



American Heart Association Food Is Medicine Initiative Request for Proposals for Clinical Trials

Key Dates (*subject to change*)

RFP Posted:	September 19 th 2023
Application Deadline:	November 6 th 2023
AHA Distributed Peer Review:	November 13 th – December 11 th 2023
Notification of Awards:	December 18 th 2023
Award Start Date:	January 1 st 2024

Purpose

The American Heart Association (AHA) announces a Request for Proposals (RFP) for its new Food Is Medicine Initiative, funded with support from The Rockefeller Foundation.

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 disease.¹⁻³ There are significant equity disparities as well, with higher rates of chronic disease mortality among Black, Latino, and Native populations,³ and higher rates of adults with poor diet quality among Black and Latino households than in the overall population.⁴ '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.⁴ In recent years, researchers have begun to systematically test these initiatives for feasibility and efficacy. Initial studies have shown promise, but these have not shown definitive evidence that would facilitate coverage decisions by public or private payors tied to specific clinical indications nor have they determined the optimal dose, duration, and intensity of FIM initiatives.

The current published literature on FIM is constrained by the inevitable methodological limitations of an emerging field, with ranges in populations, intervention intensity, duration, distribution modalities, measurement tools, ancillary behavior and lifestyle coaching precluding definitive conclusions on efficacy.^{5,6} Furthermore, few studies conducted comparative effectiveness of different intervention types or are of a necessary duration to measure cost effectiveness.

Opportunity

This first AHA FIM Request for Proposals is focused on feasibility and implementation science, specifically achieving high rates of enrollment and engagement, using input from the lived experiences of participants and practitioners to guide program design, and testing ways to achieve significant short-term changes in healthy eating behavior. The studies funded through this RFP are intended to be short term rapid cycle studies (18 months or less) that address the noted challenges in feasibility and implementation, as well as testing approaches to achieve short-term behavior change. Subsequent studies will focus on sustaining these behavior changes and achieving significant improvements in longer-term clinical outcomes, as well as cost-effectiveness and other critical questions that face the field.

A common approach that is tested to increase purchase and consumption of healthy food has been using incentives (either subsidized or free healthy food). However, a number of studies have demonstrated that even large subsidies may only increase healthy food consumption by small amounts and that nutrition incentive programs may go unused by nearly 50% of those who are eligible.⁷⁻⁹ That motivates the focus of this RFP, as more systematically incorporating input from the lived experience of study participants, and ultimately patients and practitioners, and a focus on high individual enrollment, retention and adherence will be essential for the programs to achieve the magnitude of improvements in healthy food consumption and outcomes that are theoretically possible.

As the field continues to progress, we fully anticipate that new pathways may emerge, and expect that different populations may require varied levels of support and interaction to ensure equitable access. Work in this field is tasked with balancing rigor, speed, efficiency and equity, and a key focus is to construct a strong foundation of evidence that illustrates which interventions for specific populations have levels of cost effectiveness similar or greater than already covered health services.

Science Focus Areas of Interest

As we look to purposefully invest resources towards the critical questions that are facing the field, 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 comparative effectiveness study designs. While disease outcomes will generally not be the primary focus of this RFP, we would encourage applicants to consider individuals with cardiovascular disease, and/or those with diet-related cardiovascular risk factors (e.g., obesity, diabetes, pregnancy) as the most appropriate populations for study. This includes trials that 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. Later testing will focus on sustained behavior changes leading to more definitive changes in clinical outcomes and assessment of cost-effectiveness.

Real-world evidence of successful implementation, engagement, and retention in FIM trials remains limited. There is evidence that approaches that have been tested, like provision of vouchers or subsidies for fruit and vegetables alone, sometimes do not result in achieving high rates of participant enrollment, engagement, and behavior change. Studies to date have shown that

difficulties exist in recruitment, retention, and engagement, and that sometimes those who are offered programs aren't even aware of the underlying incentives.⁷⁻¹⁰ Engagement post-enrollment may be high if enrollment is limited to a low percentage of eligible participants, and only the most motivated opt in to participate. This highlights the need to consider how programs are presented and places the onus on researchers and practitioners to ensure that lived experience is thoughtfully integrated into study design. Furthermore, behavioral strategies that recognize that individuals have limited bandwidth and that a variety of behavioral hurdles to healthy food purchase and consumption exist should be considered in addition to simply adjusting prices.¹¹ Previous research has shown that pricing mechanisms alone may be insufficient to initiate behavior change, and the field needs to go beyond the assumption that provision of free or subsidized healthy food will necessarily result in high rates of behavior change and formation of new habits. Focusing on mechanisms of behavior change is vital to facilitate the sustained changes in behavior that lead to improved health outcomes. 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 A1c or objective markers of health service utilization such as readmission rates

An overarching goal of the initiative is to achieve personalization at scale, where we create a model in which we can nimbly tailor approaches for individuals, to increase engagement and efficacy. Technological advances, including the thoughtful and careful use of artificial intelligence approaches and virtual grocery stores, will enable these approaches, and proposals are encouraged to integrate potential opportunities.

Because of the equity considerations inherent in Food Is Medicine initiatives, 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.

Example research questions that illustrate the intention of this RFP include:

1. What are the most effective ways to enroll diverse participants from the standpoint of increasing the population health effectiveness (i.e., reach) of programs (for instance, different ways of utilizing physician referral, direct outreach to participants, health plan outreach)?
2. What are effective ways of increasing the proportion of participants with chronic disease who are screened for unmet social needs and food and/or nutrition insecurity within health systems?
3. What are ways to increase the proportion of eligible participants for FIM programs signing up and following enrollment staying engaged / utilizing program components (including incentives if offered) at high rates?
4. How are participant's individual and cultural preferences best supported in program design to achieve high rates of participant engagement, satisfaction, adherence, and post-intervention sustained effects?
5. For studies that involve incentives, what is the dose response on behavior change with different incentive amounts or coverage of varied proportions of food costs? Are there behavioral strategies that can be used to make a given incentive amount more effective dollar for dollar?
6. What types of behavioral coaching or educational strategies are useful as complements to FIM provision in achieving short- and long-term behavior change? What are the intervention differences required in populations facing food insecurity compared to those with adequate resources? What is the incremental cost effectiveness of different components of multifaceted interventions? What is the impact of in-person programming compared to virtual or remote engagement with regard to behavior changes?

Use of platform for running trials: To accelerate development of the field we are requiring the use of a trial platform that allows for some degree of automation and greater efficiency of trial functions. Experience over time has shown that these approaches are far more scalable by reducing labor costs for tasks that can be easily automated such as participant outreach at specific intervals or feedback via texting. 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

We offer several possibilities that we have pre-vetted, and you are encouraged to contact them to work with you on a proposal, though you may choose another platform you prefer as long as they have similar capabilities. Investigators are also encouraged to consider access issues for vulnerable populations, including poor and aging populations, which may have less availability of Wi-Fi or digital communication.

Platforms that have been pre-vetted include: [Alira Health](#), [Hugo](#), [Penn Way to Health](#), and [UCSF Eureka](#). Contact information is available on their respective websites, linked above.

Human Centered Design

As part of your proposal, we are asking all applicants to consider human centered design. After grants are awarded, researchers will be paired with design experts for assistance in making your intervention design as user-centric as possible to maximize the likelihood of program efficacy and effectiveness.

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.¹²

The Cooperative Studies model elements that we will use include:

1. A collaborative process that envelops the entire multisite study lifecycle.
2. A team approach to study development.
3. An iterative study development process in which each research team approved in concept for funding will interact with experts in human-centered design, biostatistics, behavioral science, and cost effectiveness to refine the proposed approach. This process will be used to refine the protocols for final review before study start.
4. A structured approach to study design evaluation that specifically addresses primary hypothesis and aims; study design; inclusion/exclusion criteria; outcomes; power; statistical analysis plans; standardization of measures; and safety/ethical issues.

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

1. Every study will have access to cutting edge human-centered design expertise, as well as advice in behavioral science, statistical methods, and cost effectiveness at the beginning of the study and as needed thereafter. This provides a means to increase equitable access to state-of-the-art research support that might otherwise not be available to all investigators;
2. The AHA will develop recommended standardization of measurement to allow comparability between studies and to reduce effort in 'reinventing the wheel';
3. Plans for implementation will be assessed up front and at periodic check points to ensure that cross-learning is happening between projects;
4. Projects will benefit from assistance in leveraging infrastructure support that is developed as part of the broader initiative;
5. 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;
6. This will accelerate learning and the generation of new knowledge.

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.

For individuals associated with for-profit institutions, community-based organizations, or other non-eligible entities, there are opportunities to partner with eligible PIs in conducting this research. For those interested in connecting with project PIs, please complete the form at this [link](#), and a member of the team will follow-up with you.

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 Features of All AHA Awards on the [AHA Application Information](#) page for answers to commonly asked questions about eligibility and award details. NOTE: scroll down to see "Features of AHA Awards."
- 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 Amount and Duration

Grant amounts will be up to \$400,000 over an 18-month funding period, including up to 10 percent institutional indirect costs. The AHA anticipates funding up to \$3 million in awards.

Submission requires the following:

- Applicant/PI NIH Biosketch (5 pages) and Biosketch of Co-Investigator(s), if applicable
- Budget Request and Justification (2 pages)
 - provide a total budget request up to \$400,000 across the one-year period, inclusive of a maximum 10 percent institutional indirect costs.
 - A line-item detailed budget is not required but a budget justification narrative must be included.
- Research Project Environment (2 pages)
- Research Plan (up to 7 pages), inclusive of the following:
 - **Specific Aims**
 - Provide a clear, concise summary of the aims of the work proposed and its relationship to your long-term goals. State the hypothesis to be tested.
 - **Background and Significance**
 - Sketch the background leading to this application. Summarize important results outlined by others in the same field, critically evaluating existing knowledge. Identify gaps that this project is intended to fill.
 - State concisely the **importance and relevance of the research** towards the aim of improved feasibility and engagement, and the integration of behavioral science where appropriate. Also, it is incumbent upon the applicant to make a clear link between the project and the goals of the AHA's FIM program.
 - **Preliminary Studies** (if applicable)
 - Describe concisely previous work related to the proposed research by the applicant that will help to establish the experience and competence of the investigator to pursue the proposed project. Include pilot studies showing the work is feasible. (If none, so state.)
 - **Research Design and Methods** (includes all of the following):
 - Outline the **conceptual framework** that underlies your research question and expected findings.
 - **Define the research question using the PICOTS Framework** to Strengthen Evidence Gathered in Clinical Trials developed by AHRQ. This should include:
 - P: Participant population – define the participant population to be studied with careful consideration of baseline sociodemographic and clinical characteristics (for instance, food insecurity + elevated cardiovascular risk). Describe how you will elicit input from the defined population to help ensure your intervention is sufficiently human-centric to be engaging and builds on the lived experience of the type of individuals you hope to enroll in your study. Focus on inclusion of demographically diverse subject populations and underrepresented communities. Describe collaborating organizations and your relationship.
 - I: Intervention – define the intervention including all its components, considering contextual factors and how to design the intervention tested to have high external validity.
 - C: Comparator – Having a ‘usual care’ comparator is important. Please define the components of usual care clearly, what sort of

blinding is possible, and methods to avoid differential drop out and incomplete outcomes ascertainment.

- **O: Outcome** – define safety and effectiveness outcomes that matter to participants, the key metrics you will use to assess whether your trial was successful, and relevant health utilization or intermediate outcomes that are on the pathway to improved clinical outcomes. Costs of the intervention should be measured, as appropriate, with discussion of predictors of implementation and adoption success needed for next steps. These can be exploratory but should be pre-specified. For these pilots we are not expecting sufficient power to assess subgroups but consider what exploratory analyses could be hypothesis-generating for the next round of more expansive testing. Clearly state collection methods (including types of tools, surveys, and self-reported data), data systems that will be used, and data-based insights into the mechanism of impact of your intervention. Provide data-based insights into the mechanism of impact of your intervention.
 - **T: Timing** – we are looking for short-term studies of 3-6 months duration for interventions with the expectation that the studies, including implementation and analyses, will be complete within 12 months of project initiation.
 - **S: Setting** – define the setting and the relevance of this study setting to widespread longer-term testing that could have national implications.
- Describe **proposed tests, methods, or procedures**. These should be explicit, sufficiently detailed, and well defined to allow adequate evaluation of the approach to the problem. Describe any new methodology and its advantage over existing methodologies.
 - Describe the **overall design of the study**. This should carefully consider 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. Include details of any collaborative arrangements that have been made.
 - Discuss the **potential difficulties and limitations** of the proposed procedures and alternative approaches to achieve the aims.
 - Explicitly **state the trial platform(s)** that will be utilized for implementation of the study.
 - Describe **collaborating partners**, with their relevant expertise and role in the study. We expect the principal investigator to be someone with a track record of having conducted and published rigorous research. **Each team should include a health system or health plan partner for identification of eligible participants plus a food provider (either a community-based organization retailer, or other food vendor).** Include letters of support from each partner documenting their willingness to participate and to grant access to data

on participating individuals to facilitate analysis of impact. Please also include notes on prior experience with executing business associate agreement(s) and/or data sharing agreement(s).

- **Literature Cited (no page limit)**
- **Summary for Non-scientists/Lay Summary (max 2500 characters)**
 - The lay summary is not a document to be uploaded, rather it is entered through form fields in ProposalCentral. It is listed here so that the applicant is aware this is required.

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 of any level. This award is not intended for trainees.

Note: For Community Based Organizations (i.e., Food Is Medicine practitioners) interested in aid connecting with eligible Project PIs, please complete the form at this [link](#), and a member of our team will follow-up with you .

Required Assurances:

- For all proposals 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 on a minimum 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.

Public Access: The AHA's 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). 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.

Other Data Sharing: Awardees will also be required to deposit all data collected through this funding mechanism to the AHA's Food Is Medicine data repository.

For more information on the above policies, see AHA's [Open Science Policy](#) webpage.

Preregistration: AHA requires clinical trials to preregister using ClinicalTrials.gov. Clinical trials are defined as "a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes".¹³

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 will 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](#).

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 6-9 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 evaluated for advancement. 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.

Non-Scientist Summary:

AHA FIM Mission: Generate the evidence and tools to help the health sector design and scale programs that increase access to nutrition food, improve health and health equity, 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 FIM program? How well does the proposal and summary achieve goals around health equity and diversity?

Investigator, Investigative Team and Partners:

Investigator (applicant): 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 the partners seem committed to supporting this project and capable of helping to deliver on what is proposed?

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?

Significance:

Does this study address the core concern of this RFP, namely feasibility and implementation science and testing ways to achieve significant short-term changes in healthy eating behavior using a FIM approach? Does the 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 health equity 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 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?

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 FIM program, and on the applicant's ability to effectively describe the proposal and its potential outcomes to non-scientists.

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