

Department of Health and Human Services

Part 1. Overview Information

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

Components of Participating Organizations
NATIONAL INSTITUTE ON AGING ([NIA \(\\$issuingComponent.orgLink\)\)](#)
National Institute of Dental and Craniofacial Research ([NIDCR \(https://www.nidcr.nih.gov/\)](https://www.nidcr.nih.gov/))
National Institute of Nursing Research ([NINR \(https://www.ninr.nih.gov/\)](https://www.ninr.nih.gov/))
National Institute on Minority Health and Health Disparities ([NIMHD \(https://www.nimhd.nih.gov/\)](https://www.nimhd.nih.gov/))

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

Funding Opportunity Title
Grants for Early Medical/Surgical Specialists' Transition to Aging Research (GEMSSTAR) (R03 Clinical Trial Optional)

Activity Code
[R03 \(http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r03&Search.x=0&Search.y=0&sort=ac&Search_Type=Activity&text_prev=\)](http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r03&Search.x=0&Search.y=0&sort=ac&Search_Type=Activity&text_prev=). Small Grant Program

Announcement Type
Reissue of RFA-AG-25-021

Related Notices

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

Funding Opportunity Number (FON)
PAR-27-096

Companion Funding Opportunity
None

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

Assistance Listing Number(s)
93.866, 93.361, 93.121, 93.307

Funding Opportunity Purpose
The goal of the Grants for Early Medical/Surgical Specialists' Transition to Aging Research (GEMSSTAR) program is to provide support for early-career clinician-scientists trained in medical or surgical specialties to launch careers as future leaders in aging- or geriatric-focused research. In support of the program's goal, this GEMSSTAR Notice of Funding Opportunity (NOFO) invites applications that propose to conduct transdisciplinary aging research that will yield pilot data and experience for subsequent aging research projects. The GEMSSTAR program encourages candidates to seek out a supportive research environment to further the program's objectives of fostering the development of early-career clinician-scientists in aging- or geriatric-focused research, particularly as it applies to their clinical specialty/discipline. Toward this end, GEMSSTAR candidates should include a Professional Development Plan that reflects this supportive research environment. In selecting GEMSSTAR recipients, the National Institute on Aging (NIA) will consider the extent to which a candidate's environment is supportive of aging- or geriatric-focused research.

Funding Opportunity Goal(s)
To encourage biomedical, social, and behavioral research and research training directed toward greater understanding of the aging process and the diseases, special problems, and needs of people as they age.

Key Dates

Posted Date

Open Date (Earliest Submission Date)

October 10, 2026

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

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS - New/Renewal/Resubmission/Revision, as allowed	Scientific Merit Review	Advisory Council Review	Earliest Start Date
November 10, 2026	November 16, 2026 *	Not Applicable	March 2027	May 2027	July 2027
June 16, 2027 *	July 16, 2027 *	Not Applicable	November 2027	January 2028	April 2028
June 16, 2028 *	July 16, 2028 *	Not Applicable	November 2028	January 2029	April 2029

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).

Due Dates for E.O. 12372

Not Applicable

Expiration Date

July 17, 2028

Required Application Instructions

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

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

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

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

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

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Part 2. Full Text of Announcement

Section I. Notice of Funding Opportunity Description

Background

With the growing number of older adults with complex health challenges, there is an equally growing need for clinician-scientists with training and experience in research focused on optimizing the care of older patients. A pivotal point in the development of clinician-scientists is the completion of specialty training and the first faculty appointment. At this early stage, limited research experience and publication record preclude competitiveness for many kinds of advanced research opportunities. This transition stage may be particularly difficult for clinicians focusing on aging-related aspects of their specialty/discipline, as multidisciplinary research entails training that is rarely available in conventional programs. Thus, mechanisms

that allow these clinicians to initiate research projects and establish research track records are critical for cultivating the next generation of clinician-scientists at the interface of aging and medical, dental, and surgical specialties.

Program Description

The GEMSSTAR program is intended to support an early-career clinician's first independent research project. The program also provides an opportunity for clinicians who are funded in non-aging-related fields to refocus their research efforts on aging- or geriatrics-related topics. Thus, the program seeks applicants who aspire to continue or shift their research focus to bridge their specialty/discipline and the clinical care of older adults.

The GEMSSTAR program provides two years of funding. Applicants should emphasize integration of gerontologic or geriatric research with the candidate's clinical specialty/discipline. Proposed projects may involve pilot or feasibility studies, secondary analyses of existing data, development of research methodology, development of new research technology, or other similar approaches. Projects may span the breadth of scientific domains, including basic, translational, clinical, genetic, or epidemiologic science. Human subjects, animal models, and *in vitro* systems are all acceptable as appropriate to the research questions. Projects should be appropriate to the background and level of experience of the applicant. Potential research topics may include, but are not limited to, the following:

- Characterization of an aging-related disease, condition, syndrome, or phenomenon relevant to a clinical specialty/discipline
- Elucidation of mechanisms underlying specialty/discipline-related diseases in older age
- Identification of predictors and/or outcomes of specialty/discipline-related interventions specific to older populations
- Pilot investigation of a specialty/discipline-related intervention in older adults
- Development of strategies to address and/or integrate important complexities common in older patients typically seen within a clinical specialty/discipline, such as multiple chronic conditions; polypharmacy; multispecialty guideline integration; and preservation of function, cognition, and independence
- Multidisciplinary care strategies, such as palliative care and transitions across care settings, to improve outcomes in older patients within or across care settings
- Specific diagnostic, management, and/or decision-making and communication strategies pertaining to older adults with Alzheimer's disease (AD) or AD-related dementias (ADRD) within or across medical and/or surgical specialties and primary care/geriatrics
- Strategies for screening, primary prevention, and/or secondary prevention of specialty/discipline-related diseases in older adults
- Initial development of tools to assess the risk and/or prognosis of a specialty/discipline-related disease and/or interventions in older adults

Please refer to **Section III. Eligibility Information, Eligible Individuals (Program Director/Principal Investigator)** for clarification on eligibility. It is expected that applicants will have expertise in their clinical specialty/discipline, but may be less experienced in geriatric/gerontologic science or in other areas. As such, applicants should include participation of a senior collaborator with complementary expertise in aging-related research and, if needed, other collaborators and/or consultants in additional areas appropriate to the proposed project.

Geriatricians proposing a research project that integrates their geriatrics expertise with a specific clinical problem that is typically embraced by another specialty should involve a senior collaborator with expertise in that clinical problem as it relates to older patients. For example, a geriatrician researcher proposing a project focused on chronic kidney disease is encouraged to involve a senior nephrologist or other relevant specialist.

In addition to the research project, candidates must also include a Professional Development Plan that describes an individualized plan to garner resources, activities, collaborations, and/or didactic or practical experiences concurrent with the R03 research project that will 1) lead to enhanced knowledge and skills in aging/geriatrics science, and 2) increase the applicant's likelihood of successful completion of their proposed GEMSSTAR project. This plan would complement the GEMSSTAR R03 award and would need to be supported independent of the R03 research plan and funding.

Clinical Research

NOTE TO APPLICANTS CONSIDERING A CLINICAL TRIAL: The limited time and budget provided by this NOFO will constrain the types of clinical trials that can be proposed. In general, only mechanistic trials or small pilot trials are likely to be feasible. Applicants considering a clinical trial are highly encouraged to contact NIA program staff early to discuss the feasibility of doing so. Refer also to the [NIH's policies and requirements for clinical trials \(https://grants.nih.gov/policy/clinical-trials.htm\)](https://grants.nih.gov/policy/clinical-trials.htm).

NIA's Commitment to Population Representative Research

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 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 \(https://grants.nih.gov/policy/inclusion.htm\)](https://grants.nih.gov/policy/inclusion.htm), as appropriate.

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

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

Section II. Award Information

Funding Instrument

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

Application Types Allowed

New
Resubmission

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

Clinical Trial?

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

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

Funds Available and Anticipated Number of Awards

NIA intends to commit \$3,000,000 in each of FY 2027, FY 2028, and FY 2029 to fund 15 awards focused on general aging topics.

NIA intends to commit \$800,000 in each of FY 2027, FY 2028, and FY 2029 to fund 4 awards focused on Alzheimer's disease (AD) or AD-related dementias.

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

Award Budget

Application budgets are limited to \$125,000 in direct costs per year.

Indirect costs are those for a common or joint purpose across more than one project and that cannot be easily separated by project. Learn more at [45 CFR 75.414](https://www.ecfr.gov/current/title-45/section-75.414) (<https://www.ecfr.gov/current/title-45/section-75.414>), Indirect Costs.

To charge indirect costs applicants can select one of two methods:

Method 1 – Approved rate. The applicant organization currently has an indirect cost rate approved by the applicant organization's cognizant federal agency.

Method 2 – De minimis rate. Per [45 CFR 75.414\(f\)](https://www.ecfr.gov/current/title-45/part-75#p-75.414(f)) ([https://www.ecfr.gov/current/title-45/part-75#p-75.414\(f\)](https://www.ecfr.gov/current/title-45/part-75#p-75.414(f))), if the applicant organization has never received a negotiated indirect cost rate or is awaiting approval of an indirect cost proposal, they may elect to charge a de minimis rate. If choosing this method, costs included in the indirect cost pool must not be charged as direct costs.

This rate is 10% of modified total direct costs (MTDC). See [45 CFR 75.2](https://www.ecfr.gov/current/title-45/part-75#p-75.2(Modified%20Total%20Direct%20Cost)) ([https://www.ecfr.gov/current/title-45/part-75#p-75.2\(Modified%20Total%20Direct%20Cost\)](https://www.ecfr.gov/current/title-45/part-75#p-75.2(Modified%20Total%20Direct%20Cost))) for the definition of MTDC. Organizations can use this rate indefinitely.

Award Project Period

The project period is limited to 2 years.

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

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions - Includes all types

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

Nonprofits Other Than Institutions of Higher Education

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

For-Profit Organizations

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

Local Governments

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

Federal Governments

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

Other

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

Foreign Organizations/International Collaborations

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

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

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

NIH will no longer issue awards (i.e., new, renewal, or non-competing continuation) to domestic or foreign entities that involve foreign subawards/subcontracts. All NIH-funded research involving foreign subawards/subcontracts must be submitted in response to a NOFO that is specifically designated for funded international collaborations. See [NIH Grants Policy Statement 16.8 Collaborative International Research Awards](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_16/16.8_collab_int_res_awards.htm) (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_16/16.8_collab_int_res_awards.htm).

Applications involving foreign subawards/subcontracts submitted in response to this NOFO will be deemed noncompliant and will not be considered for funding. This policy applies to all monetary international collaborations resulting in foreign subawards/subcontracts, however, it does not preclude unfunded international collaborations or [foreign components](#)

(https://grants.nih.gov/grants/policy/nihgps/HTML5/section_1/1.2_definition_of_terms.htm), funding for foreign consultants, or procurement of unique equipment or supplies from foreign vendors.

Required Registrations

Applicant Organizations

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

- **System for Award Management (SAM)** (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82390) – Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code. Foreign organizations must obtain a [NATO Commercial and Government Entity \(NCAGE\) Code](#) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11176) (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.htm?id=11123) - Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their Grants.gov registrations; all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- **Grants.gov** (http://grants.nih.gov/grants/guide/url_redirect.htm?id=82300) – Applicants must have an active SAM registration in order to complete the Grants.gov registration.

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

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

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

Eligible Individuals (Program Director/Principal Investigator)

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

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

Candidates for this award must have a clinical doctoral degree. Such degrees include, but are not limited to, the MD, DO, DDS, DMD, OD, DC, PharmD, ND (Doctor of Naturopathy), PsyD, DNP, DPT, and DVM. Individuals holding a research doctoral degree, such as the PhD, are generally ineligible.

The GEMSSTAR award is intended for early career clinician-scientists aiming to get a "foot in the door" in research related to aging in their clinical specialty area. This award is not intended for candidates who have already received funding as a principal investigator on an NIH aging-related career development (excluding K38 and K99) or research award (e.g., R01, P01). However, candidates who have received support through institutional awards, such as KL2, R25, or NIA Center (P30) Research Education Component (REC), may apply.

Early-career clinician-scientists who have had a previous NIH individual mentored career development or research award in a non-aging-related field and who wish to refocus their research efforts on aging-related science are eligible to apply. However, such individuals must provide strong justification in their application explaining how their proposed research will entail a meaningful shift towards aging-related science within their clinical specialty or discipline. Merely supplementing one's current research efforts with aging-related science would not be considered a meaningful shift. The R03 application and Professional Development Plan proposal will be reviewed closely for substantial evidence of a commitment to aging research. Such applicants are strongly encouraged to discuss their eligibility with NIA program staff early in the application process.

Applicants considering applying for a mentored K award and a GEMSSTAR award concurrently are strongly encouraged to contact NIA program staff to ensure their plans are consistent with NIH policy and NIA programmatic interests. The aims of the two applications must not overlap [per NIH submission policies](#). (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-197.html>) NIA will weigh an applicant's funding from other NIA and NIH awards in making GEMSSTAR funding decisions. Note that NIH policy now allows investigators with K awards to receive salary compensation from Federal or non-Federal sources for effort not directly supported by their K award (see [NOT-OD-17-094](https://grants.nih.gov/grants/guide/notice-files/not-od-17-094.html) (<https://grants.nih.gov/grants/guide/notice-files/not-od-17-094.html>)).

Eligibility is limited to candidates who have, or will have, a faculty appointment at the start of GEMSSTAR funding. Candidates in the last year of training should provide documentation of institutional commitment for a faculty appointment as described in Letters of Support in Section IV. Faculty appointments that are contingent on receiving a GEMSSTAR award are not acceptable.

Candidates should typically be within 10 years of completing their training, although exceptions may be granted. Candidates should still be early in their careers with respect to aging-related research. Contact NIATraining@mail.nih.gov (<mailto:NIATraining@mail.nih.gov>) with questions.

It is expected that GEMSSTAR applications will have a single PD/PI and that other personnel will be listed as collaborators or consultants.

2. Cost Sharing

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

3. Additional Information on Eligibility

Number of Applications

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

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

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

Section IV. Application and Submission Information

1. Requesting an Application Package

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

2. Content and Form of Application Submission

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

Page Limitations

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

Instructions for Application Submission

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

SF424(R&R) Cover

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

SF424(R&R) Project/Performance Site Locations

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

SF424(R&R) Other Project Information

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

Other attachments: Applicants must include an attachment titled "Professional Development Plan" (PDP) that describes an individualized plan to garner resources, activities, collaborations, and/or didactic or practical experiences concurrent with the R03 research project that will 1) lead to enhanced knowledge and skills in aging/geriatrics science, and 2) increase the applicant's likelihood of successful completion of their proposed GEMSSTAR project. This separately supported PDP should be complementary to the applicant's R03 research plan.

Support for a PDP is not included in the NIA R03 budget and needs to be supported independent of the R03 research plan and funding. PDP support should begin at the start of R03 funding and run concurrently with the 2-year award. The level of funding and effort should be commensurate with the activities proposed in the PDP. Every PDP is different and, as such, will require a different level of funding support depending on what the applicant proposes given their level of aging/geriatrics research knowledge and skills, and what is needed to successfully complete their research and initiate a career in aging research. The amount of secured funding or protected time should be enough to provide for a GEMSSTAR applicant's serious and meaningful development into a successful aging-focused clinician-scientist.

Although it is unlikely that applicants will have PDP funding secured by the time of R03 submission, applicants should list the potential PDP funding sources they are seeking in their applications. Applicants who obtain PDP funding support after submission of the R03 application may include documentation in their Just-In-Time submission as Other Support. If PDP funding support is known at the time of application, an official letter from the institution, society, foundation, or other source should be provided that indicates the amount and duration of funding and any stipulations for use of funds. This can be submitted as an "Other Attachment."

Mentorship should be included in needed areas. If the PDP includes a mentorship plan, the mentor(s) should have sufficient expertise in specific techniques and skills related to aging research. We encourage you to seek out geriatricians or gerontologists at your institution who may be able to provide you with appropriate mentorship on unique aspects of clinical and/or research in aging/geriatrics. PDPs with multiple mentors should also describe how interactions will be coordinated among the mentorship team. Mentors and other collaborators who play a role in an applicant's PDP should submit a Letter of Support to be included with the R03 application. PDP letters of support should be uploaded under 'Letters of Support' in the R03 application, rather than with the PDP itself.

The elements of a Professional Development Plan may differ for each applicant based on career stage, research experience, institutional resources, or other factors. Applicants are encouraged to tailor their plans to meet their individual professional development needs in relation to their proposed GEMSSTAR project. Moreover, applicants are encouraged to describe specific activities that will augment their skills in geriatrics and/or aging research in order to develop into independent researchers in aging science.

This section is limited to 5 pages.

SF424(R&R) Senior/Key Person Profile

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

Applicants should use the biographical sketch of the principal investigator to illustrate how this award will advance the investigator's career in aging research. Applicants should use biographical sketches of all investigators to illustrate complementary and integrated expertise in aging and/or geriatrics among the research team, and the appropriateness of each person's role to advance the specific aims of the project.

The GEMSSTAR award offers an opportunity for investigators without substantial aging research experience to gain the necessary skills, exposure and pilot data in aging or geriatrics-related research. To achieve this goal, there should be at least one senior research collaborator with such complementary aging research experience as documented through aging-related publications, funding, and resources to be made available to the GEMSSTAR candidate. This information should be conveyed in the senior collaborator's biographical sketch.

For individuals who are not Senior/Key Personnel or Other Significant Contributors but who may have input into the application, a Letter of Support is encouraged. For example, the Division/Department Chair or other Institutional leader may submit a Letter of Support outlining available resources or commitments of protected time for the proposed research.

R&R or Modular Budget

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

Applicants should use the Modular Budget format. Annual direct costs can be requested in multiples of \$25,000 up to \$125,000.

Applicants should budget for travel to the annual GEMSSTAR grantees meeting supported by the Clin-STAR Coordinating Center. Except in unusual circumstances, only the PD/PI may be supported by R03 funds to travel to the grantees meeting. There is no specific line item in the Modular Budget format in which to list travel costs; instead, the proposed travel should be described in the budget justification section.

Salary support can be received from a GEMSSTAR award as long as 1) there is no significant budget or scientific overlap with any concurrent source of funding, and 2) the candidate is not also receiving an NIH mentored K or other award that prohibits salary supplementation from Federal sources.

R&R Subaward Budget

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

PHS 398 Cover Page Supplement

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

PHS 398 Research Plan

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

Research Strategy: In accordance with the goals of the GEMSSTAR program, the Research Strategy should emphasize how the candidate's proposed research will advance the understanding of aging- or geriatrics-related science in the candidate's specialty/discipline, as well as facilitate the candidate's transition specifically into aging research. Applicants should address to what extent the proposed project introduces aging-related research questions to the applicant's clinical specialty/disciplinary area, as well as its potential contribution to new and meaningful knowledge of geriatric or gerontologic science related to the applicant's clinical specialty/discipline.

Clinical Trials: Without duplicating information in the PHS Human Subjects and Clinical Trials Information Form, applicants proposing a clinical trial, ancillary, or feasibility study should describe the planned analyses and statistical approach and how the expected analytical approach is suited to the available resources, proposed study design, project scope, and methods used to assign trial participants and deliver interventions.

If proposing an ancillary study to an ongoing clinical trial, applicants should provide a brief description of its relationship to the larger clinical trial.

If proposing a feasibility study to begin to address a clinical question, applicants should provide justification as to why this is warranted and how it will contribute to the overall goals of the research project, including planning and preliminary data for future, larger-scale clinical trials.

Applicants should describe the proposed timelines for the proposed clinical trial, feasibility, or ancillary study, including any potential challenges and solutions (e.g., enrollment shortfalls or inability to attribute causal inference to the results of an intervention when performing a small feasibility study).

Letters of Support: Letters of support from department or division chairs, other institutional leaders, senior collaborators, and other contributors should describe, where appropriate, the following:

- Support from the applicant's institution, department, or division for the applicant's successful completion of the proposed research project
- Efforts from the letter's author to promote transdisciplinary aging research within the author's specialty/discipline
- Scientific roles of senior collaborator(s) or other contributors to the applicant's professional development
- For applicants in their last year of training, documentation of the institution's commitment to the applicant's faculty appointment, which should commence no later than the start of the GEMSSTAR R03 award

Letters of support associated with a Professional Development Plan, if included, should be placed in the Letters of Support section.

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 \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400).

Other Plan(s):

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

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

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

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

PHS Human Subjects and Clinical Trials Information

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

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

Study Record: PHS Human Subjects and Clinical Trials Information

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

Section 2 - Study Population Characteristics

2.5 Recruitment and Retention Plan

Without duplicating information in the attachments to the PHS Human Subjects and Clinical Trials Information form, applications in response to this funding opportunity must provide further rationale supporting eligibility criteria and study population characteristics. Applicants should propose innovative and proactive recruitment strategies as applicable and justified by the scientific goals. Applicants should ensure that they address the populations appropriate and relevant to the proposed research and scientific goals. 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 must:

- Describe potential barriers to participation and plans to minimize these barriers.
- Describe a plan to leverage existing relationships with and/or conduct outreach to a broad range of community groups.

In addition, without duplicating information in the attachments to the Human Subjects and Clinical Trials Information form, applications in response to this funding opportunity must provide further rationale supporting eligibility criteria and study population characteristics that are representative of the population affected by the disease/condition as well as other populations relevant to the proposed research and scientific goals.

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. Further rationale supporting eligibility criteria and study population must:

- Describe how the study results generalize to the wider patient population with this disease/condition.
- Explain how the rationale for selected eligibility criteria justifies the level of restriction in the study compared to clinical practice.

Delayed Onset Study

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

PHS Assignment Request Form

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

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

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

4. Submission Dates and Times

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

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

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

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

5. Intergovernmental Review (E.O. 12372)

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

6. Funding Restrictions

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

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

7. Other Submission Requirements and Information

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

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

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

Important reminders:

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

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

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

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

Mandatory Disclosure

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

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

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in [the policy \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=82299\)](http://grants.nih.gov/grants/guide/url_redirect.htm?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 \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11149\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11149) are evaluated for scientific and technical merit through the NIH peer review system.

Overall Impact

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

be judged likely to have a major scientific impact.

Scored Review Criteria

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

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

Significance

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

Innovation

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

Factor 2. Rigor and Feasibility (Approach)

Approach

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

Rigor:

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

Feasibility:

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

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

Investigator(s)

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

Environment

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

Additional Review Criteria

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

Protections for Human Subjects

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

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

Vertebrate Animals

When the proposed research includes Vertebrate Animals, evaluate the involvement of live vertebrate animals according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the

appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. For additional information on review of the Vertebrate Animals section, please refer to the [Worksheet for Review of the Vertebrate Animals Section \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11150\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

Biohazards

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

Resubmissions

As applicable, evaluate the full application as now presented.

Renewals

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

Revisions

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

Professional Development Plan

Evaluate the extent to which the Professional Development Plan promotes the candidate's knowledge and skills in geriatrics- or aging-related research.

Additional Review Considerations

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

Authentication of Key Biological and/or Chemical Resources

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

Budget and Period of Support

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

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by CSR, in accordance with [NIH peer review policy and procedures \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11154\)](http://grants.nih.gov/grants/guide/url_redirect.htm?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.

Applications will be assigned to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications. Following initial peer review, recommended applications will receive a second level of review by the 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.

Awarding institutes, centers, and offices may give priority to applications in the following areas:

National Institute on Minority Health and Health Disparities (NIMHD)

- Solutions-oriented research (observational to intervention-based) that addresses the clinical care of medically-underserved older adults
- Research focusing on digital literacy and medical decision-making, especially for complex health information
- Examining Artificial Intelligence and machine learning to analyze individual data (genetics, biomarkers, lifestyle) and develop personalized recommendations for disease prevention and management
- Examining delivery of evidence-based strategies and clinical guidelines in real-world community and public health settings
- Studies that include validated behavioral, clinical, or biomedical health outcomes and actionable endpoints with real-world implications

National Institute of Nursing Research (NINR)

- Research focused on the prevention and management of chronic diseases across the lifespan
- Solutions-focused research addressing care delivery across settings (e.g., hospital, home, clinic, primary care)
- Development, adaptation, implementation, or evaluation of artificial intelligence (AI) and machine learning (ML) approaches in clinical and home settings to improve individual health outcomes, prevent disease, and address system- and organizational-level challenges to optimize care
- Adaptation and implementation of evidence-based interventions and clinical guidelines across settings where nurses practice, including hospitals, homes, community settings, public health systems, and schools

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

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

3. Anticipated Announcement and Award Dates

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

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

Section VI. Award Administration Information

1. Award Notices

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

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

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

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

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

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

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

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

2. Administrative and National Policy Requirements

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

- The rules listed at [2 CFR Part 200](https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200) (<https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200>), Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.
- All NIH grant and cooperative agreement awards include the [NIH Grants Policy Statement](http://grants.nih.gov/grants/guide/redirect.htm?id=11120) (<http://grants.nih.gov/grants/guide/redirect.htm?id=11120>) as part of the terms and conditions in the Notice of Award (NoA). The NoA includes the requirements of this NOFO. For these terms of award, see the [NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General](https://grants.nih.gov/grants/policy/nihgps/HTML5/part_ii_terms_and_conditions_of_nih_grant_awards.htm) (https://grants.nih.gov/grants/policy/nihgps/HTML5/part_ii_terms_and_conditions_of_nih_grant_awards.htm) and [Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities](http://grants.nih.gov/grants/guide/redirect.htm?id=11159) (<http://grants.nih.gov/grants/guide/redirect.htm?id=11159>).

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

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

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

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

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

Successful recipients under this NOFO agree that:

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

- ongoing and consistent access to HHS owned or operated information or operational technology systems; and
- receive, maintain, transmit, store, access, exchange, process, or utilize personal identifiable information (PII) or personal health information (PHI) obtained from the awarding HHS agency for the purposes of executing the award.

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

- Develop cybersecurity plans and procedures, modeled after the [NIST Cybersecurity framework](https://www.nist.gov/cyberframework) (<https://www.nist.gov/cyberframework>), to protect HHS systems and data:
 - Identify:**
 - Develop an inventory of all assets and accounts with access to HHS owned and operated information or operational technology systems or which obtain PII or PHI for the purposes of the award.
 - Protect:**
 - Limit access to HHS owned and operated systems to only those in need of access to complete reward activities.

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

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

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

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

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

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

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

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Data Management and Sharing

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

4. Reporting

When multiple years are involved, recipients will be required to submit the [Research Performance Progress Report \(RPPR\) \(http://grants.nih.gov/grants/rppr/index.htm\)](http://grants.nih.gov/grants/rppr/index.htm) annually and financial statements as required in the [NIH Grants Policy Statement Section 8.4.1 Reporting \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.4.1_reporting.htm\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.4.1_reporting.htm). To learn more about post-award monitoring and reporting, see the NIH Grants & Funding website, see [Post-Award Monitoring and Reporting \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82428\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82428).

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 \(https://grants.nih.gov/grants/guide/notice-files/NOT-AG-23-017.html\)](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](#).

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 \(https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116\)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116), 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, 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.

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

and measure performance based on the details and outcomes that are shared within the RPPR, as described at 2 CFR Part 200.301.

Section VII. Agency Contacts

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

Application Submission Contacts

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

[Grants.gov Support Center \(https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fgrants.gov%2Fsupport&data=05%7C02%7Cantoine.caliman%40nih.gov%7Caf6dde64d644478d4e8b08dde6700581%7C14b77578977342d58507251ca2dc2b\)](https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fgrants.gov%2Fsupport&data=05%7C02%7Cantoine.caliman%40nih.gov%7Caf6dde64d644478d4e8b08dde6700581%7C14b77578977342d58507251ca2dc2b)

- Questions regarding Grants.gov registration and services (e.g., Workspace, subscriptions).

Scientific/Research Contact(s)

NIA Training

Email: NIATraining@mail.nih.gov (<mailto:niatraining@mail.nih.gov>)

National Institute of Dental and Craniofacial Research (NIDCR)

Email: NIDCR-Program@nih.gov (<mailto:NIDCR-Program@nih.gov>)

National Institute of Nursing Research (NINR)

Email: NINRProgram@mail.nih.gov (<mailto:NINRProgram@mail.nih.gov>)

National Institute on Minority Health and Health Disparities (NIMHD)

Phone: 301-402-1366

Email: NIMHDInfo@NIMHD.NIH.gov (<mailto:NIMHDInfo@NIMHD.NIH.gov>)

Peer Review Contact(s)

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

Financial/Grants Management Contact(s)

National Institute on Aging (NIA)

Email: NIA-NOFO-Grants@nih.gov (<mailto:NIA-NOFO-Grants@nih.gov>)

National Institute of Dental and Craniofacial Research (NIDCR)

Email: deeranotifications@nidcr.nih.gov (<mailto:deeranotifications@nidcr.nih.gov>)

National Institute of Nursing Research (NINR)

Email: NINRProgram@mail.nih.gov (<mailto:NINRProgram@mail.nih.gov>)

Section VIII. Other Information

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

Authority and Regulations

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