American Heart Association Health Care by Food initiative

Planning Grant Request for Proposals

Key Dates *(subject to change)*

RFP Posted:	January 6, 2025
Application Deadline:	March 11, 2025
AHA Distributed Peer Review:	March 21 – May 2, 2025
Notification of Awards:	May 19, 2025
Award Start Date:	July 1, 2025

Purpose

The American Heart Association (AHA) announces a Request for Proposals (RFP) for a planning grant opportunity through its Health Care by Food initiative (www.healthcarexfood.org).

While copious research exists on the links between nutrition and health, both access to healthy food and overall diet quality remain insufficient for many in the United States to support adequate health, contributing to the exacerbation of chronic conditions.[1-3] There are significant disparities as well, with higher rates of chronic disease mortality among Black, Hispanic, and Native American populations,[3] and higher rates of adults with poor diet quality among Black and Hispanic households than in the overall population.[1]

'Food Is Medicine' (FIM), characterized by the provision of food that supports improvements in health following referral of a patient from a health system or health plan, has historically been spearheaded by local organizations rising to meet the needs seen in their communities.[2] In recent years, researchers have begun to more systematically examine the efficacy of FIM interventions. Initial studies have shown promise, but larger scale randomized controlled trials are necessary to develop definitive evidence that would help determine the optimal composition of FIM interventions for defined populations to facilitate coverage decisions for specific clinical indications.

Opportunity

Nutrition is important to a variety of health conditions, including heart failure, high-risk pregnancy, cardio-kidney-metabolic disease, brain health and more.[3,4] Public education regarding healthy diets, clinical guidelines and nutrition recommendations are important for public health and medical care. FIM goes further, using the provision or subsidization of healthy food to help

mitigate the access and availability challenges that individuals face in enacting behavior change around food.

This AHA HCXF Request for Proposals is designed to provide support for the development of a detailed trial protocol and grant to be submitted to a federal agency or other major funder focused on developing and testing ways in which FIM interventions can be an efficacious way to improve health outcomes. Investigators funded through this RFP will be provided with salary and other support over the course of 12 months to optimize and finalize trial design, draft a grant proposal to a federal agency or other major funder, finalize a protocol and manual of procedures, establish a research team, develop tools for data management and research oversight, and prepare other items needed for the submission and conduct of a rigorous trial of a FIM intervention. The primary deliverable at the end of this grant period should be a rigorous and highly competitive proposal for funding of ≥$3M from a government agency. Proposals for industry or foundation support may also be submitted, but the planning grant proposal should provide justification for such sources of support.

Science Focus Areas of Interest

The goal of this RFP is to provide support for investigators to dedicate time to fully develop a competitive grant proposal that tests the efficacy of FIM interventions in improving health outcomes.

All proposed trials should meet the definition of Food Is Medicine, involving both the provision of food (via medically tailored meals, healthy food prescriptions, and/or medically tailored groceries) and identification of appropriate individuals through the healthcare system.

Specific areas of clinical focus may include, but are not limited to:

- Individuals with Heart Failure
- Individuals with High-Risk Pregnancy
- Individuals with Cardiovascular-Kidney-Metabolic Disease
- Brain Health, including stroke, dementia, depression, and other neurological or mental health disorders

Other focus areas of interest:

- Critical components of benefit design, including: dose, duration, tapering strategies, and ancillary services that facilitate efficacy in areas of clinical focus
- Implementation in rural settings
- Incorporation of Artificial Intelligence (AI) or other technologies to cost-effectively provide personalization at scale
- Testing of ways to achieve sustained behavioral change

Proposals should have a strong focus on inclusion of economically vulnerable individuals; demographically diverse subject populations, including some combination of historically underserved urban or rural communities, including those in US territories, LGBTQ+ communities,

communities with large portions of residents living under the Federal poverty line, communities with limited English proficiency, tribal communities, communities of color; individuals with Medicaid, Medicare, or dual Medicare-Medicaid eligibility; and those with disabilities.

Target Agencies and Funders for the Final Proposal Submission

Applicants should provide details of where they intend to submit the final proposal that will be developed during the planning grant year. They should provide details of any RFPs under which these proposals may be submitted. These target funders may include federal and related agencies (NIH, PCORI, ARPA-H, USDA, and others) or state agencies. Non-governmental funders may also be identified (e.g., foundations with substantial capacity and history of funding clinical trials, industry partners). Letters of support from potential collaborating organizations or funders where feasible are welcome, but not required.

Use of the AHA Get With The Guidelines™ registry data

Applicants may consider use of one of the AHA Get With The Guidelines™ quality improvement registries as a source of patients for their trial, as appropriate. AHA registries include stroke, heart failure, coronary artery disease, resuscitation (cardiac arrest), and atrial fibrillation. Details of the registries may be found online: https://www.heart.org/en/professional/quality-improvement/get-with-the-guidelines. This is not a requirement.

Who Should Apply

AHA awards are limited to project PIs that hold a doctoral-level degree, and are associated with eligible institutions, including 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.

American Heart Association Membership

As a reminder, each **applicant for an AHA research award is required to become an AHA professional member if they aren't already**. 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.

Diversity and Inclusion

AHA strongly supports diversity and inclusion and encourages proposals 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.

Important Notes

- Proposals must be received before 3 p.m. Central Time on the deadline date. Early submission is encouraged, as the system closes at 3 p.m. Central and will not accept submissions after that time.

- Potential applicants should review the AHA Application Information page for answers to commonly asked questions about eligibility and award details. Additional details on the award agreement terms and conditions can be found on the Award Policies page.

- All proposals must be submitted electronically via ProposalCentral. The system will open several weeks prior to the application deadline. You can, however, begin to create your documents at any time; please refer to the AHA Application Instructions (PDF).

- Award will be subject to terms and conditions of all AHA awards, as well as terms and conditions provided by the funder.

Award Amount and Duration

Grant amounts will be up to $100,000 over a 12-month funding period, including up to 10 percent institutional indirect costs. Up to $25,000 of this award amount can be dedicated to the acquisition of additional data, information and/or other necessary resources during the planning grant year, with appropriate justification.

Note that this award is not eligible for no-cost-extensions.

Submission requires the following:

I. Scientific plan (≤5 pages): plan to further develop and finalize a full final clinical trial protocol and budget for a definitive, rigorous, appropriately powered randomized clinical trial to test a Food Is Medicine intervention. The proposal submitted for this award must include the following elements, but will not itself be the full clinical trial protocol:
    a. Rationale for the proposed trial
    b. Preliminary trial design
        i. Population to be studied, including the statement of condition to be studied and inclusion/exclusion criteria
        ii. Intervention, including plans for dose, duration, frequency as well as behavior change strategies to be tested, as appropriate
        iii. Primary and secondary outcomes measures
        iv. Plan for recruitment, including plans to recruit participants who are representative of the broader population
        v. Plan for incorporating lived experience of participants into study design
        vi. Statistical design and sample size estimates

vii. Statement of additional data, information, and resources that will be needed and acquired during the planning year (allowable budget allocated can be up to $25k, with justification)
viii. Timeline and milestones for the planning year

II. References (not included in 5 pages above)
III. Statement of Qualifications of the PI and study team (1 page)
IV. Biosketches of PI (NIH format, unless otherwise justified) and any key personnel
V. Budget for the 12-mo planning grant
VI. Target Agencies and Funders for the Final Proposal Submission
VII. Letters of support (as appropriate)
VIII. Non-scientist summary of the work proposed

Requirements for Awardees

Use of Cooperative Studies Framework

Projects that are funded through this initiative will be supported using a Cooperative Studies Program model, similar to that employed by the Veterans' Administration in conducting comparative effectiveness and other types of research.[5]

The cooperative studies framework has advantages compared to the traditional model of PI-directed research:

1. Every successful planning grant applicant will have access to cutting edge human-centered design expertise, as well as advice in community engagement, implementation science, behavioral science, statistical methods, and cost effectiveness for review and advice at the beginning of the planning grant period, and in the second half of the planning grant period prior to actual submission for review and comment. This provides a means to increase access to state-of-the-art research support that might otherwise not be available to all investigators.
2. The AHA will develop recommended validated measures for a wide range of constructs commonly assessed in FIM studies to allow comparability between studies and to reduce effort in 'reinventing the wheel'. See below section on Common Measures.
3. The cooperative studies model will foster collaboration and resource sharing, allowing us to share ideas and successes and approaches to challenges being encountered by other investigators in a timelier manner.

Required Participation: All awardees will be required to connect with the cooperative studies task forces in the first half of the planning grant period, as well as submit their draft grant application to this group in the second half of the planning grant period prior to actual submission, for comments and responses. Similar to a traditional peer review process, comments will be returned to investigators, who will be asked to respond and provide revised documents, including protocols, for approval.

Lived Experience Group

Awardees will also be required to share their draft trial proposal with the HCXF Lived Experience Group, a group of approximately 10 individuals with diet-related illness. Each proposal will be reviewed by a representative of that group, who will advise on strengths and weaknesses of the proposal from the perspective of patient lived experience. This would take place in parallel with the aforementioned Cooperative Studies Group review. The group is a standing committee organized by the AHA and a virtual feedback meeting will be facilitated by AHA staff. The goal of this review will be to ensure that proposed studies address patient needs and preferences. This will be particularly valuable for studies being proposed for PCORI funding but will be valuable for all trial proposals.

Use of American Heart Association Common Measures

As part of the clinical protocol development, investigators will be asked to incorporate into their protocol the common measures as outlined on the AHA Health Care by Food website. Investigators will be asked to collect all of the core common measures and to consider the preferred and optional measures that would be appropriate for their study.

Interim Assessment: Awardees must report progress against milestones on a quarterly basis. Progress assessment 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 the achievement of stated milestones as indicated in the project timeline. AHA reserves the right to request additional updates, site visits, or reporting.

Note that this award is not eligible for no-cost-extensions.

Public Access: The AHA's public access policy requires that all journal articles resulting from AHA funding, including journal articles that are a result of a funded grant designed under an AHA-funded planning grant, 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.

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. Proposals 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 Project PIs

- Must hold a doctoral-level degree.

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

Required Assurances:

- For all proposals selected for funding, all institutional assurances (e.g., letter from an institutional official stating that individual will have 20% time available for the planning grant) must be submitted to AHA prior to release of funds.

Use of Artificial Intelligence and/or Large Language Models: The American Heart Association permits the use of a large language model (LLM – e.g. ChatGPT) or an artificial intelligence tool to generate and/or edit content in research proposals submitted for funding. This information must be disclosed at the time of submission. Disclosure of this information does not impact peer review. Should this information not be disclosed accurately, and use of these tools is identified, the proposal may be administratively withdrawn.

The American Heart Association DOES NOT permit the use of a large language model (LLM – e.g. ChatGPT) or an artificial intelligence tool to generate and/or edit content in peer review critiques. Uploading of any portion of a research proposal into a large language model (LLM – e.g. ChatGPT) or an artificial intelligence tool to assist in writing a critique of the proposal is explicitly prohibited as it is a violation of the AHA's Peer Reviewer Certification Statement (to include confidentiality, non-disclosure, and conflict of interest).

Peer Review Criteria

Peer review for this program may be conducted using a distributed peer review approach (PDF) (Merrifield and Saari, Astronomy and Geophysics, 50, 4.2, 2009). This is also known as the Mechanism Design Proposal Review Process. Use of distributed peer review may depend on the number of proposals submitted for this RFP.

Distributed peer review, in which those submitting proposals also serve as reviewers of others' proposals submitted under the same call for applications, relies on the principles of a traditional peer review panel: academic integrity, rigor, transparency, and a desire to advance the best science. As opposed to traditional peer review, distributed peer review capitalizes on the expertise of the applicant pool and incentivizes timely review in fairness to all applicants. Additionally, this peer review mechanism exposes applicants to new ideas and could foster new potential collaborations.

All applicants who submit a proposal will be required to serve as a peer reviewer within this program and will be assigned 4-6 proposals for review. By agreeing to the program terms at the time of proposal submission, the principal investigator is concurrently agreeing to serve as a peer reviewer within this program and meet all peer review expectations and requirements. Principal investigators will declare conflicts of interest and will only be assigned proposals for which they do not have an institutional or individual conflict; PIs (reviewers) are bound by all other requirements

associated with peer review. PIs will be provided ~30 days to complete review and scoring of the proposals to which they are assigned.

Only peer reviewers who complete their assigned reviews and record their scores in a timely fashion will in turn have their own proposal considered for funding. Brief written critiques to include bulleted strengths and weaknesses are required. Principal investigators who have not completed their reviews nor submitted their scores by the stated deadline will have their proposals withdrawn and returned as not in compliance with the program announcement, and they will not receive scores should any have been completed for their proposal. Peer review will require submission of scores using ProposalCentral; there will be no peer review panel discussions or meetings. All other AHA Peer Review processes apply.

Following the receipt of all peer reviewed comments, a committee of AHA science leadership will convene to make final determinations on the awardees.

Peer Review Scoring Criteria:
To judge the merit of the proposal, reviewers will score proposals according to the following criteria. The AHA uses a 1-9 score scale and AHA Peer Review Guidance (PDF). Reviewers are required to provide brief, bulleted written feedback on each proposal reviewed.

Significance:
Does the planned study address the core concern of this RFP, namely testing ways to achieve improvements in clinical outcomes using a FIM approach? Does the planned study use input from the lived experiences of participants or practitioners to guide program design (either historical, or as part of the current study)? If the aims of the proposal are achieved, how will scientific knowledge, clinical practice, and equitable health be advanced? What will be the effect of these studies on the concepts, methods and technologies that drive this field?

Approach:
Are the conceptual framework, design, methods, and analyses of the ultimate planned trial adequately developed, well-integrated, well-reasoned and feasible (as determined by preliminary data) and appropriate to the aims of the proposal? The assessment of preliminary data should be put into perspective so that bold new ideas and risk-taking by investigators are encouraged rather than stymied. Does the applicant acknowledge potential challenges and problem areas and consider alternative tactics and mitigation? How does the proposal consider the lived experience of participants and strive to center that in the proposal?

Strong justification from the scientific literature, preliminary data, or other relevant considerations must be provided for proposals proposing to study only one sex or a specific age group.

Innovation:
Is the proposal original and innovative? For example: Does the proposal challenge existing paradigms and address an innovative hypothesis or critical barrier to progress in the field? Does the proposal develop or employ novel concepts, approaches, methodologies, tools, or

technologies for this area? How does the proposal achieve the goals of working with diverse populations and capturing the lived experience of participants?

Investigator, Investigative Team and Partners:
Is the investigator appropriately trained, productive, and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator (applicant) and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)? Does the investigator have a record of diligence, commitment, and productivity that warrant support? Do Investigators have partnerships or relationships in place that could be leveraged to bring in potential partners?

Environment:
Does the environment in which the work will be done contribute to the probability of success? Does the proposal benefit from unique features of the investigative environment or subject populations, or employ useful collaborative arrangements?

Impact:
How does this proposal ensure that the resulting award will produce significant impact to the field? Proposals for research funding will be assessed for their potential impact on the AHA's HCXF program, and on the applicant's ability to effectively describe the proposal and its potential outcomes to non-scientists.

Non-Scientist Summary:
AHA HCXF Mission: Generate the evidence and tools to help the health sector design and scale programs that increase access to nutritious and healthy food, improve health equitably, and reduce overall health care costs by launching a national platform for food is medicine that removes barriers to population-scale policy and practice changes and paves the path for integrating these programs into covered medical benefits.

- How well written is the Non-Scientist Summary in explaining to a non-scientist audience the research proposed, the questions being asked and how they will be answered, and the importance and impact of this work?
- Does it relay how the proposal supports the mission of the AHA's HCXF program? How well do the proposal and summary achieve goals around equitable health and diversity?

References:

1. Hager K, Kummer C, Lewin-Zwerdling A, Li Z. Food Is Medicine Research Action Plan. In: The Aspen Institute Food & Society; 2024.
2. Volpp KG, Berkowitz SA, Sharma SV, Anderson CAM, Brewer LC, Elkind MSV, Gardner CD, Gervis JE, Harrington RA, Herrero M, et al. Food Is Medicine: A Presidential Advisory From the American Heart Association. *Circulation*. 2023;148:1417-1439. doi: 10.1161/CIR.0000000000001182

3. Micha R, Peñalvo JL, Cudhea F, Imamura F, Rehm CD, Mozaffarian D. Association Between Dietary Factors and Mortality From Heart Disease, Stroke, and Type 2 Diabetes in the United States. *Jama*. 2017;317:912-924. doi: 10.1001/jama.2017.0947
4. Li M, Grewal J, Hinkle SN, Yisahak SF, Grobman WA, Newman RB, Skupski DW, Chien EK, Wing DA, Grantz KL, et al. Healthy dietary patterns and common pregnancy complications: a prospective and longitudinal study. *Am J Clin Nutr*. 2021;114:1229-1237. doi: 10.1093/ajcn/nqab145
5. Huang GD, Ferguson RE, Peduzzi PN, O'Leary TJ. Scientific and organizational collaboration in comparative effectiveness research: the VA cooperative studies program model. *Am J Med*. 2010;123:e24-31. doi: 10.1016/j.amjmed.2010.10.005