# Department of Health and Human Services

## Part 1. Overview Information

**Participating Organization(s)**

National Institutes of Health (NIH (http://www.nih.gov))

**Components of Participating Organizations**

National Institute on Aging (NIA (https://www.nia.nih.gov/))

**Funding Opportunity Title**

Early- and Late-Stage Clinical Trials for the Spectrum of Alzheimer's Disease/Alzheimer's Disease-Related Dementias and Age-Related Cognitive Decline (R01 Clinical Trial Optional)

**Activity Code**

R01 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r01&Search.x=0&Search.y=0&Search_Type=Activity) Research Project Grant

**Announcement Type**

Reissue of PAR-23-081 (https://grants.nih.gov/grants/guide/pa-files/PAR-23-081.html)

**Related Notices**

See Notices of Special Interest (https://grants.nih.gov/grants/guide/NOSIs_targetingList.cfm?GuideDocID=41147) associated with this funding opportunity

- **August 31, 2022**- Implementation Changes for Genomic Data Sharing Plans Included with Applications Due on or after January 25, 2023. See Notice NOT-OD-22-198 (https://grants.nih.gov/grants/guide/notice-files/not-od-22-198.html).
- **August 5, 2022**- Implementation Details for the NIH Data Management and Sharing Policy. See Notice NOT-OD-22-189 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-189.html).

**Funding Opportunity Number (FON)**

RFA-AG-25-011

**Companion Funding Opportunity**

PAR-23-083 (https://grants.nih.gov/grants/guide/pa-files/PAR-23-083.html), R61 (https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=R61&Search.x=0&Search.y=0&Search_Type=Activity) Phase 1 Exploratory/Developmental Grant
PAR-23-274 (https://grants.nih.gov/grants/guide/pa-files/PAR-23-274.html), UG3 (https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=UG3&Search.x=0&Search.y=0&Search_Type=Activity)/ UH3 (https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=UH3&Search.x=0&Search.y=0&Search_Type=Activity) Phase 1 Exploratory/Developmental Cooperative Agreement/Exploratory/Developmental Cooperative Agreement Phase II
RFA-AG-25-010 (https://grants.nih.gov/grants/guide/rfa-files/RFA-AG-25-010.html), R01 (https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=R01&Search.x=0&Search.y=0&Search_Type=Activity) Research Project

**Number of Applications**

See Section III. 3. Additional Information on Eligibility.

**Assistance Listing Number(s)**

93.866

**Funding Opportunity Purpose**

The purpose of this Notice of Funding Opportunity (NOFO) is to 1) invite applications that propose to develop and implement early- to late-stage clinical trials of promising pharmacological and non-pharmacological interventions to prevent and/or treat the cognitive, behavioral, and neuropsychiatric changes associated with age-related cognitive decline and Alzheimer's disease (AD) and Alzheimer's disease-related dementias (ADRD), and 2) stimulate studies to enhance trial design and methods.

## Key Dates

**Posted Date**

July 01, 2024

**Open Date (Earliest Submission Date)**

September 17, 2024

**Letter of Intent Due Date(s)**

A letter of intent, including a direct cost budget estimate, is highly encouraged at least 10 weeks prior to the anticipated application due date.

| 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 |
| October 17, 2024 | October 17, 2024 | Not Applicable | March 2025 | May 2025 | July 2025 |

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.

No late applications will be accepted for this Notice of Funding Opportunity (NOFO).

**Expiration Date**

October 18, 2024

**Due Dates for E.O. 12372**

Not Applicable

### 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.php?id=82400), except where instructed to do otherwise (in this NOFO or in a Notice from NIH Guide for Grants and Contracts (//grants.nih.gov/grants/guide/url_redirect.php?id=11164)).

Conformance to all requirements (both in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) and the NOFO) is required and strictly enforced. Applicants must read and follow all application instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400), 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 to prepare, submit and track your application online.

   Apply Online Using ASSIST

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/) 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=RFA-AG-25-011) Workspace to prepare and submit your application and eRA Commons (http://public.era.nih.gov/commons/) to track your application.

## Table of Contents



## Part 2. Full Text of Announcement

# Section I. Notice of Funding Opportunity Description

**Background**

The biggest risk factor for Alzheimer's disease (AD) is age, and AD is the most common cause of dementia in those aged 65 and older. As populations age worldwide, this disorder, as well as AD-related dementias (ADRD; e.g., frontotemporal lobar degeneration, Lewy body dementia, vascular dementia), will reach epidemic proportions even in best-case scenarios, with an enormous human and economic burden. Dementia is one of the most persistent and devastating neurodegenerative diseases because it eventually leads to widespread brain and neuropsychological dysfunction, and the loss of the ability to interact with others and to function independently. It is estimated that over 6 million Americans aged 65 and older are living with Alzheimer's dementia today. This number could grow to 12.7 million by 2050. From an economic perspective, estimates suggest AD/ADRD cost society over $360 billion in 2024 (https://alz-journals.onlinelibrary.wiley.com/doi/10.1002/alz.13016) . These human and economic costs are untenable, and it is critical to accelerate the development of interventions to prevent, slow, or cure AD/ADRD.

Recent biomedical advances inspire optimism for the path ahead. In 2022, the Food and Drug Administration approved the disease modifying anti-amyloid agent, Aducanumab (Aduhelm), for the treatment of AD via the accelerated approval pathway. Additionally, another disease modifying anti-amyloid agent, Lecanemab (Leqembi), earned full approval from the FDA for the treatment of AD in early 2023. Lecanemab is the first medicine to demonstrate a modest yet significant slowing of cognitive decline. Together, these medications represent important advancements in the ongoing fight to effectively treat AD. Nevertheless, additional efforts remain necessary to tackle the devastating effects of AD/ADRD.

On January 4, 2011, President Obama signed into law the National Alzheimer's Project Act (NAPA) that established a National Plan to Address Alzheimer's to address the looming public health crisis. The first goal of the National Plan is to prevent and effectively treat AD/ADRD by 2025. As part of the strategic planning process for the implementation of the plan goals, NIA organized and hosted four AD Research Summits which were held in 2012, 2015, 2018, and 2021. The gaps and opportunities identified during the summits formed the basis for the AD/ADRD research implementation milestones (https://www.nia.nih.gov/research/milestones) which outline a research framework detailing specific steps and success criteria towards achieving the goals of the plan.

To meet the congressionally mandated goal of preventing and treating AD/ADRD, it is critical that we have efficient mechanisms to fund clinical trials pursuing a variety of therapeutic targets and approaches to prevent, delay, and treat AD/ADRD. The work of this NOFO will enable the early- to late-stage testing of promising pharmacological and non-pharmacological interventions that target deleterious cognitive, behavioral, and neuropsychiatric changes associated with age-related cognitive decline and AD/ADRD across the spectrum from pre-symptomatic to more severe stages of disease.

### Research Objectives

This NOFO invites research grant applications that enable the early- to late-stage testing of promising pharmacological and non-pharmacological interventions to prevent (e.g., primary, secondary prevention) and/or treat deleterious cognitive, behavioral, and neuropsychiatric changes associated with age-related cognitive decline and AD/ADRD across the spectrum from pre-symptomatic to more severe stages of disease.

A 2017 report from the National Academies of Sciences, Engineering, and Medicine (NASEM) on "Preventing Cognitive Decline and Dementia" suggested numerous ways to construct a stronger evidence base for the prevention of cognitive decline and AD/ADRD. A separate 2020 Agency for Healthcare Research and Quality (AHRQ) report on "Care Interventions for People Living With Dementia and Their Caregivers" highlighted the more general need for rigorous, well-powered, replicable research addressing issues of intervention fidelity and efficacy, as well as potential mechanisms of action (e.g., cognitive, behavioral, biological). Two issues that were highlighted in these reports were the need to identify how and why interventions work (i.e., the mechanism of action of non-pharmacological (e.g. cognitive, behavioral) interventions), and the need to ensure that complex interventions can be delivered with fidelity in "real-world" settings. The NIH Stage Model is a conceptual framework for non-pharmacological intervention development that directly addresses these two issues by: 1) offering a mechanisms-focused framework to intervention development and testing, with the goal of producing interventions defined by their principles and; 2) addressing issues related to ultimate implementation, such as determining ways to ensure that interventions can be delivered in the community with fidelity.

**Early-stage clinical trials and non-clinical trial studies of pharmacological interventions (Phase I/Phase II) and trials/studies of non-pharmacological interventions (Stage I - III)**

This NOFO supports 1) early-stage clinical testing of promising pharmacological and non-pharmacological interventions to prevent and/or treat cognitive, behavioral, and neuropsychiatric changes associated with age-related cognitive decline and AD/ADRD, and 2) studies to enhance trial design and methods. Investigators will be expected to collect DNA and other biospecimens from these studies to enable subsequent interrogation of treatment responsiveness, as well as examination of predictors of decline in the groups receiving placebo.

This NOFO encourages clinical trial applications including, but not limited to, the following focus areas:

- **Studies to refine the intervention strategy.** These studies could include work to determine appropriate dosage of drugs, duration of treatment, and the delivery system. For non-pharmacological interventions, such work might examine the intensity or duration of therapy required. This can also include modifying an intervention (consistent with its principles) to make it more scalable, and testing it to determine if it retains its potency. This can also include the modification and testing of interventions shown to be efficacious in a non-AD/ADRD population, for an AD/ADRD population. For all interventions, the potential synergistic effects of combined interventions could be explored.
- **Studies to evaluate the safety and/or efficacy of the intervention(s).**
- **Studies that elucidate mechanism of action.** In some cases, there may be interventions that have some level of demonstrated efficacy (e.g., exercise for age-related cognitive decline), but lack a real understanding of the mechanism of action. Work in this area could use a variety of approaches appropriate to the intervention in order to elucidate the mechanism of action, which could allow both the confirmation of engagement of the intervention target and the potential to optimize the intervention.

This NOFO also encourages both clinical trial and non-clinical trial applications in the following focus areas:

- **Studies to define and refine the target population and ensure adequate enrollment, protocol adherence, and subject retention.**
- **Studies that address heterogeneity of response.** This would include the identification of specific individuals according to genetic profiles, behavioral factors, and/or sociocultural or demographic factors who are more likely or less likely to benefit from the intervention(s). Mediators of the therapeutic intervention, such as continued educational opportunities and continued engagement in driving or financial decision-making, may facilitate real-life function and should be considered.
- **Studies to establish/validate trial outcome measures.** These measures may include clinical/neuropsychological/behavioral measures, neuroimaging measures, and other biological measures in blood and cerebrospinal fluid.

Examples of interventions for evaluation that are appropriate for this NOFO include, but are not limited to, the following:

- Pharmacological interventions (e.g., small molecules/biologics) that target prevention or slowing of disease progression;
- Pharmacological interventions (e.g., small molecules/biologics) that target disease symptomatology including neuropsychiatric symptoms;
- Repurposed drugs that have promise for AD/ADRD treatment such as chemotherapeutic agents or drugs for insulin dysregulation/diabetes;
- Neuromodulation;
- Assistive technology interventions;
- Novel cognitive training or cognitive engagement approaches;
- Aerobic exercise and/or other movement therapies, such as Tai Chi;
- Sleep enhancement;
- Mindfulness-based stress reduction;

- Nutritional supplementation or adoption of specific dietary programs; and/or
- Combinations of interventions including the mixture of pharmacological with non-pharmacological therapeutics.

This NOFO is not intended for applications that bundle independent phase 1 and phase 2 pharmacological clinical trial proposals. Such applications may be more appropriate for PAR-23-274 (https://grants.nih.gov/grants/guide/pa-files/PAR-23-274.html).

**Late-stage clinical trials of pharmacological interventions (Phase II/III and III) and trials of non-pharmacological interventions (Stage IV):**

This NOFO supports pivotal late-stage clinical trials testing pharmacological (small molecules and biologics) and non-pharmacological interventions, using a combination of biomarkers (fluid and imaging), cognitive measures, and functional measures as outcomes. These applications may include trials testing combinations of interventions that may act synergistically to produce a more robust and long-lasting response, as well as combinations of interventions that attempt to address multiple risk factors simultaneously (e.g., obesity, hypertension, diabetes, physical inactivity, anxiety, and depression). Investigators will be expected to collect DNA and other biospecimens from these studies to enable subsequent interrogation of treatment responsiveness, as well as examination of predictors of decline in the groups receiving placebo.

Late-stage pharmacological clinical trial applications that are appropriate for this NOFO will have established proof of mechanism or target engagement at earlier stages of clinical development for the intervention(s) being tested. The intervention(s) being tested in late-stage trials should also have adequate safety data for the populations under study. Late-stage non-pharmacological clinical trial applications will have also established that there are tested and validated procedures in place to ensure that the intervention can be delivered with fidelity to its principles (mechanisms of action) by real-world practitioners.

Studies designed to address heterogeneity of response are strongly encouraged. This would include the identification of specific individuals according to genetic profiles, behavioral factors, and/or sociocultural or demographic factors who are more likely or less likely to benefit from the intervention(s). Potential mediators of the therapeutic intervention, such as continued educational opportunities, social network exposure and engagement, and continued engagement in driving or financial decision-making, may facilitate effective real-life function and should be considered in interpreting therapeutic outcomes.

Examples of interventions for evaluation that are appropriate for this NOFO include, but are not limited to, the following:

- Pharmacological interventions (e.g., small molecules/biologics) that target prevention or slowing of disease progression;
- Pharmacological interventions (e.g., small molecules/biologics) that target disease symptomatology including neuropsychiatric symptoms;
- Repurposed drugs that have promise for AD/ADRD treatment such as chemotherapeutic agents or drugs for insulin dysregulation/diabetes;
- Neuromodulation;
- Assistive technology interventions;
- Novel cognitive training or cognitive engagement approaches;
- Aerobic exercise and/or other movement therapies, such as Tai Chi;
- Sleep enhancement;
- Mindfulness-based stress reduction;
- Nutritional supplementation or adoption of specific dietary programs; and/or
- Combinations of interventions including the mixture of pharmacological with non-pharmacological therapeutics, as well as combinations of non-pharmacological interventions.

**Design, Analysis, and Sample Size for Studies to Evaluate Group-Based Interventions:** Investigators who wish to evaluate the effect of an intervention on a health-related biomedical or behavioral outcome 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. Such studies may propose a parallel group- or cluster-randomized trial, an individually randomized group-treatment trial, a stepped-wedge design, or a quasi-experimental version of one of these designs. In these studies, special methods may be warranted for analysis and sample size estimation. Applicants should show that their methods are appropriate given their plans for assignment of participants and delivery of interventions.

### Non-responsiveness Criteria

The following types of applications will be considered non-responsive to this NOFO and will be administratively withdrawn prior to scientific peer review:

- Applications that bundle independent phase 1 and phase 2 pharmacological clinical trial proposals.

### Clinical Research Operations Management System

NIA uses a central resource to NIA staff and extramural investigators to facilitate/support the conduct and management of clinical research. NIA Clinical Research Operations & Management System (CROMS) is a comprehensive data management system to support the business functions, management, and oversight responsibilities of NIA grants that support the conduct of clinical research with human subjects. NIA investigators of grants, contracts, and cooperative agreements that are active as of July 1, 2021, including clinical trials funded as pilots, exploratory studies, or other projects through this Consortium, and support human subjects research as defined by the DHS HHS OHRP regulations at 45 CFR 46 will be required to interact with and use existing and future components of CROMS as required by NIA throughout the lifecycle of the grant, as described in NOT-AG-23-017 (https://grants.nih.gov/grants/guide/notice-files/NOT-AG-23-017.html). Data to be submitted to NIA CROMS includes those elements reported in the standard NIH requirement annual progress report (GPS 4.1.15.7). Details regarding the standard operating procedures for CROMS can be found on the NIA CROMS website (https://croms.nia.nih.gov/resources/resource-list).

When applicable, all NIA grantees must ensure:

1. The study's Informed Consent Document (ICD) lists "The National Institutes of Health (NIH) and its authorized representatives" as one of the organizations that may look at or receive copies of information in participants' study records. According to DHS HHS OHRP 45 CFR 46 §46.116 (https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.hhs.gov%2Fohrp%2Fregulations-and-policy%2Fregulations%2F45-cfr-46%2Frevised-common-rule-regulatory-text%2Findex.html%2346.116&data=05%7C01%7CNIAGuideLiaisons%40mail.nih.gov%7C65a11e0373194141af1f08db40cb1972%7C14b77578977342d58507251ca2dc2b0
all ICDs must contain "A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained." If using the NIA informed consent template (https://www.nia.nih.gov/research/clinical-research-study-investigators-toolbox#startup), please see Section 6: Statement of Confidentiality.

2. An assigned NIH ClinicalTrials.gov identifier (NCT number) is reported in its respective CROMS study record within three months after assignment, and the reporting of final enrollment data to CROMS is consistent with final enrollment data reported in ClinicalTrials.gov.

### NIA's Commitment to Inclusivity in Research Involving Human Subjects

NIA is committed to supporting and conducting research on aging that improves the health and well-being of all people. Therefore, NIA will prioritize the advancement of science that represents, in terms of race, ethnicity, sex, age, and comorbidity, the population affected by the condition being studied. Applicants should ensure as applicable that they 1) include proposed planned enrollment tables identifying the population(s) affected by the disease/condition, and 2) address the NIH Inclusion Policies for Research Involving Human Subjects (https://grants.nih.gov/policy/inclusion.htm) and NIH-designated Populations with Health Disparities (https://www.nimhd.nih.gov/about/overview/), as appropriate; as well as other populations that experience health disparities.
See Section VIII. Other Information for award authorities and regulations.

Investigators proposing NIH-defined clinical trials may refer to the Research Methods Resources (https://researchmethodsresources.nih.gov/) website for information about developing statistical methods and study designs.

# 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
Renewal
Resubmission
Revision

The OER Glossary (//grants.nih.gov/grants/guide/url_redirect.php?id=11116) and the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) provide details on these application types. Only those application types listed here are allowed for this NOFO.

**Clinical Trial?**

Optional: Accepting applications that either propose or do not propose clinical trial(s).

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

**Funds Available and Anticipated Number of Awards**

This NOFO will support clinical trials of varying size and scope, as well as studies to enhance clinical trial design and methods. NIA will commit approximately $20,000,000 to these efforts in fiscal year 2025.

**Award Budget**

Application budgets are not limited but need to reflect the actual needs of the proposed project.

**Award Project Period**

The scope of the proposed project should determine the project period. The maximum project period is 5 years.

NIH grants policies as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?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

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

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

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
- Non-domestic (non-U.S.) Entities (Foreign Organizations)

### Foreign Organizations

Non-domestic (non-U.S.) Entities (Foreign Organizations) **are** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are** eligible to apply.

Foreign components, as defined in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=11118), **are** allowed.

### Required Registrations

**Applicant Organizations**

Applicant organizations must complete and maintain the following registrations as described in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) 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 NIH Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications (//grants.nih.gov/grants/guide/url_redirect.php?id=82423) for additional information

- System for Award Management (SAM) – (https://grants.nih.gov/grants/guide/url_redirect.php?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.
  - NATO Commercial and Government Entity (NCAGE) Code (//grants.nih.gov/grants/guide/url_redirect.php?id=11176) – Foreign organizations must obtain an NCAGE code (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/url_redirect.php?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 (//grants.nih.gov/grants/guide/url_redirect.php?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. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

### 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. Individuals from diverse backgrounds, including underrepresented racial and ethnic groups, individuals with disabilities, and women are always encouraged to apply for NIH support. See, Reminder: Notice of NIH's Encouragement of Applications Supporting Individuals from Underrepresented Ethnic and Racial Groups as well as Individuals with Disabilities, (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-019.html) NOT-OD-22-019 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-019.html).

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 (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

### 2. Cost Sharing

This NOFO does not require cost sharing as defined in the NIH Grants Policy Statement NIH Grants Policy Statement Section 1.2 Definition of Terms. (//grants.nih.gov/grants/guide/url_redirect.php?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 (//grants.nih.gov/grants/guide/url_redirect.php?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 (//grants.nih.gov/grants/guide/url_redirect.php?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/url_redirect.php?id=82400) except where instructed in this notice of funding opportunity to do otherwise. Conformance to the requirements in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

### Letter of Intent

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

By the date listed in Part 1. Overview Information, prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed activity
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel
- Participating institution(s)
- Number and title of this funding opportunity

The letter of intent should be sent to:

Benfeard Williams, Ph.D.
National Institute on Aging (NIA)
Telephone: 301-496-9350
Email: benfeard.williams@nih.gov (mailto:benfeard.williams@nih.gov)

### Page Limitations

All page limitations described in the How to Apply – Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) and the Table of Page Limits (https://grants.nih.gov/grants/guide/url_redirect.php?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/guide/url_redirect.php?id=82400) 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/url_redirect.php?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/url_redirect.php?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/url_redirect.php?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/url_redirect.php?id=82400) must be followed.

For applications proposing clinical trials, members of the investigative team should have an appropriate level of experience in the conduct of clinical trials, including the collection and storage of biospecimens, and data analysis.

### R&R or Modular Budget

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

### R&R Subaward Budget

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

**For Early-Stage Clinical Trials:**

*Pharmacological interventions*

This NOFO encourages the submission of applications for the clinical testing of novel candidate therapeutics (small molecule and biologics), as well as for repurposed drugs. Investigators are strongly encouraged to incorporate pharmacodynamic biomarkers in the design. Investigators are also expected to collect and store blood and other biospecimens for future genomic and other 'omic' analyses aimed at interrogating treatment responsiveness and examining predictors of decline and progression. Additional guidance for this section is provided below, based on the clinical trial phase.

*Phase I pharmacological clinical trials*

Applications for therapeutic agents against known target(s) are expected to include information on the mechanism of action for the therapeutic agent, information regarding the target's role in disease pathogenesis and clinical relevance of the target, and information on the predicted optimal disease stage (e.g. pre-symptomatic, Mild Cognitive Impairment, mild, moderate or severe AD) to engage the target from preclinical development studies. Applicants proposing a multi-target therapeutic should summarize the available information on the pathogenic pathways that the agent engages and provide a strong clinically-relevant rationale for this approach.

If the molecular target of the therapeutic agent is not known, applications should summarize what is known about the agent's mechanism of action and whether the agent engages a disease-relevant pathophysiological process.

Finally, applications should contain a plan for future clinical development of the therapeutic agent, including details about the clinical indication (disease stage, target population), plan for use of biomarkers in the course of further clinical development (i.e., biomarkers for target engagement, responsiveness to treatment, and/or tracking of disease progression), and a clinical development timeline.

*Phase II pharmacological clinical trials*

Applications for Phase II clinical trials could be designed as proof of mechanism/target engagement/proof of concept studies. Applicants should also provide evidence of safety from earlier phase clinical trials and should include further evaluation of safety in the trial design. Finally, applications should contain a plan for future clinical development, i.e., later stage trials, if a positive signal were to be identified.

This NOFO is not intended for applications that bundle independent phase 1 and phase 2 pharmacological clinical trial proposals. Such applications may be more appropriate for PAR-23-274 (https://grants.nih.gov/grants/guide/pa-files/PAR-23-274.html).

*Early-stage non-pharmacological interventions*

This NOFO encourages the submission of applications for the testing of novel non-pharmacological interventions. Applications for clinical trials should include information on proof of mechanism for the intervention(s) being tested. The study design should align with the NIH Stage Model framework. Applications for clinical trials should also contain a plan for future clinical development, i.e., later stage trials, should a positive signal be identified. Investigators are encouraged to collect and store blood and other biospecimens for future genomic and other 'omic' analyses aimed at interrogating treatment responsiveness and examining predictors of decline and progression.

**For Late-Stage Clinical Trials:**

*Phase II/III and phase III pharmacological clinical trials*

Applications for late-stage pharmacological clinical trials that are appropriate for this NOFO will have established proof of mechanism or target engagement at earlier stages of clinical development for the intervention(s) being tested. The intervention(s) being tested in late-stage clinical trials should also have adequate safety data for the populations under study. Investigators will be expected to collect DNA and other biospecimens from these studies to enable subsequent interrogation of treatment responsiveness, as well as examination of predictors of decline in the groups receiving placebo.

*Late-stage non-pharmacological interventions*

All applications for late-stage non-pharmacological clinical trials that are appropriate for this NOFO will have an established demonstration of efficacy. The intervention(s) being tested in late-stage trials should also have adequate safety data for the populations under study. The study design should also align with the NIH Stage Model framework.

Late-stage non-pharmacological clinical trial applications will have also established that there are tested and validated procedures in place to ensure that the intervention can be delivered with fidelity to its principles (mechanisms of action) by real-world practitioners.

**Non-Clinical Trial Studies:**

This NOFO encourages the submission of applications for studies to enhance clinical trial design and methods. Applications appropriate for this NOFO can include studies to define and refine the target population, develop enhanced recruitment methods, and studies to establish/validate trial outcome measures. Study methods and approaches proposed should be appropriate for the target population and stage of disease.

**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/url_redirect.php?id=82400).

**For Early-Stage Clinical Trials and Non-Clinical Trial Studies:**

- All applications for early-stage clinical trials and non-clinical trial studies, regardless of the amount of direct costs requested for any one year, must address a Biospecimen Resource Sharing Plan where applicable. Sharing of biospecimens is expected at the time of publication of the primary results or within 9 months of database lock, whichever comes first. The plan must address which biospecimens will be shared, where they will be stored, and how approved parties will access these resources.

**For Late-Stage Clinical Trials:**

- All applications, regardless of the amount of direct costs requested for any one year, must address a Biospecimen Resource Sharing Plan. Generally, sharing of biospecimens is expected at the time of publication of the primary results or within 9 months of database lock, whichever comes first. For late-stage pivotal trials, post-randomization biospecimens must be shared after the earlier of either regulatory approval of the tested treatment or 18 months after the completion or early termination of the trial per the Collaboration for Alzheimer's Prevention (CAP) sample sharing principles. The plan must address which biospecimens will be shared, where biospecimens will be stored, and how approved parties will access these resources.

**Other Plan(s):** Note: Effective for due dates on or after January 25, 2023, the Data Management and Sharing Plan will be attached in the Other Plan(s) attachment in FORMS-H application forms packages.

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

- All applicants planning research (funded or conducted in whole or in part by NIH) that results in the generation of scientific data are required to comply with the instructions for the Data Management and Sharing Plan. All applications, regardless of the amount of direct costs requested for any one year, must address a Data Management and Sharing Plan.
- **For Early-Stage Clinical Trials:**
  - Sharing of clinical trial data (participant level and summary level data, raw and processed) is expected at the time of publication of the primary results or within 9 months of database lock, whichever comes first. The Data Management and Sharing Plan must address which data will be shared, where data will be stored, and how approved parties will access the data. NOT-OD-21-015 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-015.html) provides guidance regarding allowable costs associated with data management and sharing. The Data Management and Sharing Plan must also specify where the data will be stored. Appropriate data repositories can be publicly supported or can be hosted by the home institution. Examples of NIA-supported public repositories include the Alzheimer's Clinical Trials Consortium (ACTC) (https://www.actcinfo.org/) and the National Centralized Repository for Alzheimer's Disease and Related Dementias (NCRAD) (https://www.nia.nih.gov/research/resource/national-centralized-repository-alzheimers-disease-and-related-dementias-ncrad).
- **For Late-Stage Clinical Trials:**
  - Generally, sharing of clinical trial data (participant level and summary level data, raw and processed) is expected at the time of publication of the primary results or within 9 months of database lock, whichever comes first. For late-stage pivotal trials, post-randomization trial data must be shared after the earlier of either regulatory approval of the tested treatment or 18 months after the completion or early termination of the trial per the Collaboration for Alzheimer's Prevention (CAP) data sharing principles. Additionally, per CAP principles, late-stage trials must make screening and pre-randomization baseline data available to the scientific community within 12 months of enrollment completion. Moreover, emerging data from ongoing late-stage prevention trials must be made available as soon as possible without compromising trial integrity. The Data Management and Sharing Plan must address which data will be shared, where data will be stored, and how approved parties will access the data. NOT-OD-21-015 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-015.html) provides guidance regarding allowable costs associated with data management and sharing. The Data Management and Sharing Plan must also specify where the data will be stored. Appropriate data repositories can be publicly supported or can be hosted by the home institution. Examples of NIA-supported public repositories include the Alzheimer's Clinical Trials Consortium (ACTC) (https://www.actcinfo.org/) and the National Centralized Repository for Alzheimer's Disease and Related Dementias (NCRAD) (https://www.nia.nih.gov/research/resource/national-centralized-repository-alzheimers-disease-and-related-dementias-ncrad).

**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/url_redirect.php?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/url_redirect.php?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/url_redirect.php?id=82400) must be followed, with the following additional instructions:

***Section 2 - Study Population Characteristics***

**2.2 Eligibility Criteria**

Applications in response to this funding opportunity must provide a rationale supporting eligibility criteria that are 1) representative of the population affected by the disease/condition, and 2) address the populations outlined in the NIH Inclusion Policies for Research Involving Human Subjects (https://grants.nih.gov/policy/inclusion.htm) and NIH-designated Populations with Health Disparities (https://www.nimhd.nih.gov/resources/understanding-health-disparities/minority-health-and-health-disparities-definitions.html), as appropriate; as well as other populations that experience health disparities. The goal is for clinical trials and non-clinical trial studies to address inclusion, so that researchers can determine whether the variables being studied affect women or members of any racial and ethnic population group in accordance with the NIH Inclusion Policies.

Study teams must demonstrate that they have considered the NIH Inclusion Policies including proposed planned enrollment tables representative of the population affected by the disease/condition. Where applicable, study teams should also demonstrate that they have critically evaluated whether eligibility criteria from an earlier phase trial should be carried forward into a later phase trial. The eligibility criteria section should:

- Describe how the study results generalize to the wider patient population with this disease/condition.
- Explain how the rationale for selected eligibility criteria justify the level of restriction in the study compared to clinical practice.
- Provide evidence that the eligibility criteria support the proposed research and encourage inclusion of NIH-designated Populations with Health Disparities (https://www.nimhd.nih.gov/resources/understanding-health-disparities/minority-health-and-health-disparities-definitions.html).

**2.5 Recruitment and Retention Plan**

Applications in response to this funding opportunity should propose innovative and proactive recruitment strategies for involving understudied populations to promote representation as applicable and justified by the scientific goals. Applicants should ensure that they 1) include proposed planned enrollment tables identifying the population(s) affected by the disease/condition, and 2) address the populations outlined in the NIH Inclusion Policies for Research Involving Human Subjects (https://grants.nih.gov/policy/inclusion.htm) and NIH-designated Populations with Health Disparities (https://www.nimhd.nih.gov/resources/understanding-health-disparities/minority-health-and-health-disparities-definitions.html), as appropriate; as well as other populations that experience health disparities. Recruitment and retention plans should demonstrate an understanding of the participant burden involved in research participation and strategies for minimizing this burden, as well as leveraging community partners and outreach efforts. The recruitment and retention plan should:

- Describe potential barriers to participation and plans to minimize these barriers.
- Describe a detailed plan for the recruitment of understudied populations and a plan to leverage existing relationships with and/or conduct outreach to a broad range of community groups.
- Describe staff training to address cultural and linguistic competence (https://minorityhealth.hhs.gov/cultural-and-linguistic-competency).

**Delayed Onset Study**

Note: Delayed onset (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.php?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.php?id=82400) must be followed.

### Foreign Organizations

Foreign (non-U.S.) organizations must follow policies described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11137), and procedures for foreign organizations described throughout the How to Apply Application Guide.

## 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/url_redirect.php?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (//grants.nih.gov/grants/guide/url_redirect.php?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 (//grants.nih.gov/grants/guide/url_redirect.php?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 (//grants.nih.gov/grants/guide/url_redirect.php?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/guide/url_redirect.php?id=82400).

### 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)

### 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 (//grants.nih.gov/grants/guide/url_redirect.php?id=11120).

Pre-award costs are allowable only as described in the NIH Grants Policy Statement Section 7.9.1 Selected Items of Cost (//grants.nih.gov/grants/guide/url_redirect.php?id=11143).

### 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/url_redirect.php?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/url_redirect.php?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) 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/url_redirect.php?id=82400).

See more tips (//grants.nih.gov/grants/guide/url_redirect.php?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 NIA. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

In order to expedite review, applicants are requested to notify the NIA Referral Office by email at ramesh.vemuri@nih.gov when the application has been submitted. Please include the NOFO number and title, PD/PI name, and title of the application.

### Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in the policy (//grants.nih.gov/grants/guide/url_redirect.php?id=82299)

## 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 (//grants.nih.gov/grants/guide/url_redirect.php?id=11149) are evaluated for scientific and technical merit through the NIH peer review system.

For this particular announcement, note the following:

- A proposed Clinical Trial application may include study design, methods, and intervention that are not by themselves innovative but address important questions or unmet needs. Additionally, the results of the clinical trial may indicate that further clinical development of the intervention is unwarranted or lead to new avenues of scientific investigation.

A proposed Clinical Trial application may include study design, methods, and intervention that are not by themselves innovative but address important questions or unmet needs. Additionally, the results of the clinical trial may indicate that further clinical development of the intervention is unwarranted or lead to new avenues of scientific investigation.

### 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 review criteria and additional review criteria (as applicable for the project proposed).

### Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

#### Significance

Does the project address an important problem or a critical barrier to progress in the field? Is the prior research that serves as the key support for the proposed project rigorous? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

**In addition, for applications involving clinical trials**

Are the scientific rationale and need for a clinical trial to test the proposed hypothesis or intervention well supported by preliminary data, clinical and/or preclinical studies, or information in the literature or knowledge of biological mechanisms? For trials focusing on clinical or public health endpoints, is this clinical trial necessary for testing the safety, efficacy or effectiveness of an intervention that could lead to a change in clinical practice, community behaviors or health care policy? For trials focusing on mechanistic, behavioral, physiological, biochemical, or other biomedical endpoints, is this trial needed to advance scientific understanding?

***Specific to this NOFO:***

How well does the therapeutic target/mechanism of action for the intervention engage a disease-relevant pathophysiological process or processes? How likely is it that the intervention presented will help overcome the critical barriers to progress in Alzheimer's clinical trials?

#### Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is

collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

**In addition, for applications involving clinical trials**

With regard to the proposed leadership for the project, do the PD/PI(s) and key personnel have the expertise, experience, and ability to organize, manage and implement the proposed clinical trial and meet milestones and timelines? Do they have appropriate expertise in study coordination, data management and statistics? For a multicenter trial, is the organizational structure appropriate and does the application identify potential trial investigators and staffing for study coordination?
***Specific to this NOFO:***

How sufficient is the investigators' experience/knowledge to plan the future clinical development (i.e., later stage trials) if a positive signal were to be identified?

### Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

**In addition, for applications involving clinical trials**

Does the design/research plan include innovative elements, as appropriate, that enhance its sensitivity, potential for information or potential to advance scientific knowledge or clinical practice?

***Specific to this NOFO:***

How novel is the intervention for a clinical trial in Alzheimer's disease and related dementias; age-related cognitive decline? How novel is the proposed therapeutic target/mechanism of action or the clinical indication (disease stage, target population)?

### Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of individuals of all ages (including children and older adults), justified in terms of the scientific goals and research strategy proposed?

**In addition, for applications involving clinical trials**

Does the application adequately address the following, if applicable

*Study Design*

Is the study design justified and appropriate to address primary and secondary outcome variable(s)/endpoints that will be clear, informative and relevant to the hypothesis being tested? Is the scientific rationale/premise of the study based on previously well-designed preclinical and/or clinical research? Given the methods used to assign participants and deliver interventions, is the study design adequately powered to answer the research question(s), test the proposed hypothesis/hypotheses, and provide interpretable results? Is the trial appropriately designed to conduct the research efficiently? Are the study populations (size, gender, age, demographic group), proposed intervention arms/dose, and duration of the trial, appropriate and well justified?

Are potential ethical issues adequately addressed? Is the process for obtaining informed consent or assent appropriate? Is the eligible population available? Are the plans for recruitment outreach, enrollment, retention, handling dropouts, missed visits, and losses to follow-up appropriate to ensure robust data collection? Are the planned recruitment timelines feasible and is the plan to monitor accrual adequate? Has the need for randomization (or not), masking (if appropriate), controls, and inclusion/exclusion criteria been addressed? Are differences addressed, if applicable, in the intervention effect due to sex/gender and race/ethnicity?

Are the plans to standardize, assure quality of, and monitor adherence to, the trial protocol and data collection or distribution guidelines appropriate? Is there a plan to obtain required study agent(s)? Does the application propose to use existing available resources, as applicable?

*Data Management and Statistical Analysis*

Are planned analyses and statistical approach appropriate for the proposed study design and methods used to assign participants and deliver interventions? Are the procedures for data management and quality control of data adequate at clinical site(s) or at center laboratories, as applicable? Have the methods for standardization of procedures for data management to assess the effect of the intervention and quality control been addressed? Is there a plan to complete data analysis within the proposed period of the award?

***Specific to this NOFO:***

How well included and presented are the mechanisms of action for the intervention in regard to the target and the target's role in disease pathogenesis and clinical relevance of the target? How adequate is the information on the predicted optimal disease stage (pre-symptomatic, Mild Cognitive Impairments, mild, moderate, or severe AD/ADRD)? If there is a multi-target therapeutic approach, how well justified and clinically relevant is the rationale? How well discussed is the future clinical development of the therapeutic agent discussed, and how strong is its potential? How adequate is the evidence of safety? How well-reasoned and appropriate are the pharmacodynamic biomarkers to evaluate the success of the intervention? How appropriately will the investigator collect biospecimens ?

*Eligibility Criteria for Research Involving Human Subjects*

To what extent do the eligibility criteria promote inclusion of the population affected by the disease/condition? To what extent is justification provided for eligibility criteria, including inclusion and exclusion of NIH-designated Populations with Health Disparities (https://www.nimhd.nih.gov/resources/understanding-health-disparities/minority-health-and-health-disparities-definitions.html)? Have barriers to participation been assessed adequately?

*Recruitment and Retention Plan for Research Involving Human Subjects*

How well does the recruitment and retention plan demonstrate efforts to engage understudied populations in the clinical trial, as applicable and justified by the scientific goals? To what extent will the recruitment efforts increase community engagement, reduce identified barriers, and sustain the engagement of understudied populations? To what extent are plans described to train staff to be sensitive to NIH-designated Populations with Health Disparities (https://www.nimhd.nih.gov/resources/understanding-health-disparities/minority-health-and-health-disparities-definitions.html)?

### Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

**In addition, for applications involving clinical trials**

If proposed, are the administrative, data coordinating, enrollment and laboratory/testing centers, appropriate for the trial proposed?

Does the application adequately address the capability and ability to conduct the trial at the proposed site(s) or centers? Are the plans to add or drop enrollment centers, as needed, appropriate?

If international site(s) is/are proposed, does the application adequately address the complexity of executing the clinical trial?

If multi-sites/centers, is there evidence of the ability of the individual site or center to: (1) enroll the proposed numbers; (2) adhere to the protocol; (3) collect and transmit data in an accurate and timely fashion; and, (4) operate within the proposed organizational structure?

***Specific to this NOFO:***

How readily available is the proposed trial population, and how adequate are the resources for recruitment and retention? How adequate are the project's resources to collect and store blood and other biospecimens ?

## Additional Review Criteria

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

### Study Timeline

**Specific to applications involving clinical trials**

Is the study timeline described in detail, taking into account start-up activities, the anticipated rate of enrollment, and planned follow-up assessment? Is the projected timeline feasible and well justified? Does the project incorporate efficiencies and utilize existing resources (e.g., CTSAs, practice-based research networks, electronic medical records, administrative database, or patient registries) to increase the efficiency of participant enrollment and data collection, as appropriate?

Are potential challenges and corresponding solutions discussed (e.g., strategies that can be implemented in the event of enrollment shortfalls)?

### 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, the committee will 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, the committee will 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 (//grants.nih.gov/grants/guide/url_redirect.php?id=11175).

### Inclusion of Women, Minorities, and Individuals Across the Lifespan

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of individuals of all ages (including children and older adults) to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research (//grants.nih.gov/grants/guide/url_redirect.php?id=11174).

### Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following three points: (1) a complete description of all proposed procedures including the species, strains, ages, sex, and total numbers of animals to be used; (2) justifications that the species is appropriate for the proposed research and why the research goals cannot be accomplished using an alternative non-animal model; and (3) interventions including analgesia, anesthesia, sedation, palliative care, and humane endpoints that will be used to limit any unavoidable discomfort, distress, pain and injury in the conduct of scientifically valuable research. Methods of euthanasia and justification for selected methods, if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals, is also required but is found in a separate section of the application. For additional information on review of the Vertebrate Animals Section, please refer to the Worksheet for Review of the Vertebrate Animals Section. (//grants.nih.gov/grants/guide/url_redirect.php?id=11150)

### Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

### Resubmissions

For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

### Renewals

For Renewals, the committee will consider the progress made in the last funding period.

### Revisions

For Revisions, the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

## 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.

### Applications from Foreign Organizations

Reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

#### Select Agent Research

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

#### Resource Sharing Plans

Reviewers will comment on whether the Resource Sharing Plan(s) (e.g., Sharing Model Organisms (https://sharing.nih.gov/other-sharing-policies/model-organism-sharing-policy#policy-overview)) or the rationale for not sharing the resources, is reasonable.

#### Authentication of Key Biological and/or Chemical Resources

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

#### Budget and Period of Support

Reviewers will consider 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 NIA, in accordance with NIH peer review policies and practices (//grants.nih.gov/grants/guide/url_redirect.php?id=11154), 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.

Appeals (https://grants.nih.gov/grants/policy/nihgps/html5/section_2/2.4.2_appeals_of_initial_scientific_review.htm) of initial peer review will not be accepted for applications submitted in response to this NOFO.

Applications will be assigned to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this NOFO. Following initial peer review, recommended applications will receive a second level of review by the National Advisory Council on Aging. 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.

### 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 (//grants.nih.gov/grants/guide/url_redirect.php?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 (//grants.nih.gov/grants/guide/url_redirect.php?id=82416).

## Section VI. Award Administration Information

### 1. Award Notices

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 (//grants.nih.gov/grants/guide/url_redirect.php?id=82418). This request is not a Notice of Award nor should it be construed to be an indicator of possible funding.

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the recipient's business official.

Recipients must comply with any funding restrictions described in Section IV.6. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this NOFO will be subject to terms and conditions found on the Award Conditions and Information for NIH Grants (https://grants.nih.gov/grants/policy/nihgps/HTML5/part_ii_subpart_b.htm) website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

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 (//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

All NIH grant and cooperative agreement awards include the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11120) as part of the NoA. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (//grants.nih.gov/grants/guide/url_redirect.php?

id=11157) and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities (//grants.nih.gov/grants/guide/url_redirect.php?id=11159), including of note, but not limited to:

- Federalwide Standard Terms and Conditions for Research Grants (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_3/3.1_federalwide_standard_terms_and_conditions_for_research_grants.htm)
- Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment (//grants.nih.gov/grants/guide/url_redirect.php?id=82417)
- Acknowledgment of Federal Funding (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.2.1_acknowledgement_of_federal_funding.htm)

If a recipient is successful and receives a Notice of Award, 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.

If a recipient receives an award, the recipient must follow all applicable nondiscrimination laws. The recipient agrees to this when registering in SAM.gov. The recipient must also submit an Assurance of Compliance (HHS-690 (https://www.hhs.gov/sites/default/files/form-hhs690.pdf)). To learn more, see the Laws and Regulations Enforced by the HHS Office for Civil Rights website (https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/laws/index.html).

HHS recognizes that NIH research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research. For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this NOFO.

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to System for Award Management (SAM.gov) requirements. SAM.gov requires Federal agencies to review and consider information about an applicant in the designated integrity and performance system (currently SAM.gov) prior to making an award. 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 addition to the information available in the responsibility/qualification records in SAM.gov, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 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.

### Cooperative Agreement Terms and Conditions of Award

Not Applicable

### 3. Data Management and Sharing

Consistent with the 2023 NIH Policy for Data Management and Sharing, when data management and sharing is applicable to the award, recipients will be required to adhere to the Data Management and Sharing requirements as outlined in the NIH Grants Policy Statement (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2.3_sharing_research_resources.htm#Data). Upon the approval of a Data Management and Sharing Plan, it is required for recipients to implement the plan as described.

### 4. Reporting

When multiple years are involved, recipients will be required to submit the Research Performance Progress Report (RPPR) (//grants.nih.gov/grants/rppr/index.htm) annually and financial statements as required in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=82419).

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

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 (//grants.nih.gov/grants/guide/url_redirect.php?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.

The Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov (//grants.nih.gov/grants/guide/url_redirect.php?id=11170) on all subawards over the threshold. See the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=82420) for additional information on this reporting requirement.

In accordance with the regulatory requirements provided at 2 CFR Part 200.113 and Appendix XII to 2 CFR Part 200, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than $10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (Responsibility/Qualification in SAM.gov, formerly FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 2 CFR Part 200 – Award Term and Condition for Recipient Integrity and Performance Matters.

## Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

### Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten submission by the due date, and post-submission issues)

Finding Help Online: https://www.era.nih.gov/need-help (https://www.era.nih.gov/need-help) (preferred method of contact)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

General Grants Information (Questions regarding application instructions, application processes, and NIH grant resources)
Email: GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov) (preferred method of contact)
Telephone: 301-637-3015

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)
Contact Center Telephone: 800-518-4726
Email: support@grants.gov (mailto:support@grants.gov)

### Scientific/Research Contact(s)

Laurie Ryan, Ph.D.
National Institute on Aging (NIA)
Telephone: 301-496-9350
Email: ryanl@mail.nih.gov (mailto:ryanl@mail.nih.gov)

Kristina McLinden, Ph.D.
National Institute on Aging (NIA)
Telephone: 301-496-9350
Email: mclindenka@nih.gov (mailto:mclindenka@nih.gov)

Akanni Clarke, Ph.D.
National Institute on Aging (NIA)
Telephone: 301-496-9350
Email: akanni.clarke@nih.gov (mailto:akanni.clarke@nih.gov)

Luke E. Stoeckel, Ph.D.
National Institute on Aging (NIA)
Telephone: 202-570-9388
Email: luke.stoeckel@nih.gov (mailto:luke.stoeckel@nih.gov)

### Peer Review Contact(s)

Ramesh Vemuri, Ph.D.
National Institute on Aging (NIA (https://www.nia.nih.gov/))
Telephone: 301-402-7700
Email: ramesh.vemuri@nih.gov (mailto:ramesh.vemuri@nih.gov)

### Financial/Grants Management Contact(s)

Philip Smith
National Institute on Aging (NIA)
Telephone: 301-402-3465
Email: philip.smith2@nih.gov (mailto:philip.smith2@nih.gov)

## Section VIII. Other Information

Recently issued trans-NIH policy notices (//grants.nih.gov/grants/guide/url_redirect.php?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 (//grants.nih.gov/grants/guide/url_redirect.php?id=11164). All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?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.

---

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?07-05-24)
NIH Funding Opportunities and Notices (/grants/guide/index.html)

---