

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)
National Institutes of Health ([NIH \(http://www.nih.gov\)](http://www.nih.gov))

Components of Participating Organizations
National Center for Complementary and Integrative Health ([NCCIH \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=82467\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82467))

Note: Not all NIH Institutes, Centers, and Offices (ICOs) participate in Announcements. Applicants should carefully note which ICOs participate in this announcement and view their respective areas of research interest at the [ICO-Specific Scientific Interests website \(https://grants.nih.gov/funding/find-a-fit-for-your-research/nih-institutes-centers-offices\)](https://grants.nih.gov/funding/find-a-fit-for-your-research/nih-institutes-centers-offices). ICOs that do not participate in this announcement will not consider applications for funding.

Funding Opportunity Title
Assessing the Feasibility of Incorporating Mechanisms in Multi-site Clinical Trials of Mind and Body Interventions on Whole Person Health Restoration (R33 Clinical Trial Required)

Activity Code
[R33 \(http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r33&Search.x=0&Search.y=0&Search_Type=Activity\)](http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r33&Search.x=0&Search.y=0&Search_Type=Activity) Exploratory/Developmental Grants Phase II.

Announcement Type
New

Related Notices

- Check for any recent [Notices of NIH Policy Changes \(https://grants.nih.gov/grants/guide/url_redirect.php?id=11163\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11163) that may impact application requirements.

Funding Opportunity Number (FON)
PAR-28-091

Companion Funding Opportunity
None

Number of Applications
See Part 2, Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)
93.473, 93.213

Funding Opportunity Purpose
The National Center for Complementary and Integrative Health (NCCIH) announces this Notice of Funding Opportunity (NOFO) to solicit applications for **multi-site feasibility trials** of complementary and integrative health approaches with physical and/or psychological therapeutic inputs (often called mind and body interventions) to **reproduce** and **translate** mechanisms of emotional well-being (EWB) into large-scale clinical trials that advance our understanding of whole person health. These early-phase multi-site trials are essential for 1) demonstrating that the mind and body intervention can be delivered with fidelity across sites; 2) demonstrating reproducibility and rigor in engaging targeted mechanisms of EWB by the mind and body intervention across sites; 3) assessing feasibility of participant recruitment and retention, as well as randomization; 4) assessing feasibility of collecting comprehensive clinical (whole person health restoration) and mechanistic (EWB) data across sites; and 5) exploring correlations between changes in mechanistic targets and clinical outcome measurements pooled across sites. By laying this groundwork, studies supported under this NOFO will advance the science of whole person health and prepare the field for rigorous clinical trials and mechanistic mediation analysis with the potential to improve the health and well-being of all Americans.

Funding Opportunity Goal(s)
NCCIH is the lead Federal agency for scientific research on the fundamental science, usefulness, and safety of complementary and integrative treatments and practices. To address the need for objective evidence on the fundamental science, safety and efficacy of complementary and integrative health approaches, NCCIH supports rigorous scientific investigation to better understand how these interventions impact health, for whom, and the optimal methods of practice and delivery.

Key Dates

Posted Date
October 15, 2026

Open Date (Earliest Submission Date)

January 16, 2027

The following table includes NIH [standard due dates \(https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm\)](https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm) marked with an asterisk.

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS - New/Renewal/Resubmission/Revision, as allowed	Scientific Merit Review	Advisory Council Review	Earliest Start Date
February 16, 2027 *	March 16, 2027 *	Not Applicable	July 2027	October 2027	December 2027
June 16, 2027 *	July 16, 2027 *	Not Applicable	November 2027	January 2028	April 2028
October 16, 2027 *	November 16, 2027 *	Not Applicable	March 2028	May 2028	July 2028
February 16, 2028 *	March 16, 2028 *	Not Applicable	July 2028	October 2028	December 2028
June 16, 2028 *	July 16, 2028 *	Not Applicable	November 2028	January 2029	April 2029
October 16, 2028 *	November 16, 2028 *	Not Applicable	March 2029	May 2029	July 2029
February 16, 2029 *	March 16, 2029 *	Not Applicable	July 2029	October 2029	December 2029
June 16, 2029 *	July 16, 2029 *	Not Applicable	November 2029	January 2030	April 2030
October 16, 2029 *	November 16, 2029 *	Not Applicable	March 2030	May 2030	July 2030

All applications are due by 5:00 PM local time of applicant organization.

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

Due Dates for E.O. 12372

Not Applicable

Expiration Date

November 17, 2029

Required Application Instructions

It is critical that applicants follow the instructions in the Research (R) Instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400), except where instructed to do otherwise (in this NOFO or in a Notice from [NIH Guide for Grants and Contracts \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11164\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11164)).

Conformance to all requirements (both in the Application Guide and the NOFO) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

Applications that do not comply with these instructions may be delayed or not accepted for review.

There are several options available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners. You **must** use one of these submission options to access the application forms for this opportunity.

1. Use the [NIH ASSIST system \(https://public.era.nih.gov/assist/landing_era?tabId=0819b5fc-46b7-4f02-b6b7-127e5a4e19fa\)](https://public.era.nih.gov/assist/landing_era?tabId=0819b5fc-46b7-4f02-b6b7-127e5a4e19fa) to prepare, submit and track your application online.
2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and [eRA Commons \(https://public.era.nih.gov/commons/\)](https://public.era.nih.gov/commons/) to track your application. Check with your institutional officials regarding availability.
3. Use [Grants.gov \(https://grants.gov/search-grants?oppStatuses=closed|archived|posted|forecasted&fon=PA-25-301\)](https://grants.gov/search-grants?oppStatuses=closed|archived|posted|forecasted&fon=PA-25-301) Workspace to prepare and submit your application and [eRA Commons \(http://public.era.nih.gov/commons/\)](http://public.era.nih.gov/commons/) to track your application.

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Part 2. Full Text of Announcement

Section I. Notice of Funding Opportunity Description

Background

Chronic diseases are a major health and economic burden. Approximately 60% of Americans live with at least one chronic condition, such as heart disease, diabetes, depression, and cancer. These conditions account for 8 of the 10 leading causes of death in the United States. In addition, 90% of the nation's \$4.5 trillion in annual health care expenditures are for people with chronic conditions ([CDC, 2024 \(https://www.cdc.gov/chronic-disease/data-research/facts-stats/index.html\)](https://www.cdc.gov/chronic-disease/data-research/facts-stats/index.html)).

However, health and disease are not separate, disconnected states. Rather, they exist along a continuum in which a person can move toward or away from a state of health ([Quinlan, Baumgartner et al., 2024 \(https://pubmed.ncbi.nlm.nih.gov/39417020/\)](https://pubmed.ncbi.nlm.nih.gov/39417020/)). The process by which individuals travel from a less healthy state to a healthier state can be referred to as **health restoration**. Aligned with the Making America Health Again (MAHA) and National Institutes of Health (NIH) priorities to improve population health, there is a critical need to develop rigorous and reproducible science that identifies the pathways and interventions that reduce chronic disease and promote health restoration.

One way to assess health restoration is to explore positive changes in whole person health. Whole person health involves looking at the whole person – not separate organs or body systems – and considering multiple interconnected factors that influence health. Instead of just treating one specific disease, whole person health focuses on restoring health and preventing disease across the lifespan. To support this approach, NCCIH, in collaboration with the Centers for Disease Control and Prevention (CDC), developed and validated the current gold standard measurement of whole person health: the **Whole Person Health Index**. (<https://wwwn.cdc.gov/QBank/Search/Reports.aspx#/Reports/1260>). This comprehensive measurement captures key domains contributing to health, including diet, physical activity, chronic stress, sleep, and quality of life.

Mind and body interventions are widely used by the public for pain management, stress reduction, general health maintenance, and increasingly for improving **emotional well-being (EWB)** ([Nahin et al., 2024 \(https://pmc.ncbi.nlm.nih.gov/articles/PMC10811586/\)](https://pmc.ncbi.nlm.nih.gov/articles/PMC10811586/)). Emotional well-being is a multidimensional construct that includes positive emotional experiences, a sense of meaning and purpose in life, and overall life satisfaction ([Park et al., 2023 \(https://pmc.ncbi.nlm.nih.gov/articles/PMC10104995/\)](https://pmc.ncbi.nlm.nih.gov/articles/PMC10104995/)). To advance the science of EWB, NCCIH partnered with multiple NIH Institutes, Centers, and Offices to establish the [Emotional Well-Being: High Priority Research Networks \(https://reporter.nih.gov/search/PO9FhYeNP0SaBsXC2laBuA/projects?shared=true\)](https://reporter.nih.gov/search/PO9FhYeNP0SaBsXC2laBuA/projects?shared=true).

The funded Emotional Well-Being Research Networks and broader literature have identified promising mechanisms supporting EWB that may drive improvements in whole person health. However, much of the existing evidence comes from single-site or small-scale studies. This limits confidence in reproducibility, generalizability, and readiness for translation to clinical trials conducted in real-world settings. Before conducting fully powered efficacy or effectiveness trials, [NIH Gold Standard Science \(GSS\) principle \(https://www.nih.gov/about-nih/nih-director/statements/nih-publishes-plan-drive-gold-standard-science\)](https://www.nih.gov/about-nih/nih-director/statements/nih-publishes-plan-drive-gold-standard-science)s require strong preliminary evidence.

Research Objectives

This NOFO will support multi-site feasibility trials to collect preliminary evidence that:

- Target engagement of EWB mechanisms is reproducible and generalizable;
- Mechanistic and clinical measures can be collected using harmonized and standardized protocols in populations and contexts where mind and body interventions will be delivered; and
- Changes in mechanistic and clinical data are correlated over time.

Consistent with NIH Gold Standard Science principles, multi-site feasibility clinical trials are the necessary next step and can serve as a translational bridge between mechanistic discovery and fully powered efficacy and mediation studies.

Scientific Areas of Research Interest

Examples of EWB mechanisms include, but are not limited to:

- Social connectedness;
- Emotion regulatory processes;
- Affective and/or interoceptive neural networks;
- Inflammatory processes;
- Mitochondrial functioning; or
- Epigenetics, gene expression, and DNA repair.

Applications Not Responsive to this NOFO

The following types of applications are not responsive to this NOFO and will not be reviewed:

- Applications that propose research to analyze data to assess clinical efficacy/effectiveness; and
- Applications that propose research that includes a waitlist control condition.

Investigators proposing NIH-defined clinical trials may refer to the [Research Methods Resources \(http://grants.nih.gov/grants/guide/url_redirect.php?id=82448\)](http://grants.nih.gov/grants/guide/url_redirect.php?id=82448) website for information about developing statistical methods and study designs.

See Section VIII. Other Information for award authorities and regulations.

Section II. Award Information

Funding Instrument

Grant: A financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

Application Types Allowed

New
Resubmission
Revision

The [OER Glossary \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11116\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11116) and the How to Apply Application Guide provide details on these application types. Only those application types listed here are allowed for this NOFO.

Clinical Trial?

Required: Only accepting applications that propose clinical trial(s).

[Need help determining whether you are doing a clinical trial? \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82370\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82370)

Funds Available and Anticipated Number of Awards

The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.

Award Budget

Application budgets are not limited but are strongly encouraged not to exceed \$500,000 in direct costs per year, reflecting the translational and multi-site nature of this work. Budgets exceeding these guidelines will be considered only in exceptional circumstances and must be extremely well justified.

Award Project Period

Applicants are strongly encouraged to request no more than 3 years unless there is a strong scientific justification related to multi-site clinical and mechanistic feasibility assessment and cross-site reproducibility of target engagement. The maximum allowable project period is 4 years.

NIH grants policies as described in the [NIH Grants Policy Statement \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120) will apply to the applications submitted and awards made from this NOFO.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions - Includes all types

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Local Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized).

Federal Governments

- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations

Foreign Organizations/International Collaborations

Non-domestic (non-U.S.) Entities (Foreign Organizations) **are not** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.

Foreign components, as [defined in the NIH Grants Policy Statement \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11118\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11118), **are not** allowed.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the How to Apply- Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. Failure to complete registrations in advance of a due date is not a valid reason for a late submission, please reference the [NIH Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=82423\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82423) for additional information.

- [System for Award Management \(SAM\) \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82390\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82390) – Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code. Foreign organizations must obtain a [NATO Commercial and Government Entity \(NCAGE\) Code \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11176\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11176) (in lieu of a CAGE code) in order to register in SAM.
 - Unique Entity Identifier (UEI)- A UEI is issued as part of the SAM.gov registration process. The same UEI must be used for all registrations, as well as on the grant application.

- [eRA Commons \(https://grants.nih.gov/grants/guide/redirect.htm?id=11123\)](https://grants.nih.gov/grants/guide/redirect.htm?id=11123) - Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their Grants.gov registrations; all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- [Grants.gov \(http://grants.nih.gov/grants/guide/redirect.htm?id=82300\)](http://grants.nih.gov/grants/guide/redirect.htm?id=82300) – Applicants must have an active SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. Obtaining an eRA Commons account can take up to 2 weeks.

All PD(s)/PI(s) must be registered with [ORCID \(https://orcid.org/\)](https://orcid.org/). The personal profile associated with the PD(s)/PI(s) eRA Commons account must be linked to a valid ORCID ID. For more information on linking an ORCID ID to an eRA Commons personal profile see the [ORCID topic in our eRA Commons online help \(https://era.nih.gov/erahelp/Commons/default.htm#orcid.htm%3FTocPath%3D29\)](https://era.nih.gov/erahelp/Commons/default.htm#orcid.htm%3FTocPath%3D29).

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with their organization to develop an application for support.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the How to Apply-Application Guide.

2. Cost Sharing

This NOFO does not require cost sharing as defined in the [NIH Grants Policy Statement Section 1.2 Definition of Terms \(http://grants.nih.gov/grants/guide/redirect.htm?id=11126\)](http://grants.nih.gov/grants/guide/redirect.htm?id=11126).

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

The NIH will not accept duplicate or highly overlapping applications under review at the same time, per [NIH Grants Policy Statement Section 2.3.7.4 Submission of Resubmission Application \(http://grants.nih.gov/grants/guide/redirect.htm?id=82415\)](http://grants.nih.gov/grants/guide/redirect.htm?id=82415). This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see [NIH Grants Policy Statement 2.3.9.4 Similar, Essentially Identical, or Identical Applications \(http://grants.nih.gov/grants/guide/redirect.htm?id=82423\)](http://grants.nih.gov/grants/guide/redirect.htm?id=82423)).

Section IV. Application and Submission Information

1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace are available in Part 1 of this NOFO. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the Research (R) Instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/redirect.htm?id=82400) except where instructed in this notice of funding opportunity to do otherwise (in this NOFO, in a [policy notice \(https://grants.nih.gov/grants/guide/redirect.php?id=11163\)](https://grants.nih.gov/grants/guide/redirect.php?id=11163), or other notice from [NIH Guide for Grants and Contracts \(https://grants.nih.gov/grants/guide/redirect.php?id=11164\)](https://grants.nih.gov/grants/guide/redirect.php?id=11164)). Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Page Limitations

All page limitations described in the [How to Apply- Application Guide \(https://grants.nih.gov/grants/how-to-apply-application-guide.html\)](https://grants.nih.gov/grants/how-to-apply-application-guide.html) and the [Table of Page Limits \(https://grants.nih.gov/grants/guide/redirect.htm?id=61134\)](https://grants.nih.gov/grants/guide/redirect.htm?id=61134) must be followed.

Instructions for Application Submission

The following section supplements the instructions found in the [How to Apply- Application Guide \(https://grants.nih.gov/grants/how-to-apply-application-guide.html\)](https://grants.nih.gov/grants/how-to-apply-application-guide.html) and should be used for preparing an application to this NOFO.

SF424(R&R) Cover

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/redirect.htm?id=82400) must be followed.

SF424(R&R) Project/Performance Site Locations

All instructions in the [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/redirect.htm?id=82400) must be followed.

SF424(R&R) Other Project Information

All instructions in the [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/redirect.htm?id=82400) must be followed.

SF424(R&R) Senior/Key Person Profile

All instructions in the [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/redirect.htm?id=82400) must be followed.

R&R Budget

All instructions in the [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/redirect.htm?id=82400) must be followed.

The budget for the first year of the grant should reflect the time needed for trial startup.

Applicants are strongly encouraged to request no more than \$500,000 direct costs per year for 3 years of support. The request for a longer project period or higher per-year costs must be extremely well justified. The maximum allowable project period is 4 years. The budget for the number of participants included in the trial should be based on the number of participants needed to demonstrate feasibility benchmarks, not on the power for assessing efficacy on a clinical outcome, which will not be supported by this NOFO.

If parts of the costs of the trial are to be provided by sources other than NIH, these contributions must be presented in detail in the budget justification. Include budget support for the publication and dissemination of findings. Applicants should budget for the services of appropriate safety monitoring (e.g., medical safety monitor, independent medical monitor, or safety monitoring committee, as indicated).

R&R Subaward Budget

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed.

PHS 398 Cover Page Supplement

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed.

PHS 398 Research Plan

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed, with the following additional instructions:

Multi-site feasibility trials proposed should include aims to address the following:

- Reproducibility in target engagement of the emotional well-being (EWB) mechanism across sites;
- Feasibility of collecting mechanistic and clinical data across sites;
- Demonstration that the intervention can be delivered with fidelity across sites; and
- Correlation between changes in mechanistic and clinical data pooled across sites.

In general, applicants should keep the following in mind, regarding:

Preliminary Data Requirements

The following preliminary data from previous single-site studies from published literature or the team's previous research are **required**:

- Demonstration that a similar intervention produces a measurable impact on target engagement of the EWB mechanism of action (e.g., cite a study or secondary data analysis showing that the intervention is associated with or modulates the mechanism or specific aspects of the mechanism);
- Demonstration that a similar intervention does not produce frequent or severe adverse events in humans; and
- Pilot single-site feasibility data on a similar intervention in a population similar to the one that will be studied in the proposed trial.

For applications studying the feasibility or acceptability of including a natural product as part of a multi-component intervention, the application must provide published data that the formulation of the natural product proposed has demonstrated efficacy for the condition being studied from at least one fully powered placebo-controlled trial.

Study Design Considerations

For this Notice of Funding Opportunity (NOFO), the proposed multi-site feasibility clinical trial **must enroll research participants from at least two sites that are geographically distinct** (e.g., recruiting from more than one city or region). Sites should be **non-overlapping** with respect to clinical trial populations and should support the recruitment of a representative sample.

All studies are **required to include the Whole Person Health Index** (<https://wwwn.cdc.gov/QBank/Search/Reports.aspx#/Reports/1260>) and an **EWB mechanism** as part of their data collection protocol. Such a design should demonstrate that the collection of both clinical and mechanistic measures is feasible across sites. This also provides justification for testing a model in the future by which intervention-related changes in the clinical outcome are mediated through the EWB mechanism. This approach is intentionally designed to demonstrate rigor and reproducibility of target engagement and facilitate translation. Additional measurements of other clinically relevant and validated outcome measurements capturing positive movements toward health (i.e., health restoration) may also be included.

Investigators should propose a **randomized controlled trial design** with at least one intervention arm and one comparator arm. **The intervention arm must include a mind and body intervention.** There should be strong scientific rationale for the comparator condition (e.g., time and attention control, usual care, standard of care, sham condition, and/or active comparator). The selection should align with the research question to be addressed in the future fully powered trial. Waitlist comparator conditions are *not* allowed due to lack of rigor and expectancy effects.

Applications that do not follow the study design requirements stated above will be considered non-compliant and withdrawn prior to review.

Multidisciplinary collaborations are strongly encouraged. Teams may include experts in mind and body research, clinical care, biology, psychology, neuroscience, physiology, and related fields. Such collaborative, team-science supports innovation and advances the mission of the National Institutes of Health (NIH).

Statistics and Power

Pilot or feasibility studies are conducted to prepare for future adequately powered trials. These studies should focus on key issues of process (e.g., recruitment, retention, adherence, and/or fidelity) and feasibility of outcomes assessment (e.g., data collection methods, frequency, burden, and duration). Multi-site feasibility trials submitted under this NOFO are **not** allowed to include aims to assess the efficacy/effectiveness of an intervention on clinical outcomes or evaluate mediation effects. Statistical methods for clinical outcomes should be descriptive.

Investigators must collect mechanistic measures of EWB across sites to reproduce target engagement. They must also assess correlations between mechanistic and clinical measures (including the Whole Person Health Index) to inform future mediation analysis. Studies should be powered to reproduce the impact of the mind and body intervention on the target EWB mechanism observed in a previous study.

Group-Based Interventions

In some cases, investigators may propose a study in which (1) groups or clusters are assigned to study arms and individual observations are analyzed to evaluate the effect of the intervention, or (2) participants are assigned individually to study arms but receive at least some of their intervention in a real or virtual group or through a shared facilitator. Investigators should provide a strong rationale for the choice among trial design options. Study designs should align with intervention delivery and account for contamination and logistical considerations. Applicants should demonstrate that their methods are appropriate for participant assignment and intervention delivery. Refer to the Research Methods Resources website for additional information.

Applications should also address the following criteria:

Importance of Research

- Clearly state the importance of the proposed multi-site feasibility trial and planned future efficacy/effectiveness trial in terms of its scientific and public health impact. Explain why the multi-site feasibility trial is *scientifically necessary* to plan the subsequent future trial. Discuss how the trial results (positive or negative) will guide decisions about whether to proceed to a full-scale study or conduct additional preparatory work.
- Justify the selection of the intervention. This justification may include potential public health impact if the future trial is successful, ethical considerations, and patient perspectives on acceptability. Provide a clear description of the intervention to appropriately characterize all components of the intervention.
- Discuss any preliminary research results supporting the proposed project, whether conducted by the applicant or others. Present this information clearly so reviewers can evaluate the strength of the evidence and limitations.

Rigor and Feasibility

- Provide a plan to evaluate the following components across sites:

- Feasibility of delivering the measurement protocol (including the Whole Person Health Index) and intervention with fidelity across sites;
 - Reproducibility of target engagement of the EWB mechanism; and
 - The correlation between mechanistic and clinical measures, aligned with a well-justified conceptual model.
- Both feasibility and mechanistic components must be developed with equal rigor, as they represent co-primary determinants of significance.
 - Clearly describe the EWB mechanism of action and its established or hypothesized links to whole person health. Provide evidence from preliminary research or the literature showing that a similar intervention influences this mechanism in the expected direction. Include a conceptual model or figure illustrating how changes in the mechanism may mediate effects on clinical outcomes in a future large-scale trial.
 - Provide evidence that a similar intervention in a comparable population is well tolerated and does not produce frequent adverse events in humans. Demonstrate that the intervention has been reliably delivered in a single-site study and is appropriate for the proposed population and setting. If the intervention includes a natural product, provide evidence of efficacy for the condition being studied.
 - Describe prior single-site research demonstrating acceptable intervention adherence and retention for a similar protocol. Explain how these findings justify multi-site feasibility as the next step.
 - Justify how the intervention will be delivered (e.g., format, duration, frequency, timing, setting). Preliminary data should demonstrate that the selected dose and delivery approach are feasible, likely to maximize clinical benefit, and minimize risk.

Expertise and Resources

Applicants should describe relevant prior experience demonstrating the team's collective ability to conduct clinical trials, including:

- Delivered a similar intervention with fidelity using the same delivery mode;
- Successfully recruited and accrued comparable participants;
- Successfully randomized participants to similar intervention and control conditions;
- Achieved adherence to a similar protocol;
- Retained participants for a comparable study duration;
- Completed follow-up data collection with minimal missing data; and
- Published results from completed trials.

Applications should also provide evidence of multidisciplinary research experience and documentation demonstrating the availability of eligible participants at each site.

Letters of Support

Provide letters of support from clinicians or department chairs at all participating sites whose involvement is necessary for successful study conduct. Applicants are encouraged to include documentation confirming commitment from subcontractors and consultants, as well as service agreements for personnel and facilities. Letters of commitment must be co-signed by the business official of each collaborating center. If other sources will support trial costs, include letters of support signed by an authorized representative.

If the intervention includes a natural product, provide a letter of support confirming that sufficient supply will be available at the time of award, including expiration date. The supplier will meet Chemistry, Manufacturing, and Controls (CMC) specifications and provide necessary data to support compliance with NIH policies and Food and Drug Administration (FDA) regulations. The documentation should include a letter of agreement from the third party supplying the natural product.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400).

Other Plan(s):

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400) must be followed, with the following additional instructions:

- A Data Management and Sharing Plan (DMS Plan) is required for any NIH-funded or conducted research that will generate scientific data. Applicants must submit the DMS Plan at the time of application using the [NIH DMS Plan Format Page \(https://grants.nih.gov/grants-process/write-application/forms-directory/data-management-and-sharing-plan-format-page\)](https://grants.nih.gov/grants-process/write-application/forms-directory/data-management-and-sharing-plan-format-page). The DMS Plan must address the elements in the structured format. Where the DMS Plan Format Page requires a "Yes or No" response, no additional narrative is allowed.

Appendix: Only limited Appendix materials are allowed. Follow all instructions for the Appendix as described in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400).

- No publications or other material, with the exception of blank questionnaires or blank surveys, may be included in the Appendix.

PHS Human Subjects and Clinical Trials Information

When involving human subjects research, clinical research, and/or NIH-defined clinical trials (and when applicable, clinical trials research experience) follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400), with the following additional instructions:

If you answered "Yes" to the question "Are Human Subjects Involved?" on the R&R Other Project Information form, you must include at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or **Delayed Onset Study** record.

Study Record: PHS Human Subjects and Clinical Trials Information

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400) must be followed.

Section 2 - Study Population Characteristics

2.5 Recruitment and Retention Plan

Describe the following: (1) planned recruitment methods, including use of contact lists, databases, other pre-screening resources, advertisements, outreach, media/social media, and referral networks or groups; (2) any known (based on literature or prior experience) participant or study-related barriers to accrual or participation (list the barriers and describe plans to address them to optimize success); (3) contingency plans for participant accrual if enrollment significantly lags behind accrual benchmarks; (4) participant retention and adherence strategies; and (5) possible competition from other trials for study participants.

Study Accrual and Retention for Human Subjects Research

To ensure ethical conduct, scientific integrity, and appropriate stewardship of public funds, NCCIH requires all clinical research supported under this NOFO to include a Study Accrual and Retention Plan (SARP) prior to initiation of participant enrollment. Accrual and retention benchmarks should be realistic and tailored to the study design and target population, specifying the anticipated start of enrollment, the number of participants to be accrued over defined time periods, and projected retention rates through study completion. NCCIH and the grantee will agree to these benchmarks, which will be formally reviewed and approved prior to initiation of clinical research activities.

Once enrollment begins, grantees must monitor and report accrual and retention progress at regular intervals. NCCIH compares actual performance against the agreed benchmarks and will work collaboratively with grantees to identify and address accrual challenges early in the study. Persistent accrual or retention shortfalls relative to the approved benchmarks may

prompt enhanced monitoring, requests for corrective action plans, adjustments to trial operations, or other NIH actions to optimize study feasibility and protect participant welfare. This accrual and retention framework ensures that clinical studies have a high likelihood of meeting their aims and generating meaningful contributions to scientific knowledge.

Section 3 - Protection and Monitoring Plans

3.3 Data and Safety Monitoring Plan

In addition to the NIH application requirements for data and safety monitoring for clinical trials, NCCIH requires independent monitoring for research involving human subjects. Applicants should refer to NIH's policy on data and safety monitoring (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html>) (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html>)), as well as NCCIH's Guidelines for Data and Safety Monitoring.

Data and Safety Monitoring

All clinical research supported under this NOFO must include a Data and Safety Monitoring Plan (DSMP). The DSMP must clearly describe procedures for monitoring participant safety, protecting data integrity, and ensuring study quality throughout the conduct of the trial. The monitoring plan must specify:

- The type of oversight structure to be used (e.g., Independent Monitoring Committee [IMC], Data and Safety Monitoring Board [DSMB], or independent medical monitor), with justification appropriate to the study's risk level;
- Roles and responsibilities of the monitoring entity;
- Frequency and format of data review meetings (at least twice annually for studies requiring an IMC/DSMB);
- Procedures for reporting and managing adverse events (AEs) and serious adverse events (SAEs);
- Predefined stopping rules or criteria for protocol modification or early termination;
- Processes for ensuring data quality, integrity, and confidentiality; and
- Plans for remote monitoring when applicable.

The DSMP must explicitly describe plans to remotely monitor participant safety with appropriate safeguards to minimize risk. The Independent Monitoring Committee (IMC) or Data and Safety Monitoring Board (DSMB) will have the responsibility to review interim and final data, recommend whether the protocol should be modified, and, at each meeting, recommend whether the study should continue or be terminated early. Thus, its ethical responsibilities to the participants, as well as to the integrity of the study, are of paramount importance to NCCIH. The IMC/DSMB will meet in person or by phone at least twice a year. To avoid conflicts of interest in peer review, applicants should not appoint IMC/DSMB members in advance of peer review, or even inquire about possible DSMB members.

Section 4 - Protocol Synopsis

4.5. Will the study use an FDA-regulated intervention?

4.5.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status

If the proposed clinical trial will use a device, natural product (e.g., botanicals, probiotics, and products marketed as dietary supplements), or drug, this attachment should describe correspondence from the FDA indicating whether the proposed study will require an Investigational New Drug (IND) or Investigational Device Exemption (IDE) application. Investigators should describe the process and the associated timeline that will be used to attain all FDA or other applicable regulatory agency approvals necessary to the conduct of the trial. For trials using an FDA-regulated product that requires an IND or IDE application, the grant application must include evidence regarding the outcome of a pre-IND meeting, or other evidence of communication with the FDA. If the protocol is being conducted under a non-U.S. regulatory agency, the applicant should submit a plan for attaining those regulatory approvals. If the protocol is exempt from an IND or IDE, a copy of the exemption letter from the FDA should be provided as part of the PDF file attachment. The FDA has provided guidance indicating that for substances that are Generally Recognized as Safe (GRAS) that are used in a clinical trial to evaluate the product's ability to diagnose, cure, mitigate, treat, or prevent disease it may require an IND under part 312 (<https://www.fda.gov/media/79386/download>) (<https://www.fda.gov/media/79386/download>). If the FDA requires an IND application for the proposed clinical trial, the IND application must be submitted to the FDA, with no clinical hold imposed by the FDA before the application is funded.

Section 5 - Other Clinical Trial-Related Attachments

5.1 Other Clinical Trial-Related Attachments

The following attachments must be included as a part of the application. Attachments permit expansion of certain elements that cannot be appropriately described in the Research Strategy. All attachments listed below must be provided or the application will not be peer-reviewed.

1. Clinical Trial Experience

Applicants must provide a detailed table listing the characteristics of trials that demonstrate key personnel experience in trial coordination in the past 5 years. One table must be provided for each study record, with a unique filename for each study record as an attachment (e.g., "Clinical Trial Experience1.pdf" "Clinical Trial Experience 2.pdf," etc.), and must not exceed three pages.

The table columns should include:

- Clinical trial title
- Applicant's role in the trial
- A brief description of the trial design
- Planned enrollment
- Actual enrollment
- Number of sites
- Whether the trial was completed on schedule
- Publication reference(s)

Delayed Onset Study

Note: [Delayed onset](https://grants.nih.gov/grants/glossary.htm#DelayedOnsetStudy) (<https://grants.nih.gov/grants/glossary.htm#DelayedOnsetStudy>) does NOT apply to a study that can be described but will not start immediately (i.e., delayed start). All instructions in the [How to Apply- Application Guide](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed.

PHS Assignment Request Form

All instructions in the [How to Apply- Application Guide](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed.

3. Unique Entity Identifier and System for Award Management (SAM)

See Part 2. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov

4. Submission Dates and Times

Part I. contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or [Federal holiday \(https://grants.nih.gov/grants/guide/uri_redirect.html?id=82380\)](https://grants.nih.gov/grants/guide/uri_redirect.html?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to [Grants.gov \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11128\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11128) (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the [eRA Commons \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11123\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11123), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the [NIH Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=82423\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=82423).

Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the [How to Apply-Application Guide \(https://grants.nih.gov/grants-process/write-application/how-to-apply-application-guide\)](https://grants.nih.gov/grants-process/write-application/how-to-apply-application-guide).

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to [intergovernmental review \(https://grants.nih.gov/grants/policy/nihgps/html5/section_10/10.10.1_executive_orders.htm\)](https://grants.nih.gov/grants/policy/nihgps/html5/section_10/10.10.1_executive_orders.htm).

6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the [NIH Grants Policy Statement \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11120\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11120).

Pre-award costs are allowable only as described in the [NIH Grants Policy Statement Section 7.9.1 Selected Items of Cost \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11143\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11143).

For trials using an FDA-regulated product and requiring an IND application, the applicant must either hold or be able to reference an open IND for the trial, or the applicant must obtain an IND with no clinical hold from the FDA prior to any award. The details of the IND status of the product should be provided in the attachment included in the study record for section 4.5. If the FDA has granted a waiver for either trial proposed in the application, then the applicant can provide this letter as part of the response to item 4.5 in the study record. If the protocol is conducted under a non-U.S. regulatory agency, then equivalent determinations and documentation must be provided to NCCIH prior to a grant award. Funding will not be made until the necessary regulatory approvals are in place for the conduct of the proposed clinical trial. If the product to be studied is on the Drug Enforcement Agency (DEA) controlled substance list, the applicant must describe the DEA license and registrations necessary to complete the proposed trial. Again, no awards will be made until all necessary DEA licenses and registrations are in place.

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the [How to Apply – Application Guide \(https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400). Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit [How to Apply – Application Guide \(https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the [Dealing with System Issues \(https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm\)](https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm) guidance. For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile form. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH. See Section III of this NOFO for information on registration requirements.

The applicant organization must ensure that the unique entity identifier provided on the application is the same identifier used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the [How to Apply – Application Guide \(https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400).

See [more tips \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11146\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11146) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review and responsiveness by components of participating organizations, NIH. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

Mandatory Disclosure

Recipients or subrecipients must submit any information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. See Mandatory Disclosures, [2 CFR 200.113 \(https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-B/section-200.113\)](https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-B/section-200.113) and [NIH Grants Policy Statement Section 4.1.35 \(https://grants.nih.gov/grants/policy/nihgps/html5/section_4/4.1.35_mandatory_disclosures.htm\)](https://grants.nih.gov/grants/policy/nihgps/html5/section_4/4.1.35_mandatory_disclosures.htm).

Send written disclosures to the NIH Chief Grants Management Officer listed on the Notice of Award for the IC that funded the award and to the [HHS Office of Inspector Grant Self Disclosure Program \(https://oig.hhs.gov/compliance/self-disclosure-info/hhs-oig-grant-self-disclosure-program/\)](https://oig.hhs.gov/compliance/self-disclosure-info/hhs-oig-grant-self-disclosure-program/) at [grantdisclosures@oig.hhs.gov \(mailto:grantdisclosures@oig.hhs.gov\)](mailto:grantdisclosures@oig.hhs.gov).

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in [the policy \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=82299\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=82299).

In addition to the post-submission materials allowed by NIH Policy and described in NOT-OD-19-083 (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-083.html>), the following post-submission materials are allowed:

- Revised Clinical Trial Experience Table (e.g. due to updated enrollment numbers, publication of trial results, or newly started clinical trials).
- Updates to section 4.5 on communication with FDA in regard to Investigational New Drug (IND)/ Investigational Device Exception (IDE) requirements.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. Applications submitted to the NIH in support of the [NIH mission \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11149\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11149) are evaluated for scientific and technical merit through the NIH peer review system.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following scored review criteria and additional review criteria (as applicable for the project proposed). An application does not need to be strong in all categories to

be judged likely to have a major scientific impact.

Scored Review Criteria

Reviewers will consider Factors 1, 2 and 3 in the determination of scientific merit, and in providing an overall impact score. In addition, Factors 1 and 2 will each receive a separate factor score.

Factor 1. Importance of the Research (Significance and Innovation)

Significance

- Evaluate the importance of the proposed research in the context of current scientific challenges and opportunities, either for advancing knowledge within the field, or more broadly. Assess whether the application addresses an important gap in knowledge in the field, would solve a critical problem, or create a valuable conceptual or technical advance.
- Evaluate the rationale for undertaking the study, the rigor of the scientific background for the work (e.g., prior literature and/or preliminary data) and whether the scientific background justifies the proposed study.

Innovation

- Evaluate the extent to which innovation influences the importance of undertaking the proposed research. Note that while technical or conceptual innovation can influence the importance of the proposed research, a project that is not applying novel concepts or approaches may be of critical importance for the field.
- Evaluate whether the proposed work applies novel concepts, methods or technologies or uses existing concepts, methods, technologies in novel ways, to enhance the overall impact of the project.

Specific to this NOFO:

- Evaluate the significance of the proposed research as it is informed by equally weighing the justification for the research aims, as well as the justification of the conceptual model linking the EWB mechanism to the clinical outcome intended for future testing.
- Evaluate whether the selection of the intervention is well-justified and the strengths and limitations of any preliminary research results supporting the overall proposed project.
- Evaluate whether the proposed multi-site feasibility trial is scientifically necessary to inform the design and conduct of the future adequately powered efficacy or effectiveness trial and mediation analysis.
- Evaluate the justification for why performing the larger future clinical study is important in the context of the present knowledge on mind and body research and whole person health.

Factor 2. Rigor and Feasibility (Approach)

Approach

- Evaluate the scientific quality of the proposed work. Evaluate the likelihood that compelling, reproducible findings will result (rigor) and assess whether the proposed studies can be done well and within the timeframes proposed (feasibility).

Rigor:

- Evaluate the potential to produce unbiased, reproducible, robust data.
- Evaluate the rigor of experimental design and whether appropriate controls are in place.
- Evaluate whether the sample size is sufficient and well-justified.
- Assess the quality of the plans for analysis, interpretation, and reporting of results.
- Evaluate whether the investigators presented adequate plans to address relevant biological variables, such as sex or age, in the design, analysis, and reporting.
- For applications involving human subjects or vertebrate animals, also evaluate:
 - the rigor of the intervention or study manipulation (if applicable to the study design).
 - whether outcome variables are justified.
 - whether the results will be generalizable or, in the case of a rare disease/special group, relevant to the particular subgroup.
 - whether the study population appropriately models the target population.
- For applications involving human subjects, including clinical trials, assess the adequacy of inclusion plans as appropriate for the scientific goals of the research. Considerations of appropriateness may include disease/condition/behavior incidence, prevalence, or population burden, population representation, and/or current state of the science.

Feasibility:

- Evaluate whether the proposed approach is sound and achievable, including plans to address problems or new challenges that emerge in the work. For proposed studies in which feasibility may be less certain, evaluate whether the uncertainty is balanced by the potential for major advances.
- For applications involving human subjects, including clinical trials, evaluate the adequacy and feasibility of the plan to recruit and retain a study population that appropriately models the target population. Additionally, evaluate the likelihood of successfully achieving the proposed enrollment based on age, race, ethnicity, and sex.
- For clinical trial applications, evaluate whether the study timeline and milestones are feasible.

Specific to this NOFO:

- Evaluate the plan across sites to assess feasibility of delivering the measurement protocol (including the [Whole Person Health Index \(https://www.cdc.gov/QBank/Search/Reports.aspx#/Reports/1260\)](https://www.cdc.gov/QBank/Search/Reports.aspx#/Reports/1260)) and intervention with fidelity across sites, reproducibility of target engagement of the EWB mechanism, and the correlation between mechanistic and clinical measures.
- Evaluate the strength of the preliminary data about the intervention and how well single-site findings justify multi-site feasibility as the next step.
- Evaluate the strength of the preliminary data concerning the extent to which the intervention is associated with or alters a known EWB mechanism or aspect of that mechanism.
- Evaluate the rigor and strength of the evidence for the proposed conceptual model linking mind and body-related effects on the EWB mechanisms of action and its association with whole person health.
- Evaluate whether the mind and body intervention has been appropriately characterized and whether intervention delivery has been well-justified.
- Evaluate if the application adequately addresses the appropriate regulatory requirements [Investigational New Drug (IND) application, Investigational Device Exemption (IDE), Drug Enforcement Agency (DEA)] and the required training and/or licensure/credentialing of individuals providing the intervention across the proposed site(s) if necessary.

Factor 3. Expertise and Resources (Investigator(s) and Environment)

Investigator(s)

Evaluate whether the investigator(s) have demonstrated background, training, and expertise, as appropriate for their career stage, to conduct the proposed work. For Multiple Principal Investigator (MPI) applications, assess the quality of the leadership plan to facilitate coordination and collaboration.

Environment

Evaluate whether the institutional resources are appropriate to ensure the successful execution of the proposed work.

Specific to this NOFO:

- Evaluate the investigative team's collective track record of completing and publishing the results of clinical trials.
- Based on the clinical trial experience attachment, consider whether the team has successfully recruited a similar study population in previous single- or multi-site clinical trials.
- Based on the clinical trial experience attachment, consider whether the investigative team has successfully delivered a similar intervention with fidelity in previous single- or multi-site clinical trials.
- Evaluate the documentation of the availability of the requisite eligible subject pool at the proposed clinical trial sites and the documentation of the commitment of any subcontractors and consultants, as well as service agreements for personnel and facilities.

Additional Review Criteria

As applicable for the project proposed, reviewers will consider the following additional items while determining scientific and technical merit, but will not give criterion scores for these items, and should consider them in providing an overall impact score.

Protections for Human Subjects

For research that involves human subjects but does not involve one of the categories of research that are exempt under 45 CFR Part 46, evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects; 2) adequacy of protection against risks; 3) potential benefits to the subjects and others; 4) importance of the knowledge to be gained; and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the categories of research that are exempt under 45 CFR Part 46, evaluate: 1) the justification for the exemption; 2) human subjects involvement and characteristics; and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the [Guidelines for the Review of Human Subjects](https://grants.nih.gov/grants/guide/redirect.htm?id=11175) (<https://grants.nih.gov/grants/guide/redirect.htm?id=11175>).

Vertebrate Animals

When the proposed research includes Vertebrate Animals, evaluate the involvement of live vertebrate animals according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. For additional information on review of the Vertebrate Animals section, please refer to the [Worksheet for Review of the Vertebrate Animals Section](http://grants.nih.gov/grants/guide/redirect.htm?id=11150) (<http://grants.nih.gov/grants/guide/redirect.htm?id=11150>).

Biohazards

When the proposed research includes Biohazards, evaluate whether specific materials or procedures that will be used are significantly hazardous to research personnel and/or the environment, and whether adequate protection is proposed.

Resubmissions

As applicable, evaluate the full application as now presented.

Renewals

As applicable, evaluate the progress made in the last funding period.

Revisions

As applicable, evaluate the appropriateness of the proposed expansion of the scope of the project.

Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

Authentication of Key Biological and/or Chemical Resources

For projects involving key biological and/or chemical resources, evaluate the brief plans proposed for identifying and ensuring the validity of those resources.

Budget and Period of Support

Evaluate whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by the Center for Scientific Review (CSR), in accordance with NIH peer review policies and practices, using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications will receive a written critique.

Applications may undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications. Following initial peer review, recommended applications will receive a second level of review by the appropriate national Advisory Council or Board. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the [NIH Grants Policy Statement Section 2.5.1. Just-in-Time Procedures](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=82418) (http://grants.nih.gov/grants/guide/uri_redirect.htm?id=82418). This request is not a Notice of Award nor should it be construed to be an indicator of possible funding.

Prior to making an award, NIH reviews an applicant's federal award history in SAM.gov to ensure sound business practices. An applicant can review and comment on any information in the Responsibility/Qualification records available in SAM.gov. NIH will consider any comments by the applicant in the Responsibility/Qualification records in SAM.gov to ascertain the applicant's integrity, business ethics, and performance record of managing Federal awards per 2 CFR Part 200.206 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the [eRA Commons](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11123) (http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11123). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

Information regarding the disposition of applications is available in the [NIH Grants Policy Statement Section 2.4.4 Disposition of Applications](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=82416) (http://grants.nih.gov/grants/guide/uri_redirect.htm?id=82416).

Section VI. Award Administration Information

1. Award Notices

A Notice of Award (NoA) is the official authorizing document notifying the applicant that an award has been made and that funds may be requested from the designated HHS payment system or office. The NoA is signed by the Grants Management Officer and emailed to the recipient's business official.

In accepting the award, the recipient agrees that any activities under the award are subject to all provisions currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

Recipients must comply with any funding restrictions described in Section IV.6. Funding Restrictions. Any pre-award costs incurred before receipt of the NoA are at the applicant's own risk. For more information on the Notice of Award, please refer to the [NIH Grants Policy Statement Section 5. The Notice of Award](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_5/5_the_notice_of_award.htm) (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_5/5_the_notice_of_award.htm) and NIH Grants & Funding website, see [Award Process](https://grants.nih.gov/grants/pre-award-process.htm#award). (<https://grants.nih.gov/grants/pre-award-process.htm#award>)

Individual awards are based on the application submitted to, and as approved by, the NIH and are subject to the IC-specific terms and conditions identified in the NoA.

ClinicalTrials.gov: If an award provides for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register and submit results information for certain "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration and Results System Information Website (<https://register.clinicaltrials.gov>) (<https://register.clinicaltrials.gov>). NIH expects registration and results reporting of all trials whether required under the law or not. For more information, see <https://grants.nih.gov/policy/clinical-trials/reporting/index.htm> (<https://grants.nih.gov/policy/clinical-trials/reporting/index.htm>)

Institutional Review Board or Independent Ethics Committee Approval: Recipient institutions must ensure that all protocols are reviewed by their IRB or IEC. To help ensure the safety of participants enrolled in NIH-funded studies, the recipient must provide NIH copies of documents related to all major changes in the status of ongoing protocols.

Data and Safety Monitoring Requirements: The NIH policy for data and safety monitoring requires oversight and monitoring of all NIH-conducted or -supported human biomedical and behavioral intervention studies (clinical trials) to ensure the safety of participants and the validity and integrity of the data. Further information concerning these requirements is found at http://grants.nih.gov/grants/policy/hs/data_safety.htm (http://grants.nih.gov/grants/policy/hs/data_safety.htm) and in the application instructions (SF424 (R&R) and PHS 398).

Investigational New Drug or Investigational Device Exemption Requirements: Consistent with federal regulations, clinical research projects involving the use of investigational therapeutics, vaccines, or other medical interventions (including licensed products and devices for a purpose other than that for which they were licensed) in humans under a research protocol must be performed under a Food and Drug Administration (FDA) investigational new drug (IND) or investigational device exemption (IDE).

2. Administrative and National Policy Requirements

The following Federal wide and HHS-specific policy requirements apply to awards funded through NIH:

- The rules listed at [2 CFR Part 200](https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200) (<https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200>), Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.
- All NIH grant and cooperative agreement awards include the [NIH Grants Policy Statement](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11120) (http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11120) as part of the terms and conditions in the Notice of Award (NoA). The NoA includes the requirements of this NOFO. For these terms of award, see the [NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11120) (http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11120) and [Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11159) (http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11159).

All federal statutes and regulations relevant to federal financial assistance, including those highlighted in [NIH Grants Policy Statement Section 4 Public Policy Requirements, Objectives and Other Appropriation Mandates](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4_public_policy_requirements_objectives_and_other_appropriation_mandates.htm). (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4_public_policy_requirements_objectives_and_other_appropriation_mandates.htm)

By applying for or accepting federal funds from HHS, recipients certify compliance with all federal antidiscrimination laws and these requirements and that complying with those laws is a material condition of receiving federal funding streams. Recipients are responsible for ensuring subrecipients, contractors, and partners also comply.

Applicants and recipients are strongly encouraged to refer to the [NIH Director's Statement of Priorities](https://www.nih.gov/about-nih/nih-director/statements/advancing-nih-mission-through-unified-strategy) (<https://www.nih.gov/about-nih/nih-director/statements/advancing-nih-mission-through-unified-strategy>), entitled "Advancing NIH's Mission Through a Unified Strategy."

Recipients are responsible for ensuring that their activities comply with all applicable federal regulations. Pursuant to 2 CFR 200.340, by accepting an NIH award, the recipient agrees that continued funding for the award is contingent upon the availability of appropriated funds, recipient satisfactory performance, compliance with the Terms and Conditions of the award, and may also otherwise be terminated, to the extent authorized by law, if the agency determines that the award no longer effectuates the program goals or agency priorities, in line with 2 CFR 200.340(a)(4).

Pursuant to the Cybersecurity Act of 2015, Div. N, § 405, Pub. Law 114-113, 6 USC § 1533(d), the HHS Secretary has established a common set of voluntary, consensus-based, and industry-led guidelines, best practices, methodologies, procedures, and processes.

Successful recipients under this NOFO agree that:

When recipients, subrecipients, or third-party entities have:

- ongoing and consistent access to HHS owned or operated information or operational technology systems; and

- receive, maintain, transmit, store, access, exchange, process, or utilize personal identifiable information (PII) or personal health information (PHI) obtained from the awarding HHS agency for the purposes of executing the award.

Cybersecurity plans and procedures **must** at minimum include the following:

- Develop cybersecurity plans and procedures, modeled after the [NIST Cybersecurity framework \(https://www.nist.gov/cyberframework\)](https://www.nist.gov/cyberframework), to protect HHS systems and data:
 - **Identify:**
 - Develop an inventory of all assets and accounts with access to HHS owned and operated information or operational technology systems or which obtain PII or PHI for the purposes of the award.
 - **Protect:**
 - Limit access to HHS owned and operated systems to only those in need of access to complete reward activities.
 - Require all staff to complete annual cybersecurity and privacy awareness training. Visit [405\(d\): Knowledge on Demand \(hhs.gov\) \(https://405d.hhs.gov/kod/five-threats\)](https://405d.hhs.gov/kod/five-threats) to obtain free trainings, if needed.
 - Enable multifactor authentication for all employees, subrecipients, and third-party entities to access HHS owned and operated information or operational technology systems.
 - Regularly backup sensitive data and test backups.
 - **Detect:**
 - Install anti-virus or anti-malware software on all devices, servers, and accounts used to connect to HHS owned and operated systems.
 - **Respond:**
 - Develop an incident response plan. See [Incident-Response-Plan-Basics_508c.pdf \(cisa.gov\) \(https://www.cisa.gov/sites/default/files/publications/Incident-Response-Plan-Basics_508c.pdf\)](https://www.cisa.gov/sites/default/files/publications/Incident-Response-Plan-Basics_508c.pdf) to learn about developing incident response plans.
 - Have cybersecurity incident reporting procedures that ensure the relevant HHS awarding agencies are notified of a cybersecurity incident within 48 hours of discovery. A cybersecurity incident is defined as an unplanned interruption to a technology service or reduction in the quality of a technology service, or an occurrence that actually or potentially jeopardizes the confidentiality, integrity, or availability of an information system or the information the system processes, stores, or transmits.
 - **Recover:**
 - Investigate incidents and plug any security gaps identified.

All activities proposed in your application and budget narrative must align with applicable law, including but not limited to statutes, executive orders, federal regulations and applicable judicial holdings. Accordingly, discretionary awards shall not be used to fund, promote, encourage, subsidize, or facilitate; racial preferences or other forms of racial discrimination by the recipient, including activities where race or intentional proxies for race will be used as a selection criterion for employment or program participation; denial by the recipient of the sex binary in humans, or the belief that sex is a chosen or mutable characteristic; illegal immigration; or any other initiatives that compromise public safety. If an application does not align, the application will not receive funding to the extent permitted by law and applicable court orders.

For applications involving substance abuse, the application must not support harm reduction. Please see [Updated Funding Guidance for Recipients on Supplies and Services \(https://www.samhsa.gov/sites/default/files/dear-colleague-letter-updated-hr-funding-guidance.pdf\)](https://www.samhsa.gov/sites/default/files/dear-colleague-letter-updated-hr-funding-guidance.pdf).

For applications involving funding Medication-Assisted Treatment (MAT) or medications for opioid use disorder (MOUD), this funding should be used to provide comprehensive treatment and recovery support services rather than medication-only models for opioid use disorder. Services should include medications, where clinically indicated, in conjunction with psychosocial and other treatment and recovery support services. Funding can also be used to support individualized tapering and discontinuation of medications when clinically indicated. Please see [Updated Funding Guidance for Recipients on MAT/MOUD \(https://www.samhsa.gov/sites/default/files/dear-colleague-letter-mat-moud-guidance.pdf\)](https://www.samhsa.gov/sites/default/files/dear-colleague-letter-mat-moud-guidance.pdf).

Recipients of both Clinical Trial Required and Clinical Trial Optional awards subject to this term shall report standardized clinical trial activation and enrollment performance data for any [interventional \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-063.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-063.html) clinical trial supported under the award. These metrics are intended to assess trial startup efficiency, site activation, and post-activation performance and to support continuous quality improvement in clinical trial operations (see supplemental guidance). Recipients shall report required data annually at the time of Research Performance Progress Report (RPPR) submission on clinical trial activation and enrollment performance milestone dates as calendar dates; NIH will calculate standardized interval metrics from these dates.

Institutions are expected to maintain capabilities that support efficient clinical trial startup, participant enrollment, and performance monitoring, including streamlined workflows and systems for electronic tracking of milestones. Recipients are encouraged to implement and evaluate approaches that improve trial efficiency and the participant experience.

As of October 1, 2025, HHS has adopted [2 CFR Part 200 \(https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200\)](https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200), with some modifications included in 2 CFR Part 300. These regulations replace those in 45 CFR Part 75. However, for NIH, under the Consolidated Appropriations Act for FY 2026, ([P.L. 119-75 \(https://www.congress.gov/bills/119/th-congress/house-bill/7148\)](https://www.congress.gov/bills/119/th-congress/house-bill/7148)), Division B, Title II, Sec. 224), the provisions relating to indirect costs in 45 CFR 75 continue to apply to NIH awards. Consistent with the statute, NIH will not apply updated thresholds outlined within 2 CFR Part 200, at this time.

In administering programs under this and all funding announcements, NIH prioritizes:

- Research involving rigorous scientific methods, including for studies related to children and adolescents, where NIH is committed to approaches that reflect the highest standards of clinical care and child safety.
- Biological and physiological integrity: Recognizing the relevance of biological sex to health outcomes, NIH encourages applicants to account for sex-based health factors in program design, data collection, and service delivery where scientifically appropriate.
- NIH will implement these priorities consistent with applicable laws, regulations, court orders, and all required administrative procedures. Applicants are encouraged to describe how their proposed programs align with these priorities in their project narratives. Funded activities must advance NIH's vision of protecting and improving the health and well-being of Americans. The particular focus is on those who are medically vulnerable, or live in areas with limited access to care. NIH's duty is to serve wisely, effectively, and with measurable results that justify every taxpayer dollar invested. NIH will implement these priorities consistent with applicable laws, regulations, court orders, and all required administrative procedures. Applicants are encouraged to describe how their proposed programs align with these priorities in their project narratives. Funded activities must advance NIH's vision of protecting and improving the health and well-being of Americans. The particular focus is on those who are medically vulnerable, or live in areas with limited access to care. NIH's duty is to serve wisely, effectively, and with measurable results that justify every taxpayer dollar invested.

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Data Management and Sharing

A Data Management and Sharing Plan (DMS Plan) is required for any NIH-funded or conducted research that will generate scientific data. Applicants must submit the DMS Plan at the time of application using the [NIH DMS Plan Format Page \(https://grants.nih.gov/grants-process/write-application/forms-directory/data-management-and-sharing-plan-format-page\)](https://grants.nih.gov/grants-process/write-application/forms-directory/data-management-and-sharing-plan-format-page). The DMS Plan must address the elements in the structured format. Where the DMS Plan Format Page requires a "Yes or No" response, no additional narrative is allowed.

4. Reporting

When multiple years are involved, recipients will be required to submit the [Research Performance Progress Report \(RPPR\) \(http://grants.nih.gov/grants/rppr/index.htm\)](http://grants.nih.gov/grants/rppr/index.htm) annually and financial statements as required in the [NIH Grants Policy Statement Section 8.4.1 Reporting. \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.4.1_reporting.htm\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.4.1_reporting.htm) To learn

more about post-award monitoring and reporting, see the NIH Grants & Funding website, see [Post-Award Monitoring and Reporting \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82428\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82428).

A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the [NIH Grants Policy Statement Section 8.6 Closeout \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=82420\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82420). NIH NOFOs outline intended research goals and objectives. Post award, NIH will review and measure performance based on the details and outcomes that are shared within the RPPR, as described at 2 CFR Part 200.301.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants. When contacting the email addresses below please add the NOFO number to the subject line to assist routing.

Application Submission Contacts

[eRA Service Desk \(https://www.era.nih.gov/need-help\)](https://www.era.nih.gov/need-help) - Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten submission by the due date, and post-submission issues.

[Grants.gov Support Center \(https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fgrants.gov%2Fsupport&data=05%7C02%7Cantoine.caliman%40nih.gov%7Caf6dde64d644478d4e8b08dde6700581%7C14b77578977342d58507251ca2dc2b\)](https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fgrants.gov%2Fsupport&data=05%7C02%7Cantoine.caliman%40nih.gov%7Caf6dde64d644478d4e8b08dde6700581%7C14b77578977342d58507251ca2dc2b)
- Questions regarding Grants.gov registration and services (e.g., Workspace, subscriptions).

Scientific/Research Contact(s)

National Center for Complementary and Integrative Health (NCCIH)
Division of Extramural Research (DER)
Email: NCCIHDERFunding@nih.gov (<mailto:NCCIHDERFunding@nih.gov>)

Peer Review Contact(s)

Examine your eRA Commons account for review assignment and contact information (information appears two weeks after the submission due date).

Financial/Grants Management Contact(s)

National Center for Complementary and Integrative Health (NCCIH)
Office of Grants Management (OGM)
Email: NCCIHDERFunding@nih.gov (<mailto:NCCIHDERFunding@nih.gov>)

Section VIII. Other Information

Recently issued trans-NIH [policy notices \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11163\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11163) may affect your application submission. A full list of policy notices published by NIH is provided in the [NIH Guide for Grants and Contracts \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11164\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11164). All awards are subject to the terms and conditions, cost principles, and other considerations described in the [NIH Grants Policy Statement \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 2 CFR Part 200.