American Heart Association Food Is Medicine Request for Proposals Frequently Asked Questions

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 must be AHA members; however, other partners on the proposal are not required to have AHA membership.

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 an 18-month period. The award start date will be January 1st, 2024, and the award end date will be June 30th, 2025.

What is the total award amount?

The award amount is up to \$400,000, including all indirect costs. The AHA limit for indirect costs is 10%.

While these questions seem of import, I work on research that applies to longer term interventions and questions. Will there be a future RFP that addresses other questions under the FIM umbrella?

There is a likelihood that we will have future requests for proposals. Future requests for proposals will probably center on a variety of other questions related to effective Food Is Medicine interventions.

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 <u>link</u>. 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?

As practitioners fill out the above form, we will share the list for prospective PIs on our <u>website</u>. You may also contact AHA FIM staff at <u>AHA.FIM@heart.org</u>.

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

Yes. If selected, the study team will be introduced to a human-centered design expert who will create templates for the group to use, provide guidance to the group and a high-level tutorial on human-centered design, and be available for ad hoc questions as needed to help with implementation of this element of the study design.

I noticed that equity and lived experience are emphasized in the RFP, but are not a separate element under the peer review process. Are those part of the scoring criteria for the peer review?

Yes. These considerations should be considered by reviewers when assessing significance, approach, innovation and the non-scientist summary components of the proposal.

Are clinical trials investigating the efficacy of a specific dietary intervention in clinical population of interest of this RFA?

This RFP is not intended to test the efficacy of specific diets or supplements. The expectation for these proposals is that investigators will use evidence-based dietary approaches, such as the AHA Dietary Guidelines for Cardiovascular Disease (e.g., Gardner CD et al. Popular Dietary Patterns: Alignment With American Heart Association 2021 Dietary Guidance: A Scientific Statement From the American Heart Association. Circulation. 2023 May 30;147(22):1715-1730. PMID: 37128940; Lichtenstein AH et al. 2021 Dietary Guidance to Improve Cardiovascular Health: A Scientific Statement From the American Heart Association. Circulation. 2021 Dec 7;144(23):e472-e487. PMID: 34724806; and others.)

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. We expect that clinical populations will include patients with cardiovascular risk factors such as diabetes and hypertension, heart failure, and pregnant women, as well as people at high risk for cardiovascular disease, but we are not limiting the participant population. 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.

Can a 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.

Can awardees partner with technology companies?

Yes, awardees can partner with technology companies. As with all partners, please ensure that corresponding letters of support are uploaded as part of the application.

Does the Food Is Medicine Intervention have to occur in a clinic setting and be physician delivered?

No, the interventions do not have to occur in a clinic setting or be physician delivered. However, Food Is Medicine interventions should have a connection with health care, which is to say that participants or patients need to be identified or referred via a health care system or health plan.

Can you submit multiple grants?

Yes.

Can this funding be used to support Food Is Medicine benefits as well as costs for program administration? And, if the intervention involves food delivery, are costs for food boxes/delivery allowed as part of the budget?

Yes, intervention costs are allowable expenses under the budget. Note that indirect costs to institutions are limited to 10% per AHA policies.

How many grants will be awarded?

Approximately 8 grants will be awarded.

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.

How much preliminary data is necessary, given that this will fund feasibility studies? How much will it impact the overall proposal evaluation, if I don't have enough preliminary data?

There should be an adequate amount of background information, which may include preliminary data, to highlight the rationale behind your hypothesis.

The preliminary data and background information provided will be graded as part of the 'Approach' scoring criterion, in which reviewers will be asked if the conceptual framework, design, methods and analyses are adequately developed, well-integrated, well-reasoned, and feasible, per the preliminary data and background information. However, reviewers are encouraged to put the assessment of preliminary data into perspective, so that bold new ideas and risk-taking by investigators are encouraged rather than stymied.

If you have existing funding for a trial, are you able to apply for the opportunity?

Yes, as long as the funding requested under this RFP is being used to address an additional research question or build on the previous trial in some way. For additional information on declaring overlapping and alternative funding, please refer to the AHA_Research_Funding_Application_Instructions_AC.pdf (heart.org).

Can you explain and give examples of the Cooperative Studies Framework?

This framework is modeled after that used in various organizations, such as the Veteran's Administration and National Cancer Institute, and is intended to allow some consistency in the frameworks we are using across funded studies, to better facilitate progress forward.

We will use human centered design as an example. We note in the RFP that human centered design will be important to design effective interventions, but we are not expecting all teams to include this in their proposals, given that it is not a resource widely available. Under the cooperative studies framework, we will recruit a team of human centered designers, who will be made available to the funded teams. These designers will provide free training and coaching, with the goal of helping to refine protocols by incorporating the human centered design perspective.

This will be done for incorporating human centered design, behavioral science, and cost-effectiveness. For statistics, the expectation is that each project team will have their own statistician, though there will be FIM Initiative statisticians who can support project teams on an as needed basis.

Can you please discuss how human centered design should be considered in these applications?

Human centered design principles are not a requirement within proposals. For funded teams, designers will work with project teams to ensure that human centered design principles are embedded within study designs.

Is a formative phase allowed, such as working with stakeholders to tailor a FIM model to a certain population, and then testing that model using some sort of experimental design? Would a project like that be in scope?

Yes, as long as objectives can be met within 18 months.

Is comparative effectiveness required in the proposal?

No, comparative effectiveness is not required. The focus of this RFP is on conducting rigorous testing of ways to significantly increase the initiation and short-term sustaining of changes in purchase and consumption of healthy foods, including but not limited to comparative effectiveness study designs.

Can projects be located outside of the US?

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

May we use funding to pay for healthy meal plans and incorporation of dietary consultation in our EMR?

Yes, funding may be used for intervention costs, including healthy meal plans and incorporation of dietary consultation in EMRs, so long as this is for the purposes of research, and not program development.

Can proposals focus on families and children?

Yes.

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

The maximum dollar amount per grant is \$400,000, including a maximum of 10% indirect costs. Either would apply, as long as you can demonstrate the feasibility of answering the research question with the given budget.

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No.

Would a delayed start date be considered?

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Would a Delphi study to define competencies for health care provider training in this area meet the funding specifications?

No.

Would short-term studies within ongoing USDA NIFA-supported produce prescription programs be considered?

Yes.

Can more than one application from an institution be submitted?

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

The platform requirement is difficult to implement with our target population (rural veterans who often do not have access to the internet). Is this grant not a good fit if we cannot use such a platform? We will still be able to meet the listed features required (randomization, etc.), but not through the use of an innovative platform unfortunately.

The platform requirement within the RFP is intended to aid in the focus of running the trial itself, to ensure that trials are run efficiently, in a way that could be replicated, and to allow later coalescing of data as appropriate.

To this point, end users may not have to interact with the platform, and study teams should focus on outlining the ways in which they are meeting the needs of their proposed population, in terms of how different populations might interface with the platform, while still collecting and documenting the appropriate data.

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 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.

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 HgbAlc 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 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, <u>Food is Medicine Initiative | American Heart</u> Association.

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.

In our experience, the most fruitful projects integrating academic and design frameworks incorporate both from the start. Is it possible for us to submit a joint proposal that has design techniques built in from the start?

Yes, eligible PIs may submit study ideas that have design techniques built in from the start. All funded study teams will still have access to additional human centered design support.

What types of institutions will FIM be sourcing food from? Will there be a longtime relation with local agriculture institutions/farmers markets?

While a long-term consideration, these considerations are not a requirement for this RFP.

Are the outcomes focused on reception of the food/program and retention of participants or are lab values encouraged as well (like Lipoprotein A and HbA1c)? Are you looking for health markers/indicators to improve for this pilot?

Proposals must be explicit about their measurement strategies for enrollment, adherence, retention, and engagement, and investigators are strongly encouraged to implement qualitative metrics alongside the quantitative measures. Examples of potential metrics to track include:

- -Rates of enrollment (%) among potentially eligible participants
- -Rates of initiation of program among enrollees, retention, and ongoing engagement
- -Changes in food purchasing behavior over the study course
- -Changes in dietary intake over the study course
- -Changes in food security status over the study course
- -Quantitative and/or qualitative assessments of food consumption behavior
- -Quantitative and/or qualitative assessments of participant-reported outcomes including but not limited to mood, energy, vitality, self-sufficiency etc.
- -Improvements in intermediate health outcomes such as hemoglobin Alc or objective markers of health service utilization such as readmission rates

Is there any interest in this RFP measuring aspects of the partnerships between the healthcare and food sectors? So not outcomes and impacts of the patients, but collaborative partnerships that might lead to these outcomes?

At this time, the RFP does not apply to measuring aspects of those partnerships, though this is certainly important for the field overall.

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

You may use another title as desired.

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.

Will there be another cycle for this RFP?

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

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.

Is RedCap considered an automated trial platform? Or are you looking for a specific platform?

There is no specific platform that is required. The platform you choose should have the capabilities listed below:

- Randomization
- Remote Consent
- Survey Administration
- Bi-directional texting and other channels for reaching participants (IVR or email)
- Automation of follow-up
- Automation of participation incentive payments
- Data on individual participants easily and securely transferrable for analysis

Hi 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.

If an organization is already implementing a similar program could this be used to expand patient enrollment, program capacity and creation of expanded services offered?

This RFP is focused on funding research questions that would aid in building the evidence base of generalizable knowledge for implementation questions and short-term behavior change. Funding is not available for expanding existing infrastructure, without an accompanying research question.

Can you speak more about the data platform and how it works with (or doesn't work with) the health system's EHR?

The importance of the ability of a data platform to integrate with an electronic health record will depend on the specific aims of a given trial. These considerations should be brought up in careful discussion with the platforms, as you outline whether they can or cannot work with the health system's EHR that you are working with, if needed.

We'd love to know if there is a way to collaborate on the proposals as design folks before they're reviewed?

Unfortunately we cannot offer that as part of the RFP.

Can you please clarify this statement "specifically achieving high rates of enrollment and engagement, using input from the lived." Does this statement means that focus groups/interviews must be conducted with potential participants?

Focus groups/interviews are not a requirement, but the lived experience should be considered and explored through the resources that are available.

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

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

What types of budget items do you expect to see?

Please review our <u>AHA Award Guide</u>; allowed and not allowed budget items are outlined beginning on pg. 18.

If we have an existing FIM program and are capable of longer-term outcomes during the grant period, are you interested in those as part of the application?

Yes, we are interested in long-term outcomes if available, though all outcomes must be collected within the 18 month window.

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.

Would the award funds be available to offer patients as food subsidies ...assuming we want to A/B test \$\$ 'dosage' and duration at different levels for various socioeconomic populations?

Yes, award funds can be used for food subsidies or other intervention costs.

Is a power analysis necessary to include?

A formal power analysis is not necessary for all proposed studies. When providing the design of the study, however, we do ask for you to consider and outline statistical aspects of the approach, the adequacy of controls, the outcomes of interest and number of observations, as well as how results will be analyzed. Power calculations will be welcome if appropriate to your study plan.

What level of power are you looking for in proposed trials?

There is not a specific level of power that we are looking for. Decisions on power should be made in partnership with the study statistician based on study parameters.

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.

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

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

Should a 6 month pilot include two different populations?

It is not a requirement for pilots to use two different populations; and applicants should be mindful of budget and award duration requirements when developing interventions.

I represent a non 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 Pls 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 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.

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

Pls do need to be US-based.

Can the outcomes being measured be focused on behavioral changes, or do the investigations need to demonstrate biometric/clinical impacts?

Outcomes can vary; we defer to your study question. Examples of potential metrics to track include:

- -Rates of enrollment (%) among potentially eligible participants
- -Rates of initiation of program among enrollees, retention, and ongoing engagement

- -Changes in food purchasing behavior over the study course
- -Changes in dietary intake over the study course
- -Changes in food security status over the study course
- -Quantitative and/or qualitative assessments of food consumption behavior
- -Quantitative and/or qualitative assessments of participant-reported outcomes including but not limited to mood, energy, vitality, self-sufficiency etc.
- -Improvements in intermediate health outcomes such as hemoglobin Alc or objective markers of health service utilization such as readmission rates

There was mention of standardized measures for nutrition assessments postaward 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?

For teams that receive awards, we will work with the study teams to determine the best approach for collecting outcomes. While future work is focused on developing a set of common measures for Food Is Medicine interventions, we would also work with teams to consider preferences on measures based on considerations such as respondent burden, validity in certain populations, etc.

Since this is about uptake and influence of resources or incentives on incorporating into diet, does the population have to be restricted to high-risk; e.g. patients with diabetes versus those with unmanaged diabetes.

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's is efficacious and cost-effective for improving people's health through food is medicine interventions.

Does point of entry into a program need to be a clinic/health provider? Would AHA be supportive of direct community enrollment across the country if the intervention could ultimately deploy in a healthcare system?

Under this RFP, Food Is Medicine interventions should have a connection with health care, which is to say that participants or patients need to be identified and/or referred via a health care system or health plan.

Can other trials platform not listed in the RFP be used? What should teams look out for if engaging platforms outside of the ones listed?

Teams are welcome to use other platforms outside of those listed in the RFP; the platform you choose must have the capabilities listed below:

- Randomization
- Remote Consent
- Survey Administration
- Bi-directional texting and other channels for reaching participants (IVR or email)
- Automation of follow-up
- Automation of participation incentive payments
- Data on individual participants easily and securely transferrable for analysis

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.

We have a behavioral/nutrition change project for low-income urban African Americans with coronary disease or poorly controlled CAD risk factors. Would a randomized intervention (active coaching vs. none) be preferred, or is an evaluation of before and after intervention allowable?

This RFP does have a strong focus on rigorous study designs. While randomized controlled trials are not the only type of trial that is allowable, study teams should work to develop the strongest possible study design to answer their research question.

You talk about increasing access for all populations, but the RFP is focused on specific diseases. Will identifying those with "only" food insecurity be disqualifying? Can patients with food insecurity be the target or do they need to also have a concurrent medical condition?

The RFP is not intended to focus on specific disease states. Study teams should be able to make the case that the population being proposed is one where a Food Is Medicine program can improve the health trajectory, and plausibly down the road, the health care cost trajectory.

Will TA 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.

We have a FiM intervention already running and have identified a very targeted barrier to participation - i.e. transportation, would this be an acceptable intervention. And could the measure be enrollment, retention and completion? Would we need to collect health data as well (ex AIC, weight...)

While this could be a possibility under the RFP, it would be important to outline the background information and preliminary data carefully to brief reviewers on the rationale behind this specific addendum to the existing intervention (e.g. Qualitative data that points to transportation being the primary barrier as opposed to any other potential barriers). Outcome measures can include enrollment, retention, and completion, and need not include health data, as appropriate.

The primary objective is enrollment and adherence rather than health outcomes. Is that correct?

The primary objective of the RFP is enrollment and adherence; health outcomes may be considered as well, and are noted as potential metrics.

Can you elaborate on differences in considering health system and health plan? is it required to engage insurance companies/agencies?

Connection with health care should be interpreted as participants or patients need to be identified via a health care system or health plan, which includes self-insured employer organizations. Health systems and health plans are eligible sources of patients and data, and there is no requirement to engage insurance companies or agencies at this stage of the research.

Can the control group be a comparable group of patients who were not referred to the FIM program? Or is it a requirement that they consent to the program and then be randomized to a control group?

For this RFP, the preference is for randomization, so as to avoid inherent biases from self-selection and/or the impact of unmeasured confounders. Proposals that use other designs should include a strong rationale for the reasons behind their research design.

Can funding be used to purchase technology (smart phones, units, pads, etc.) for clients to increase access to support / program to improves health outcomes?

Yes, funding can be used for these intervention costs.

Is enrollment and retention rate of persons under-represented in research/clinical trials as an outcome of particular interest?

Yes, there is interest in increasing enrollment rates among historically underrepresented groups.

The RFP reads mostly like a feasibility study of engagement, but you're talking about trials of FIM. Are you saying we should use the lived experience to design an FIM program, or to design ways to increase reach and engagement?

Lived experience should be used to design the FIM program in a way that increases reach and engagement.

Would you be interested in a comparison between intervention designs (e.g. food prescription vs. food box) or are you more interested in the mechanisms involved in a specific intervention approach?

The focus on this specific RFP is on the initial engagement and short-term behavior change. While we welcome studies that optimize that while using a comparative effectiveness framework with two different types of interventions, comparative effectiveness study designs are not a requirement of the RFP. We do not require that studies are mechanistic.

Can we work with specific components of the health system (e.g. if we are focused on early life course, work with Department of Pediatrics within a large health system) as our designated partner? Or must be system-wide partnership?

Yes, you can work with specific components of the health system as your designated partner; it does not have to be a system-wide partnership.

If a program exists, but we want to change it through a human center design process to increase enrollment and engagement, does this fall under the RFP?

This RFP does welcome interventions focused on increasing enrollment, engagement, and short-term behavior change, for which there is a specific research question that is being addressed. We do not anticipate funding program development or expansion.

Would an existing program that can utilize an ongoing program to test various circumstances (e.g., routes of enrollment, delivery vs. vouchers) have an advantage in their proposal?

It can be helpful to leverage the capabilities of existing organizations and infrastructure, especially given the complexities of getting these studies off the ground in a timely fashion.

While there is no inherent advantage in the peer review scoring criteria, there is a scoring domain entitled "investigator, investigative team, and partners", in which the ability of the team to execute the proposal will be evaluated.

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's is efficacious and cost-effective for improving people's health through food is medicine interventions.

Given the preference for standardized measures, should we not specify the measurement tool in the proposal? For example, should we say we plan to measure diet quality, but not specify that we want to use a food frequency questionnaire or 24-hour dietary recall?

Proposals should be explicit about their measurement strategies.

Are you interested in a project that uses Cal Aim FIM as usual care?

Proposals that take advantage of interesting programs that are already in place, where investigators can layer on top some randomized testing that achieve the objective of the RFP, are welcome. Particularly for this style of proposals, it will be important to have a detailed description of the current program, and to consider what is known about effectiveness in the current program.

When do you expect the applications to be reviewed (by the applicants)?

The Peer Review Process will take place between Nov 13th - Dec 11th.

What are the next steps for for-profit organizations interested in collaboration who submitted their names via the provided form?

These names have been posted online with the information provided, and PIs are welcome to reach out to parties they may be interested in partnering with. We are unable to provide additional connections at this time.

The awards are announced in Dec, and expected start date Jan 1st; and somewhere it said that IRB approvals have to be in before funding is released. Since IRBs will be submitted after finalization of programs/research, I'm a little confused about when funding might begin.

Awards will start on January 1st.

The first payment for this award will be planned for April 1st 2023, provided all deliverables, including the IRB approvals, are completed.

The AHA will remit quarterly installments to your institution for your Award. These payments will occur in the months of April, July, October 2023, and January 2024 via electronic funds transfer. The AHA pays research Awards by direct deposit on or around the third Tuesday of the month.

What are your thoughts on involving participants who are already receiving some type of food benefit? WIC, SNAP? Do you have interest in seeing outcomes above and beyond these benefits with additional FIM programming?

Yes, we would welcome proposals that include outcomes examining use, or changes in use, of WIC and SNAP because of the Food Is Medicine intervention.

Would you consider a study looking at chronic kidney disease? Yes.

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