**American Heart Association Health Care by Food initiative**

**Planning Grant Request for Proposals**

**Frequently Asked Questions**

## 1. Eligibility

### I am not an AHA member. Can I still apply?

Each applicant (Principal Investigator, or PI) must be an AHA Professional Member before submitting a full proposal. Join or renew when preparing an application in ProposalCentral, **online**, or by phone at 301-223-2307. Membership processing may take 3-5 days; do not wait until the application deadline to renew or join. Co-investigators do not need to be AHA members.

### Is an educational institution required to become an AHA professional member if partnering with an AHA affiliate?

All PIs and Co-PIs must be AHA members; however, other partners on the proposal are not required to have AHA membership.

### Are multi-PI applications allowed? And is there a minimum level of effort for PIs or Co-PIs? For projects with multiple PIs, do all PIs need to have an AHA membership or just one?

Yes, multiple PI applications are allowed. No minimum percent effort is required; however, the Principal Investigators must demonstrate that adequate time will be devoted to ensuring successful completion of the project.

All PIs must be AHA members. Co-investigators and other partners do not need to be AHA members.

### Can the State Department of Health apply?

American Heart Association research 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, except for applications specifically related to the AHA's Institute for Precision Cardiovascular Medicine. The phrase "others that can demonstrate the ability to conduct the proposed research" can include state departments of health as long as they meet other requirements. An investigator may be allowed to request approval to conduct work outside the United States temporarily.

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 Administration employees.

**Are NGO's eligible to submit a grant?**

As long as the NGO meets the requirements outlined in the eligibility statement as follows: American Heart Association research 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, except for applications specifically related to the AHA's Institute for Precision Cardiovascular Medicine. An investigator may be allowed to request approval to conduct work outside the United States temporarily.

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 Administration employees.

**Can more than one application from an institution be submitted?**

There is no limit on the number of applications from a single institution.

**Can multiple PIs from the same institution apply if the projects are different?**

Yes, they may.

**Co-PI or multiple PI applications allowed?**

Yes, they are.

**Is it possible to PI one application and be a co-PI on another application? Or PI one application and be a co-I on another application?**

PIs can only serve as PIs (or Co-PIs) on one grant, but Co-Is can be involved in multiple submissions; in other words, a PI on one application can also be a Co-I on another application.

**I am a doctoral level degree holder at a community-based organization - could we apply?**

Yes. 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.

**Does a PI need to have both PhD and MD, or is MD alone sufficient?**

PIs must hold at least one doctoral level degree; it is not a requirement to be an MD, PhD.

**Do you include MD as one of the Doctoral requirements? Is there a specific requirement for the Non-Profit and Academic institution affiliations? A certain title, relationship or time period of affiliation?**

Yes - and all eligibility criteria are outlined in our application instructions.

**I represent a not for profit and will be working with a PI in a US based institution. In that case can the non for profit be the applicant, or does the applicant be the PI and the academic institution?**

Eligible applicants should be 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.

**Will AHA accept a Co-PI without a doctoral degree?**

No, AHA awards are limited to project PIs and Co-PIs that hold a doctoral-level degree.

**What do you consider an equivalent to a faculty rank position?**

As long as the role is not considered a trainee-level role and is equivalent to a faculty-rank position, it will be considered.

**Are Research Scientists eligible to apply as PI?**

As long as they meet the eligibility criteria that is outlined within the application guide.

**Are clinicians not affiliated with an institution eligible to apply?**

Clinicians must be affiliated with an eligible institution, 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.

**We are an organization with multiple PHD level staff and experts in human centered design on staff who collaborate on projects that have had a focus on nutrition and health. We noticed on the form that our type of organization is not listed. Is there a space for us to find a partner to submit on this?**

Feel free to use the "Other" form field within the form for practitioners.

**Can projects be located outside of the US?**

Studies should be conducted in the US, including US territories.

**Can this grant support an existing awarded grant through USDA? We are in the planning phase.**

Unfortunately, no, this would not be eligible.

**Is there a limit on the number of applications that can be submitted?**

There is not a limit on the number of applications that can be submitted; but individuals can only be a PI on one awarded grant.

**Are federally qualified health centers run through local government health departments eligible?**

American Heart Association research 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 - so if the FQHC has that ability, they are welcome to apply.

**If you are working on a current FIM pilot with a local chapter of AHA, does this disqualify you from applying?**

No.

## 2. Partnership & Collaboration

**Would it be appropriate to include investigators as part of the team that are funded in-kind (i.e, not funded on this award)?**

Yes.

**I am a FIM practitioner but do not meet the requirements to apply for the RFP. How can I get involved?**

Please fill out the form at this link. We will gather all of the information provided and post it for use by research teams that are interested in finding FIM practitioner partners.

**I am a PI and would like to partner with a community-based organization or other food vendor. How do I find information for interested parties?**

This list of practitioners below is made up of those practitioners that have expressed interest in collaboration. **Are there existing FIM programs interested in partnering with academic researchers to respond to this call?**

Yes; as well as other practitioners. The list of practitioners interested in partnership can be found on our website, Food is Medicine Initiative | American Heart Association.

**Can you clarify what "connection with health care" means? Does this mean it has to be directly connected with a clinical enterprise? Or would measurement of a clinical outcome like BP or HgbA1c count?**

Connection with health care should be interpreted that participants or patients need to be identified and/or referred via a health care system or health plan.

**Are community-based organizations limited to partnership on one submission? Or could we be partners on two submissions?**

There is no limit to the number of submissions that a CBO may be a part of.

## 3. Award/Funding Duration

**Does this application require a letter of intent?**

No. The only submission required is the completed proposal application.

**How long is the award for?**

This award is for a 12-month period. The award start date will be July 1, 2025, and the award end date will be June 30th, 2026. This award is not eligible for no cost extensions.

**Would a delayed start date be considered?**

No.

## 4. Budget & Funding Allocation

**What is the total award amount?**

The award amount is up to $100,000, including all indirect costs. The AHA limit for indirect costs is 10% of the total award.

**What is the max dollar amount per grant? Are these statewide multi-site grants or more of a one county-pilot grant?**

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.

**Can you support salary of two PIs and a consultant within the $75K salary?**

If appropriately justified, yes.

**Can we apply for less than 75K for salary? (If a PI is already paid for a portion of their salary from other places for example)**

Yes.

**Will the salary support be only allowed for PI or MPIs?**

No, salary support is not limited to those individuals.

**I work at a nonprofit that creates medically tailored meals and implements FIM programing. We would be providing the food and the programming for our researcher. How much of the funds are eligible to come to us as a nonprofit?**

Those costs would be covered in the ultimate trial but shouldn't be part of the planning grant given its focus.

**Are sub-contracts allowed in the planning grant?**

After hearing from applicants, we have decided to allow subcontracts for this planning grant.

**Can I allocate budget to the participant in terms of providing some cash to encourage to participate to enroll in the study and this incentive will help to buy the fresh food?**

No, this planning grant is focused on the development of the trial, not the execution of it.

**Would running a small pilot FIM program and collecting data (focus groups, participant interviews, etc.) to help shape a larger study be an appropriate expense in the budget?**

If appropriately justified, up to $25k of the budget can be used for this.

## 5. Proposal Expectations & Requirements

**Do we have to use FIM as the title for the program? Can we use another title?**

You may use another title as desired.

**Is there a place on ProposalCentral to upload letters of support?**

Yes, there is room to do so under the Uploads section.

**What preliminary data are required from the PIs? Do the PIs need to have one FIM intervention already in place to apply for this RFP? or can we start from scratch with a research question that aligns with the goals of this RFP?**

Proposals should be well-justified for why the research question is feasible and reasonable based on existing evidence; however, 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. PIs do not need to have a FIM intervention in place already.

**Is there a minimum %FTE that each PI (or MPIs) are required to have?**

There is not a minimum % FTE, but please ensure that you have an appropriate amount to complete the proposal.

**Could you use the USDA biosketch format, if you plan is to submit to the USDA? It is slightly different than NIH.**

Yes.

**Will there be a list of potential funders to whom applications can be submitted?**

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.

**Is inclusion of preliminary data in our proposal expected?**

Proposals should be well-justified for why the research question is feasible and reasonable based on existing evidence; however, 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.

**Can incorporating AI for providing personalization of food and help achieve behavior change fall in scope of this RFP?**

Yes.

**Is there a requirement on number of enrolled participants? will you prioritize larger RCTs?**

Yes, proposed studies should be appropriately powered, rigorous randomized controlled trials.

**Will the proposal be considered more competitive if collaborators have already received NIH funding previously? For example, if considering a community site collaborator, is it better to choose a site who has a published representative?**

While this is part of the peer review criteria, it is only one part of the overall analysis.

**If the ultimate goal is for insurers (Medicaid) to cover this benefit, should some of the study include evaluation of FIM interventions underway through**

**Medicaid? Or, navigating Medicaid/insurance funding structures? Or, just focus on the clinical outcomes?**

It depends on the goal of your clinical trial, but we do not require those evaluations.

## 6. Research Design & Focus Areas

**Can proposals focus on families and children?**

Yes.

**Is it ok if the PI is from Canada working with institutions in the US**

PIs do need to be US-based.

**Are there any specific focus areas or populations that the Food Is Medicine Initiative aims to serve through these grants?**

No, this RFP is not intended to focus on a specific disease state or population. The charge for this overall Initiative is to develop evidence on what is efficacious and cost-effective for improving people's health through Food Is Medicine interventions. 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

Adults and children are appropriate. The choice of population should be well-defended in the proposal. Additionally, proposals should have a strong focus on inclusion of 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.

**Does SNAP count as Food Is Medicine if we encourage healthy food? Can a health system encourage uptake of SNAP, or does it have to be a more rigorous Food Is Medicine program?**

SNAP interventions would not qualify as a Food Is Medicine intervention. However, data collected as part of the study may include changes in SNAP use.

**Are proposals utilizing preventive or proactive models welcome, or just intervention?**

Preventive studies and interventions are welcome.

**Will proposals that focus completely on constructing/testing/ improving/ evaluating referral pathways to FIM interventions (e.g. innovating screenings within healthcare) without an actual food-based intervention like MTM or PRx, be considered?**

Yes, these proposals would be considered.

**Are you interested in a design that uses cultural values, norms, beliefs, and behaviors to create culturally palatable menus to increase engagement and adherence?**

We are very interested in designs that use all of the above; the caveat would be that the proposal should involve the provision of food/stipends for food and not just the development of menus.

**Is working with relatively rare disease populations (pediatric diseases with known high CVD risk) acceptable if these high-risk groups might serve as model population for future scaling of the intervention to other chronic illness populations?**

Yes, we welcome a broad scope of disease states. The charge for this overall Initiative is to develop evidence on what is efficacious and cost-effective for improving people's health through food is medicine interventions.

**Would you consider a study looking at chronic kidney disease?**

Yes.

**Are outcomes like hypertension or diabetes still acceptable for this RFP?**

This RFP is for a planning grant to develop a clinical trial, and that clinical trial can certainly focus on those clinical areas of interest.

**If you were interested primarily in gestational diabetes would that qualify?**

Yes.

**With a recent executive order that prevents new refugees coming to the U.S., does this RFP accept refugees as the target population, considering that we still have many refugees in the U.S. experiencing high rates of food insecurity and its related health outcomes?**

Yes, that would be an appropriate population of focus, as long as the criteria of a FIM intervention are met as defined within the RFP.

**Is the provision of an individual food (e.g., nuts) considered "Food is Medicine"? thank you.**

All proposals should be sure to center a food is medicine intervention as defined in the RFP, including the provision of food that is appropriate for a condition, and a connection with health care. Supplements would not be considered a part of a FIM program, and single foods should be well justified.

**Could dietary supplements be used in the proposal? Could we use pre-clinical mouse models in the proposal?**

Supplements would not be considered a part of a FIM program; and animal models are not allowed as part of this RFP.

**Can this be used to help build off of existing (pilot) research or in hopes of researchers exploring FIM projects?**

Yes, as long as applicants clearly outline how their proposal meets the FIM definition and research objectives when applying.

**We have approved Medicaid waivers in NYs- can that be something that is incorporated in the application?**

Yes, as long as applicants clearly outline how this proposal meets the FIM definition and research objectives when applying.

**Will Maternal health be a part of the RFA?**

Yes, this is a clinical area of interest.

## 7. Peer Review Process

**Will there be any compensation for applicants who complete the peer review? I have seen this in other, similar models.**

No, there will not be compensation awarded for participation in the distributed peer review process.

**With peer review of others' proposals, is it expected that part of this process means that your proposal might/will change AFTER submission?**

The distributed peer review process will be used to determine the final awards. We do not expect that comments made therein will impact the proposal that has been submitted, once chosen.

Once chosen, however, studies may expect some changes based on support provided from human centered design experts, etc. under the Cooperative Studies Model.

**For dual or multi-PI applications, will all PIs be required to peer review, or can one elect to review for that application?**

The contact PI will be the one to conduct the peer review.

**What are the ethics regulations that are put in place for the distributed peer review process (e.g., around confidentiality)?**

This will follow AHA's standard peer review policies, with the corresponding regulations. These are outlined here: https://professional.heart.org/en/research-programs/peer-review.

**How is conflict of interest managed in peer review?**

Once assigned, reviewers will have a set period of time to review and report on any potential conflicts of interest so that assignments may be reassigned.

**While the contact PI is the one who gets the peer review applications, can both PIs on an MPI split the work?**

Unfortunately, no.

## 8. AHA supports/resources

**I do not have access to a human-centered design expert. Will the AHA provide that access?**

Yes. Selected applicants 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.

**Will office hours be held, perhaps for us to run our research question by before a proposal is drafted?**

Unfortunately, this is not something that we can offer at this time.

**Can you comment on the 'incorporation of lived experience' into study design?**

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 illnesses. 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.

### 9. Post-Award Expectations & Requirements

**There was mention of standardized measures for nutrition assessments post-award relying on the collaborative model. Are you already anticipating a set of instruments that are preferred for this RFP? Teams may already have a set of preferred measures to reduce participant burden for example. Could those preferences be 'overruled' post-award?**

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.

**For funded collaborative grants, will AHA have requirements/award terms for the project proposals that are ultimately submitted (e.g., data sharing, measures used)?**

Yes, there are some requirements, and these are outlined within the RFP (pg. 5-6).

### 10. Others

**Will there be another cycle for this RFP?**

While there will probably be future RFPs, they will not address the same questions.

**Does an award at this stage put you at an advantage for later awards in the timeline?**

Future RFPs will undergo a similar review process, with peer reviewers rating the strongest proposals using a specific criteria that will be outlined in the RFP. There is not expected to be a relationship between receiving an award from this RFP and any potential RFPs.

**For other questions regarding the general AHA application process, and the use of Proposal Central, please refer to the Application Resources page. Please also reach out to HCXF@heart.org with additional questions.**