate the institutional biases often faced by Black mothers in the health system (Wint, et al., Health Equity, 3(1): 109, 2019). The ability of many women to access doula care remains insufficient, however (https://www.healthaffairs.org/do/10.1377/forefront.20210525.295915/full/). Further building the evidence base for this and other interventions and approaches to care may facilitate changes in policy resulting in substantially improved outcomes.

In addition to the social and structural factors that impact disparities in maternal health outcomes, biological factors may have an important role. As an example, preeclampsia, a pregnancy-specific disease characterized by high blood pressure, increased protein levels and other factors, occurs in approximately 5% of pregnancies and is a major contributor to mortality and morbidity. The precise mechanism(s) underlying preeclampsia remains unclear, although a number of likely contributing factors have been identified (Chaiworapongsa et al., Nat Rev Nephrol 10(8): 466, 2014). Its prevalence is significantly higher in Black women and in Alaska Native and American Indian women compared to non-Hispanic white women (see Johnson and Louis, Am. J. Obstet. Gynecol doi: 10.1016/j.ajog.2020.07.038, 2020 and references therein). The ability to accurately predict susceptibility to likelihood of mothers developing preeclampsia could minimize these disparities and improve outcomes for all mothers. Whereas there has been some progress in this area, lack of knowledge of biomarkers of preeclampsia and other conditions that increase the likelihood of poor outcomes with pregnancy remains a significant limitation in maternal care (MacDonald et al., EBioMedicine 2022;75:103780).

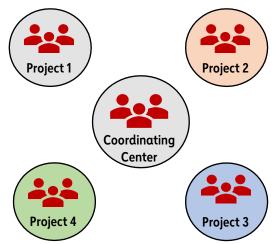
Disparities in maternal-infant health outcomes in the United States is an issue for which the urgency cannot be overstated. Indeed, in December 2021 Vice President Kamala Harris announced a Call to Action to reduce maternal mortality and morbidity (https://www.whitehouse.gov/briefing-room/statements-releases/2021/12/07/fact-sheet-vice-president-kamala-harris-announces-call-to-action-to-reduce-maternal-mortality-and-morbidity/), noting in particular the unacceptable reality of the disproportionate impact on Black women, Native American women, and those living in rural areas. This AHA Health Equity Research Network provides an opportunity to significantly advance our understanding of the factors underlying this crisis in women's health.

NETWORK OVERVIEW AND STRUCTURE

GENERAL OVERVIEW – The Health Equity Research Network (HERN) on Disparities in Maternal-Infant Health will be a single Network that will include multiple projects. An overall project plan will be developed by self-identified sites and submitted to the AHA as a coordinated submission. Proposed projects will have a common fundamental theme that will assess pathophysiologic mechanisms, an intervention or approach to the optimization of health outcomes for mothers and/or infants. All aspects of the network application (each Project and the Coordinating Center) will be reviewed as a collective program. The successful Network application will be one wherein each Project and the Coordinating Center are judged to be exemplary, and thus all components will be funded (i.e., either the entire Network [with some possible budgetary adjustments] will be funded, or the entire Network will not be funded).

PROJECTS - Each Network application will include **a minimum of three and no more than five projects.** Each project will be at a distinct institution, and each will be led by a Project Principal Investigator (PI). Each project must have the necessary research team, required infrastructure and ability to recruit and retain a diverse group of study participants.

COORDINATING CENTER – At the agreement of the Project PIs during development of the Network application, one Project investigator will be designated the HERN Coordinating Center PI. The Coordinating Center PI is not required to also be a Project PI, but this individual will be at one of the institutions submitting a project application and have some scientificrole in a project. The Coordinating Center PI will have an additional set of responsibilities to coordinate the efforts of the funded projects, facilitate and manage communication among the HERN Project awardees, and establish collaborations and resource sharing as appropriate. The Coordinating Center PI will coordinate the



dissemination of all findings resulting from this award mechanism. And whereas each site will have its own budget (see Award Details section below) and be separately awarded a grant from the AHA, the Coordinating Center PI will be responsible for collation and submission of annual progress reports to the AHA (see Interim Assessment section below).

Representative types of projects responsive to this RFA

The AHA encourages applicant teams to submit innovative intervention or investigative projects that can prevent or reduce poor maternal or infant health outcomes. With the exception that studies must be conducted using human participants and must include interventions, the AHA is not advocating for a particular study topic or design. Below are examples of general themes; this list is not exhaustive and is not meant to direct applicants to a particular approach:

- Identification and assessment of training needs for health professionals who provide care to those giving birth in the United States, including implementation of antiracist policies and practices to promote health equity and eliminate structural racism in health care
- Research to further understand the impact of social determinants of health, structural racism, and chronic stress on cardiovascular disease as it relates to maternal health
- Implementation and evaluation of interventions to mitigate the effect of social and structural determinants of health, including racially based discrimination, on maternal and infant health and mortality, including rural and/or other medically underserved communities

- Identification, implementation and evaluation of strategies that incorporate cardiovascular health professionals and integrated care delivery outpatient models (e.g., doulas, midwives, community health workers) in the continuum of care for those giving birth in the United States
- Assessment of the potential role of telemedicine in reducing maternal and infant mortality in populations that have poor access to health care
- Research to understand biological mechanisms as well as clinical and social maternal fertility risk factors, particularly among racial and ethnic diverse people and development of strategic care models to attenuate associated maternal and fetal morbidity and mortality
- Identification of biomarkers that could be predictive in determining likelihood of high-risk pregnancies in susceptible populations

A Network may address a single research approach using one or more study populations with possible inclusion of comparator study arms. Alternatively, a Network may propose to address multiple approaches that are closely aligned thematically. Regardless of the study approach, successful applications will clearly convey the ability to address maternal and/or infant health in high-risk populations, and their study cohorts should be representative of a high-risk population. Whereas it is anticipated the majority of projects proposed within an overall Network application will utilize human subjects, up to one project per Network application may be epidemiologically focused in nature or pursue a more basic/translational focus. In addition, pursuit of basic science studies to assess cellular and/or molecular mechanisms contributing to disparate maternal health outcomes are appropriate as long as those studies are conducted using samples from the designated and diverse human population(s).

Human Subject Study Population(s):

• This HERN is specifically focused on disparities in maternal and infant health. Thus, by default, all project proposals must have as a focus a population(s) for which disparities in maternal and/or infant health are well-documented.

Additional Expectations and Opportunities

- Each Network application must include at least one project that incorporates the use of community-based participatory research (CBPR) into its research design.
- The use of technology in at least one of the projects (e.g., telehealth or telemedicine solutions, health applications, wearables/sensors) is strongly encouraged.
- In keeping with AHA's commitment to diversity and inclusion and in alignment with the goals of this initiative, Network applications from investigators at academic institutions that disproportionately 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.
- Network 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))
- At least 25% of key personnel of the research team must be from a group that is underrepresented in science and medicine (Black/African-American; Hispanic/Latino; Native American or Alaska Native; Hawaiian or other Pacific Islander; LGBTQ+; women). Projects with principal investigators who are under-represented in science and medicine are strongly encouraged.
- Each Project MUST name at least two full-time (≥75% FTE) pre- or postdoctoral trainees during the award term.
 - At least 50% of the trainees named to each project must be from a racial or ethnic group that is under-represented in science (Black/African-American; Hispanic/Latino; American Indian or Alaska Native; and/or Hawaiian or other Pacific Islander), an LGBTQ+ person, or a woman.
 - There is no salary cap for trainees; however, the minimum salary of \$65,000/year for post-doctoral trainees and \$32,036/year for pre-doctoral trainees (including fringe) must be met. The institution may supplement funding, if desired.
- Additionally, at least one early-career faculty member (assistant professor or equivalent) must be included in a substantive manner during the award period.

AWARD DETAILS

Duration: Four years.

Number of Awards: The AHA will fund one Health Equity Research Network comprised of 3-5 Projects and the associated Coordinating Center. Each institution that is part of the Network will receive an award directly from the American Heart Association. The HERN awardees will be selected based on scientific merit and how each proposal aligns with the AHA's mission and goals.

Award Amount: The maximum budget amount that may be awarded to the Network is **\$20 million; this** is inclusive of funds to support the Coordinating Center responsibilities, and indirect costs of 10% maximum for all Projects and the Coordinating Center. The AHA reserves the right to determine the final award amount for competitive projects based on need and potential impact.

There is no requirement that all sites receive an equal allocation of the total available budget. However, **all sites must meaningfully contribute to the overall Network outcomes.** As such, it is expected that all sites will have a reasonable portion of the total funds available to the Network.

Appropriate Budget Items:

All budgeted items must be justified explicitly in the application. Broad categories of allowable costs for both the Project Sites and the Coordinating Site include the following:

Projects

- Salary and fringe benefits for the Project PIs, collaborating investigator(s), and other participating
 research staff or trainees.
 - Each Project PI is expected to commit a minimum 10% effort.
 - There is no salary cap; however, salary must be commensurate with experience and level of effort.
 - Naming of Project Co-PIs is acceptable for this funding mechanism; however, one person must be named in the application in ProposalCentral as PI and take full responsibility for the role, including committing the requisite minimum percent effort.
- Non-salary, project-related expenses such as supplies and consumables, funds to offset costs incurred by study participants, equipment, travel, and publication costs in accordance with institutional and AHA policies.
- Travel/meetings: PIs will use award dollars to pay for required face-to-face (as feasible), Network-wide meetings and other meetings where HERN research is presented. It is anticipated that one or two face-to-face meetings will be held each year at which awardees will share results, discuss best practices, challenges to progress, developing opportunities, etc. Project PIs should anticipate hosting and paying for at least one of these meetings on a rotating basis; alternatively, a Network may propose all meetings be held at the Coordinating Center. In that event, costs related to hosting should be included in the Coordinating Center's budget. More information about planned face-to-face meetings, the *Coordinating Center plan should include frequently recurring virtual meetings*).
- Maximum of 10% institutional indirect costs may be claimed on the award.

Coordinating Center

- Salary and fringe benefits for the Coordinating Center PI, collaborating investigator(s), and other participating research staff or trainees.
 - The Coordinating Center PI is expected to commit a minimum of 10% effort for responsibilities specifically associated with the Coordinating Center.
 - Naming of Co-Coordinating Center PIs is not acceptable for this funding mechanism. If one Individual serves as both a Project PI and the Coordinating Center PI, that individual will be expected to devote at least 20% effort to these responsibilities (i.e., at least 10% for role as the

Project PI and at least 10% for role as Coordinating Site/Center PI).

• Non-salary expenses related to the activities of the Coordinating Center, such as supplies and consumables, tele- and web-based communications costs, equipment, travel, and publication costs in accordance with institutional and AHA policies.

NOTE: Each PI will be responsible for overseeing the total budget for their award. The PIs 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 research programs of the American Heart Association.

In the event of potential performance issues at a particular site, the Coordinating Center PI, in consultation with the Oversight Advisory Committee and AHA staff, may request to rebudget across sites to ensure optimal progress of the Network. Any potential rebudgeting would only occur with explicit, written approval of the American Heart Association.

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.

Eligibility of Coordinating Center PI

- Must hold a doctoral-level degree.
- Must hold a faculty-rank position of any level. This award is not intended for trainees.

Eligibility of Project PIs

- Must hold a doctoral-level degree, or comparable credentials and experience documenting the ability to effectively lead the proposed project.
- Must hold a faculty-rank position of any level, or comparable research-related position from any project application originating from a non-academic institution.

Required Assurances:

• For all applications selected for funding, all institutional assurances (e.g., IRB) must be submitted to AHA prior to release of funds.

Interim Assessment: Awardees must report progress at least annually. Progress assessment may take the form of a required written report in addition to video conferencing, phone calls, and/or face-to-face visits. The AHA reserves the right to request additional updates, site visits, or reporting.

Public Access: The AHA public access policy requires that all journal articles resulting from AHA funding be made freely available in PubMed Central (PMC) and attributed to a specific AHA award within 12

months of publication. It is the responsibility of the awardee to ensure journal articles are deposited into PMC.

Open Data: Any factual data that is needed for independent verification of research results must be made freely and publicly available in an AHA-approved repository within 12 months of the end of the funding period (and any no-cost extension).

Other Data Sharing: Awardees must also deposit all data collected through this funding mechanism to the AHA's Precision Medicine Platform (below). Supporting information needed to verify results, such as data dictionaries and codebooks, should also be deposited to adhere to the FAIR (Findable, Accessible, Interoperable and Reusable) guiding principles of data stewardship.

Preregistration: The 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.

For more information on the above policies, see AHA's Open Science Policy webpage.

Use of AHA's Precision Medicine Platform:

AHA awardees may apply for a Precision Medicine Platform Workspace to perform data analysis. A workspace will provide up to \$50,000 in AWS credits per year during the course of the AHA award.*

- Register for a free account on the AHA Precision Medicine Platform.
- Learn more about the platform (video).
- Explore the capabilities of the platform (video).
- <u>Contact us</u> for more information.
- The AHA Precision Medicine Platform provides a friendly web User Interface that allows you to write code in various languages (for example, Python, R, SAS, and more), execute the code, and view the results as they are processed. Workspaces are equipped with pre-installed software packages ranging from machine learning, statistical analysis, data analysis, visualization, and genomic and bioinformatic tools. Researchers are also able to upload their own software. View a <u>complete list</u> of languages, packages, and kernels available on the Precision Medicine Platform.

* Grantees requesting a workspace are asked to pay a nominal annual license fee, which may be charged to the AHA award or invoiced to the grantee directly. Please refer to this <u>FAQs (PDF)</u> document for more details.

Other: Proposals may not have scientific or budgetary overlap with other funded work. Any inventions, intellectual property, and patents resulting from this funding will be subject to the AHA Intellectual Property Policy for Research Funding or modified terms of such 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: <u>AHA Policies Governing All Research Awards</u>

Application Submission: Applications must be submitted using <u>ProposalCentral</u>, AHA's online submission portal.

For **Project applications**, the following uploads (within listed maximum page allowances) are required:

- Applicant/PI Biosketch (5 pages) Use your NIH biosketch NIH OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 approved through 02/28/2023). It is not necessary to reformat to AHA page specifications. The AHA will accept biosketches with or without the NIH's changes that took effect on January 25, 2022.
- Budget Justification (2 pages)
- Research Project Environment (2 pages)
- Research Plan (up to 12 pages) See Peer Review Phase I below for the criteria against which the proposal will be evaluated.
- Literature Cited (4 pages)
- Coordinating Center Vision and Approach to Foster Synergy and Collaboration (obtain from Coordinating Center PI)
- Summary for Non-scientists/Lay Summary The lay summary is not a document to be uploaded, rather it is entered through form fields in ProposalCentral. We list it here, so the applicant may be aware that this is required.
- All project professionals listed in third party (i.e. Co-PIs, Co-Is, Collaborators) personnel must submit Biosketch.

For the **Coordinating Center application**, the following uploads (within listed maximum page allowances) are required:

- Applicant/PI Biosketch (5 pages) Use your NIH biosketch NIH OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 approved through 02/28/2023). It is not necessary to reformat to AHA page specifications. The AHA will accept biosketches with or without the NIH's changes that took effect on January 25, 2022.
- Budget Justification (2 pages)
- Infrastructure to Support Coordinating Center (2 pages)
- Coordinating Center Vision and Approach to Foster Synergy and Collaboration (8 pages)
- Coordinating Center PI Qualifications (2 pages)
- Literature Cited (4 pages)
- Summary for Non-scientists/Lay Summary -- The lay summary is not a document to be uploaded, rather it is entered through form fields in ProposalCentral. We list it here, so the applicant may be aware that this is required.

For additional instructions related to required application materials, view the AHA Application Instructions at https://professional.heart.org/-/media/PHD-Files/Research/Application-Information/Application-Instructions/AHA_Research_Funding_Application_Instructions_ucm_495100.pdf

PEER REVIEW

Applicants for all funding mechanisms 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.

Peer Review will be a two-phase process. In Phase I, individual projects and the broad approach to coordination of the Network will be assessed by a convened panel of experts, based on the criteria described below.

Network applications that advance past Phase I will undergo a separate Phase II review. In this review, invited Network teams will present either virtually or in-person to a convened expert panel. Phase II review will focus predominantly on the overall Network as a whole, and how the various projects can collectively enhance the likelihood of significantly advancing opportunities for improving maternal and/or infant health or preventing barriers to equitable care for mothers or infants.

Phase I Review

Projects – Each **Project** within a Network application and the Coordinating Center plan will be scored individually according to the criteria below. An overall composite score will be derived based on the individual scores.

Potential impact of the project on research in the field of the maternal or infant care; 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:

- **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?
- **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)?
- **Significance**: Does this study address an important problem related to maternal or infant health outcomes? 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, and AHA's 2024 Impact Goal, to advance cardiovascular health for all, including identifying and removing barriers to health care access and quality by 2024?
- **Synergy**: How does this project enhance the entire Network application? i.e., does this project enhance the likelihood that the collective Network outcomes will exceed outcomes of the individual sum of its distinct components?
- **Summary for Non-Scientists:** How well does this lay summary convey to a non-scientific audience the purpose and importance of the research? The following attributes will be assessed:
 - How well written is the lay summary in explaining to a non-scientist audience the research proposed and its 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?
 - \circ Does it relay how the proposal supports the mission of the AHA?

Coordinating Center - A detailed and cohesive plan for coordination among the projects will be critical for success of the Network. This plan will be assessed based on the following criteria:

- **Approach**: Has the Coordinating Center PI developed a plan that will optimize the synergies and collaborative opportunities across the Network? Will the delineated plan ensure clear, consistent and frequent communication with and between the project sites? Does the applicant acknowledge potential problem areas and have a plan to mitigate those should they arise?
- Innovation: In addition to the expectation of innovation in the proposed projects, is the Coordinating Center PI proposing to utilize innovative approaches and tools to ensure effective engagement with and optimal performance of Project sites? Does the project develop or employ novel concepts, approaches, methodologies, tools or technologies for this area?
- Investigator(s): Is the Coordinating Center PI experienced in leading collaborative initiatives, or has he/she/they demonstrated strong potential to do so? Has he/she/they demonstrated the ability to manage large-scale, multi-site initiatives? Does he/she/they demonstrate the ability to foster communications between distinct teams of investigators? AHA is committed to facilitating diversity in the biomedical research enterprise. Consistent with this, AHA anticipates successful applicant teams will be those that are diverse with regard to gender and/or race and ethnicity.
- **Significance**: Does this study address an important problem related to maternal or infant health outcomes? If the aims of the Network are achieved, what is the likelihood of advances in clinical practice or policies regarding improving outcomes for maternal and infant care? What will be the effect of these studies on the concepts, methods and technologies that drive this field?
- **Environment and Infrastructure**: Does the scientific environment and available infrastructure contribute to the probability of success? Is there evidence of institutional support?

- **Summary for Non-Scientists:** How well does this lay summary convey to a non-scientific audience the purpose and importance of the research? The following attributes will be assessed:
 - How well written is the lay summary in explaining to a non-scientist audience the research proposed and its 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?
 - \circ Does it relay how the proposal supports the mission of the AHA?

Only projects that demonstrate synergy and a strong coordination plan, in addition to exemplary science, will move forward to Phase II.

Phase II Review

As noted above, Phase II review will assess how the projects will work together to achieve optimal outcomes. As such, the plan for coordination and collaboration across the Network will be a key aspect of this review, and application scoring will be based on the following criteria:

- **Synergy** A clear vision of scientific direction is expected. A HERN 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.
- 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 and diverse Network.
 Evidence of formal training in leadership skills with an emphasis on collaborative leadership of diverse
 teams will be favorably reviewed. What collaborations do you envision between investigators working
 on individual projects?
- Network Team (Coordinating Center PI and Project PIs and Co-PIs) Qualifications of the Coordinating Center PI to provide scientific and administrative leadership for the Network; experience leading complex multi-site, collaborative and inclusive initiatives; 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; qualifications of Project PIs and Co-investigators; training experience.
- **Project teams** Qualifications of each PI to provide scientific and administrative leadership for their respective projects; demonstrated commitment of each Project PI, and experience with studies in the field outlined by the RFA; qualifications and experience of named Co- investigators and Project team members.
- **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 Network; institutional resources available to complete the project; analytical resources available to the project.

Timeline for Peer Review Phases

The two phases of Peer Review will be conducted separately. Network teams will not be present for Phase 1 reviews but will be required to participate in Phase II. Applicant teams should be prepared to be available for Phase II review in June. The AHA will share exact times with Network teams as soon as is feasible.

Please direct inquiries to strategicawards@heart.org