

**March 31, 2025**

This funding opportunity was updated to align with agency priorities. Carefully reread the full funding opportunity and make any needed adjustments to your application prior to submission.

## Department of Health and Human Services

### Part 1. Overview Information

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**Participating Organization(s)**

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

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**Components of Participating Organizations**

National Cancer Institute ([NCI \(https://www.cancer.gov/\)](https://www.cancer.gov/))

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**Funding Opportunity Title**

**Exploratory Grants in Cancer Control (R21 Clinical Trial Optional)**

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**Activity Code**

[R21 \(https://grants.nih.gov/grants/funding/ac\\_search\\_results.htm?text\\_curr=r21&Search.x=0&Search.y=0&Search\\_Type=Activity\)](https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r21&Search.x=0&Search.y=0&Search_Type=Activity)  
Exploratory/Developmental Research Grant

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**Announcement Type**

Reissue of [PAR-21-341 \(https://grants.nih.gov/grants/guide/pa-files/PAR-21-341.html\)](https://grants.nih.gov/grants/guide/pa-files/PAR-21-341.html)

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**Related Notices**

See [Notices of Special Interest \(https://grants.nih.gov/grants/guide/NOSIs\\_targetingList.cfm?GuideDocID=41799\)](https://grants.nih.gov/grants/guide/NOSIs_targetingList.cfm?GuideDocID=41799) associated with this funding opportunity

- **March 31, 2025** - This funding opportunity was updated to align with agency priorities. Carefully reread the full funding opportunity and make any needed adjustments to your application prior to submission.
- **April 4, 2024** - Overview of Grant Application and Review Changes for Due Dates on or after January 25, 2025. See Notice [NOT-OD-24-084 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-084.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-084.html).
- **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 \(https://grants.nih.gov/grants/guide/notice-files/not-od-22-198.html\)](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 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-189.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-189.html).

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**Funding Opportunity Number (FON)**

PA-25-253

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**Companion Funding Opportunity**

None

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**Number of Applications**

See [Section III. 3. Additional Information on Eligibility](#).

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**Assistance Listing Number(s)**

93.393, 93.399

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**Funding Opportunity Purpose**

Through this Notice of Funding Opportunity (NOFO), the National Cancer Institute (NCI) encourages the submission of exploratory/developmental research grant (R21) applications that focus on different aspects of cancer control by modifying behavior, screening, and understanding etiologic factors contributing to the development of cancer, and developing ways to control cancer. The overarching goal is to provide support to promote the early and conceptual stages of research efforts on novel scientific ideas that have the potential to substantially advance population-based cancer research, such as the development of novel techniques, agents, methodologies, models, or applications that could have a major impact on a field of cancer research (e.g. epidemiologic, biomedical, behavioral, health care delivery or clinical).

### Funding Opportunity Goal(s)

The overall goals of this NOFO are to reduce cancer risk, incidence, morbidity, and mortality and enhance quality of life in cancer survivors through an orderly sequence from research on interventions and their impact in defined populations to the broad, systematic application of the research results through dissemination and diffusion strategies.

## Key Dates

### Posted Date

November 08, 2024

### Open Date (Earliest Submission Date)

January 16, 2025

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

| Application Due Dates |  |  | Review and Award Cycles |                         |                     |
|-----------------------|--|--|-------------------------|-------------------------|---------------------|
| New                   | Renewal / Resubmission / Revision (as allowed) | AIDS - New/Renewal/Resubmission/Revision, as allowed | Scientific Merit Review | Advisory Council Review | Earliest Start Date |
| February 16, 2025 *   | March 16, 2025 *                               | May 07, 2025 *                                       | July 2025               | October 2025            | December 2025       |
| June 16, 2025 *       | July 16, 2025 *                                | September 07, 2025 *                                 | November 2025           | January 2026            | April 2026          |
| October 16, 2025 *    | November 16, 2025 *                            | January 07, 2026 *                                   | March 2026              | May 2026                | July 2026           |
| June 16, 2026 *       | July 16, 2026 *                                | September 07, 2026 *                                 | November 2026           | January 2027            | April 2027          |
| October 16, 2026 *    | November 16, 2026 *                            | January 07, 2027 *                                   | March 2027              | May 2027                | July 2027           |
| June 16, 2027 *       | July 16, 2027 *                                | September 07, 2027 *                                 | November 2027           | January 2028            | April 2028          |
| October 16, 2027 *    | November 16, 2027 *                            | January 07, 2028 *                                   | March 2028              | May 2028                | July 2028           |
| February 16, 2028 *   | March 16, 2028 *                               | May 07, 2028 *                                       | July 2028               | October 2028            | December 2028       |
| June 16, 2028 *       | July 16, 2028 *                                | September 07, 2028 *                                 | 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.

### Expiration Date

September 08, 2028

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**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 \(https://grants.nih.gov/grants/guide/uri\\_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/uri_redirect.php?id=82400), except where instructed to do otherwise (in this NOFO or in a Notice from [NIH Guide for Grants and Contracts \(https://grants.nih.gov/grants/guide/uri\\_redirect.php?id=11164\)](https://grants.nih.gov/grants/guide/uri_redirect.php?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 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 \(https://public.era.nih.gov/commons/\)](https://public.era.nih.gov/commons/) to track your application. Check with your institutional officials regarding availability.
3. Use [Grants.gov \(https://grants.gov/search-grants?oppStatuses=closed|archived|posted|forecasted&fon=PA-25-253\)](https://grants.gov/search-grants?oppStatuses=closed|archived|posted|forecasted&fon=PA-25-253) 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

#### Purpose

Through this notice of funding opportunity (NOFO), the National Cancer Institute (NCI) encourages the submission of exploratory/developmental research grant (R21) applications, which can be completed in 2 years, that focus on different aspects of cancer control by modifying behavior, screening, and understanding etiologic factors contributing to the development of cancer, and developing ways to control cancer. The overarching goal is to provide support to promote the early and conceptual stages of research efforts on novel scientific ideas that have the potential to substantially advance population-based cancer research, such as the development of novel techniques, agents, interventions, methodologies, models, or applications that could have a major impact on a field of cancer research (e.g. epidemiologic, biomedical, behavioral, health care delivery or clinical).

#### Background

The Division of Cancer Control and Population Sciences (DCCPS) has long enhanced NCI's ability to alleviate the burden of cancer through research in surveillance, epidemiology, health services, behavioral science, and cancer survivorship. This mission includes using different approaches to facilitate movement of discoveries in the basic sciences to studies in human populations and translate discoveries about the determinants of cancer incidence and cancer-related health outcomes into clinical and public health practice. Determinants of cancer occurrence and health outcomes include behavioral, environmental, infectious, medical, social, and cultural factors and life events and experiences that have a health impact, as well as genetic and other personal susceptibility factors. Health outcomes after cancer include survival, recurrence, second primary cancers, new or exacerbated health conditions, and patient morbidity, and quality of life.

Most cancers are multi-factorial in their etiology and require an understanding of how different risk factors modify and interact with each other. Translating paradigms and findings from basic biological, behavioral and social sciences into cancer control studies is critical and can be accomplished through a mechanism that supports high-risk, high-reward research endeavors. To initiate a project in population sciences and generate hypotheses, data from mechanistic studies, early-phase trials, and pilot studies are needed.

DCCPS supports research in the areas of cancer surveillance, psychological, social, and behavioral risk factors, health care delivery, and epidemiologic studies. Evidence generated by these studies has been useful in providing the basis for the design and testing of many preventive and therapeutic interventions and their integration into cancer care. Large biorepositories established by cancer epidemiology cohorts already support genetic and epigenetic studies as well as microbiome, proteomic, and metabolomic studies. Further, data from retrospective and prospective studies that include environmental, behavioral, and health services have provided the basis for hypothesis-driven testing of patient and health system factors that may provide information on etiology and improve outcomes. The data and biospecimens accumulated through these large-scale studies afford opportunities for investigators to examine the factors that lead to cancer and influence cancer outcomes, through smaller exploratory, high-risk/high-reward studies.

The exploratory grant mechanism (R21) provides 2 years of support to generate data so that larger studies can be planned. An R21 grant application should not have extensive background material or preliminary information. Extensive preliminary data demonstrating feasibility is an indication that the project is beyond the scope of this notice of funding opportunity (NOFO). This mechanism has been successfully used for developing novel approaches in different aspects of cancer control in population sciences.

## Scientific Research Objectives

Scientific emphasis in the reissuance of this NOFO reflects high-priority areas in cancer control in population sciences research. DCCPS has several broad areas of interest: development and validation of methods, technologies, and tools in surveillance, statistics, epidemiology, health care delivery, and the behavioral sciences; identification of modifiable risk factors or host susceptibility factors associated with cancer etiology, cancer prevention, and treatment outcomes; and clinical and translational science to reduce risk, incidence, and death from cancer, as well as enhance the quality of life for cancer survivors. DCCPS also has an interest in cross-cutting themes, such as geospatial approaches to cancer risk and outcome, early risk factors, health disparities, etc. Specific topics in each of these research areas represent examples of research that DCCPS supports and could be supported through this NOFO.

**Epidemiology and genomics research** focuses on population studies to understand determinants of cancer occurrence and outcomes and translating findings to clinical and public health interventions. This includes identifying personal susceptibility factors such as genetic, epigenetic, immunological, inflammation and hormonal biological pathways, and social, cultural, and race/ethnic factors; characterizing factors to reduce cancer risk in humans, including exposures to physical and chemical agents; social and behavioral built environments; nutritional components; physical activity and energy balance; and infectious agents. Research topics may include, but are not limited to, the following:

- Approaches to data harmonization for epidemiologic research;
- Methods, technologies, and approaches to detect biological, immunological, and metabolic; memory circuits for assessing cancer risk, causation, survival and prognosis;
- Development of tools for integrating multi-omics data in cancer epidemiology;
- Artificial Intelligence approaches in cancer epidemiology;
- Validation of measurements of exogenous exposures associated with the development of cancer in body fluids and tissues;
- Applying epigenetic and metabolomics approaches to cancer epidemiology;
- Understanding the population genetic architecture of cancer more broadly in diverse populations and in particular in understudied populations or in populations with cancer health disparities;
- Development of novel tools to capture clinically relevant patient-generated health data (e.g., wearable technologies and mobile apps); and
- Understanding the effects of cancer and its treatment on patient symptoms, functioning, and health outcomes.

**Behavioral research** addresses key psychosocial and behavioral targets across the cancer control continuum, from prevention to end-of-life care. Priorities include basic behavioral and psychosocial science, interventions in cancer control areas such as tobacco use, diet and energy balance, sun protection, and processes and effects of communication and informatics. Research topics may include, but are not limited to, the following:

- Identifying, assessing, and/or testing the effects of engaging novel interventional targets related to cancer-related risk behaviors based on basic behavioral science research;
- Designing early phase formative and experimental studies that identify treatment targets, define and refine interventional components, and describe optimal intervention characteristics (e.g., dosage, frequency, duration, and mode of delivery). The use of new frameworks for developing behavioral interventions based on basic behavioral research - such as the Obesity-Related Behavioral Intervention Trials (ORBIT) model for developing behavioral treatments for chronic diseases - are especially useful for providing a phased, systematic approach to developing innovative, new behavioral interventions for cancer-related behavioral risk factors.
- Multilevel interventions addressing complex health behaviors and the social determinants of health to advanced cancer care and reduce health disparities;
- Examining the design, implementation, and evaluation of behavioral studies delivered by connected health technologies (e.g., wearables, sensors, telemedicine, patient portals, mobile health);
- Evaluating multilevel communication processes among individuals and in public health practice, community settings, clinics, and health care systems to advance and improve cancer prevention and control;
- Integration of patient-level cognitive measurements across multiple studies of cancer-related cognitive impairments; and
- Development of new methods or tools to assess the contribution of interoception to behaviors that influence cancer risk.

**Health care delivery research** focuses on the study of cancer care, multilevel factors influencing care, and outcomes of care. Cancer care refers to medical services offered across the cancer continuum, such as screening individuals not known to have cancer; treating cancer

patients; following cancer survivors for recurrence or new cancers; and providing psychosocial support at the end of life for patients and their caregivers. Research topics may include, but are not limited to, the following:

- Using information technology to improve evidence-based screening, treatment, and survivorship care;
- Identifying optimal intervention delivery models, dosage, and timings;
- Developing strategies to enhance patient-centered care, shared decision-making, and patient-provider communication;
- Examining approaches to enhance the integration of palliative care through cancer treatment and beyond; and
- Research that explores strategies to enhance prognostic awareness, goals of care, and advanced care planning to optimize end-of-life care.

**Surveillance research** focuses on developing analytical tools and methodologies in collecting, interpreting, and disseminating population-based cancer statistics in the US. Cancer surveillance provides a quantitative portrait of cancer and its determinants in a defined population. Research topics may include, but are not limited to, the following:

- Development and validation of statistical methods in epidemiologic studies;
- Improving and validating methodologies to extract, collect, and synthesize clinical data via electronic medical records for use in observational studies of cancer patients and survivors; and
- Testing semantic tools to facilitate mapping and querying of cancer registry data with other linked data sources.

### Applications Not Responsive to this NOFO

The following types of studies are not responsive to this NOFO. Applications proposing such studies will be considered non-responsive and will not be reviewed.

Studies of basic science aspects of cancer biology, such as studies of the following:

- Basic cellular pathways, mechanisms, and oncogenic events that drive the development of tumors and behavior of cancer cells; and
- Development of in vivo or in vitro models of tumors, when the purpose is to interrogate basic oncogenic pathways or mechanisms.

Studies focusing on the development of novel diagnostics or therapies for cancer, such as studies of the following:

- Discovery, development, and evaluation of agents to treat cancer; chemotherapy, molecular targeted therapy, radiation therapy, gene therapy, biologics and immunotherapy;
- Development of innovative technologies and devices for cancer diagnosis;
- Development, evaluation, translation, and dissemination of the use of in vivo imaging or image-guided interventions to detect, diagnose, treat, and provide prognosis and follow-up for cancer; and
- Development of bioassays for the discovery and validation of cancer markers and their use in the clinic for defining prognosis and improving the prediction of response to therapy.

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

See [Section VIII. Other Information](#) for award authorities and regulations.

## Section II. Award Information

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### Funding Instrument

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

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### Application Types Allowed

New  
Resubmission

The [OER Glossary \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=11116\)](https://grants.nih.gov/grants/guide/url_redirect.php?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.

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### 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? \(https://grants.nih.gov/grants/guide/url\\_redirect.php?id=82370\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82370)

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### Funds Available and Anticipated Number of Awards

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

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### Award Budget

The combined budget for direct costs for the two-year project period may not exceed \$275,000. No more than \$200,000 may be requested in a single year.

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### Award Project Period

The maximum project period is 2 years.

NIH grants policies as described in the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=11120\)](https://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

##### 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 \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=11118\)](https://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 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 \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=82423\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82423) for additional information.

- [System for Award Management \(SAM\) – \(https://grants.nih.gov/grants/guide/url\\_redirect.php?id=82390\)](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 \(//grants.nih.gov/grants/guide/uri\\_redirect.php?id=11176\)](https://grants.nih.gov/grants/guide/uri_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 \(https://grants.nih.gov/grants/guide/uri\\_redirect.php?id=11123\)](https://grants.nih.gov/grants/guide/uri_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 \(//grants.nih.gov/grants/guide/uri\\_redirect.php?id=82300\)](https://grants.nih.gov/grants/guide/uri_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.

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

## 2. Cost Sharing

This NOFO does not require cost sharing as defined in the [NIH Grants Policy Statement Section 1.2 Definition of Terms \(//grants.nih.gov/grants/guide/uri\\_redirect.php?id=11126\)](https://grants.nih.gov/grants/guide/uri_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 \(//grants.nih.gov/grants/guide/uri\\_redirect.php?id=82415\)](https://grants.nih.gov/grants/guide/uri_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 \(//grants.nih.gov/grants/guide/uri\\_redirect.php?id=82423\)](https://grants.nih.gov/grants/guide/uri_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 \(https://grants.nih.gov/grants/guide/uri\\_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/uri_redirect.php?id=82400) except where instructed in this notice of funding opportunity to do otherwise. 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 \(https://grants.nih.gov/grants/guide/uri\\_redirect.php?id=61134\)](https://grants.nih.gov/grants/guide/uri_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 \(https://grants.nih.gov/grants/how-to-apply-application-guide.html\)](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 \(https://grants.nih.gov/grants/guide/uri\\_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/uri_redirect.php?id=82400) must be followed.

#### SF424(R&R) Project/Performance Site Locations

All instructions in the How to Apply- Application Guide must be followed.

### **SF424(R&R) Other Project Information**

All instructions in the How to Apply- Application Guide must be followed.

### **SF424(R&R) Senior/Key Person Profile**

All instructions in the How to Apply- Application Guide must be followed.

### **R&R or Modular Budget**

All instructions in the How to Apply- Application Guide must be followed.

### **R&R Subaward Budget**

All instructions in the How to Apply-Application Guide must be followed.

### **PHS 398 Cover Page Supplement**

All instructions in the How to Apply- Application Guide must be followed.

### **PHS 398 Research Plan**

All instructions in the How to Apply- Application Guide must be followed, with the following additional instructions:

**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.

#### **Other Plan(s):**

All instructions in the How to Apply-Application Guide 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.

**Appendix:** Only limited Appendix materials are allowed. Follow all instructions for the Appendix as described in the How to Apply- Application Guide.

- 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, 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 must be followed.

#### **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 must be followed.

### **PHS Assignment Request Form**

All instructions in the How to Apply- Application Guide must be followed.

### **Foreign Organizations**

Foreign (non-U.S.) organizations must follow policies described in the [NIH Grants Policy Statement \(https://grants.nih.gov/grants/guide/uri\\_redirect.php?id=11137\)](https://grants.nih.gov/grants/guide/uri_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 \(https://grants.nih.gov/grants/guide/uri\\_redirect.php?id=82380\)](https://grants.nih.gov/grants/guide/uri_redirect.php?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to [Grants.gov \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=11128\)](https://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 \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=11123\)](https://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 \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=82423\)](https://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.

## 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 \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=11120\)](https://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 \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=11143\)](https://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. 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 \(https://grants.nih.gov/grants/guide/url\\_redirect.php?id=82400\)](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 \(https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm\)](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.

See [more tips \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=11146\)](https://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 (CSR) and responsiveness by NCI. Applications that are incomplete, or non-compliant, and/or nonresponsive will not be reviewed.

## Mandatory Disclosure

Recipients or subrecipients must submit any information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. See Mandatory Disclosures, [2 CFR 200.113 \(https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-B/section-200.113\)](https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-B/section-200.113) and [NIH Grants Policy Statement Section 4.1.35 \(https://grants.nih.gov/grants/policy/nihgps/html5/section\\_4/4.1.35\\_mandatory\\_disclosures.htm\)](https://grants.nih.gov/grants/policy/nihgps/html5/section_4/4.1.35_mandatory_disclosures.htm).

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

## Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in [the policy \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=82299\)](https://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 \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=11149\)](https://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: The R21 exploratory/developmental grant supports investigation of novel scientific ideas or new model systems, tools, or technologies that have the potential for significant impact on biomedical or biobehavioral research. An R21 grant application need not have extensive background material or preliminary information. Accordingly, reviewers will emphasize the conceptual framework, the level of innovation, and the potential to significantly advance our knowledge or understanding. Appropriate justification for the proposed work can be provided through literature citations, data from other sources, or, when available, from investigator-generated data. Preliminary data are not required for R21 applications; however, they may be included if available.

## 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 sample is appropriate and sufficiently diverse to address the proposed question(s).
- 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 \(https://grants.nih.gov/grants/guide/uri\\_redirect.php?id=11175\)](https://grants.nih.gov/grants/guide/uri_redirect.php?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 \(https://grants.nih.gov/grants/guide/uri\\_redirect.php?id=11150\)](https://grants.nih.gov/grants/guide/uri_redirect.php?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.

Not applicable

**Revisions**

Not applicable

**Additional Review Considerations**

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

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

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

**Budget and Period of Support**

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

**2. Review and Selection Process**

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by the Center for Scientific Review, in accordance with [NIH peer review policy and procedures \(https://grants.nih.gov/grants/guide/uri\\_redirect.php?id=11154\)](https://grants.nih.gov/grants/guide/uri_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.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this NOFO. Following initial peer review,

recommended applications will receive a second level of review by the National Cancer Advisory Board. The following will be considered in making funding decisions:

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

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the [NIH Grants Policy Statement Section 2.5.1. Just-in-Time Procedures \(//grants.nih.gov/grants/guide/uri\\_redirect.php?id=82418\)](https://grants.nih.gov/grants/guide/uri_redirect.php?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 \(//grants.nih.gov/grants/guide/uri\\_redirect.php?id=11123\)](https://grants.nih.gov/grants/guide/uri_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 \(//grants.nih.gov/grants/guide/uri\\_redirect.php?id=82416\)](https://grants.nih.gov/grants/guide/uri_redirect.php?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) ([https://grants.nih.gov/grants/policy/hs/data\\_safety.htm](https://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 \(//grants.nih.gov/grants/guide/uri\\_redirect.php?id=11120\)](https://grants.nih.gov/grants/guide/uri_redirect.php?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/guide/url_redirect.php?id=11120) ([//grants.nih.gov/grants/guide/url\\_redirect.php?id=11120](https://grants.nih.gov/grants/guide/url_redirect.php?id=11120)) and [Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities](https://grants.nih.gov/grants/guide/url_redirect.php?id=11159) ([//grants.nih.gov/grants/guide/url\\_redirect.php?id=11159](https://grants.nih.gov/grants/guide/url_redirect.php?id=11159)).

- 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) (<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) (<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.

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](https://grants.nih.gov/grants/policy/nihgps/html5/section_4/4_public_policy_requirements_objectives_and_other_appropriation_mandates.htm)).

Recipients are responsible for ensuring that their activities comply with all applicable federal regulations. NIH may terminate awards under certain circumstances. See [2 CFR Part 200.340 Termination](https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-D/subject-group-ECFR86b76dde0e1e9dc/section-200.340) (<https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-D/subject-group-ECFR86b76dde0e1e9dc/section-200.340>) and [NIH Grants Policy Statement Section 8.5.2 Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support](https://grants.nih.gov/grants/policy/nihgps/html5/section_8/8.5.2_remedies_for_noncompliance_or_enforcement_actions_suspension_termination_and_withholding_of_support.htm) ([https://grants.nih.gov/grants/policy/nihgps/html5/section\\_8/8.5.2\\_remedies\\_for\\_noncompliance\\_or\\_enforcement\\_actions\\_suspension\\_termination\\_and\\_withholding\\_of\\_support.htm](https://grants.nih.gov/grants/policy/nihgps/html5/section_8/8.5.2_remedies_for_noncompliance_or_enforcement_actions_suspension_termination_and_withholding_of_support.htm)).

Successful recipients under this NOFO agree that:

Where the award funding involves implementing, acquiring, or upgrading health IT for activities by any funded entity, recipients and subrecipient(s) are required to: Use health IT that meets standards and implementation specifications adopted in 45 CFR part 170, Subpart B, if such standards and implementation specifications can support the activity. Visit <https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-B> (<https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-B>) to learn more.

Where the award funding involves implementing, acquiring, or upgrading health IT for activities by eligible clinicians in ambulatory settings, or hospitals, eligible under Sections 4101, 4102, and 4201 of the HITECH Act, use health IT certified under the ONC Health IT Certification Program if certified technology can support the activity. Visit <https://www.healthit.gov/topic/certification-ehrs/certification-health-it> (<https://www.healthit.gov/topic/certification-ehrs/certification-health-it>) to learn more.

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:

1. ongoing and consistent access to HHS owned or operated information or operational technology systems; and
2. 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.

Recipients shall develop 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. Please refer to [NIH Post-Award Monitoring and Reporting](https://grants.nih.gov/grants/post-award-monitoring-and-reporting.htm) (<https://grants.nih.gov/grants/post-award-monitoring-and-reporting.htm>) for additional information.

## 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) ([https://grants.nih.gov/grants/policy/nihgps/html5/section\\_8/8.2.3\\_sharing\\_research\\_resources.htm#Data](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 \(RPPR\)](https://grants.nih.gov/grants/rppr/index.htm) ([//grants.nih.gov/grants/rppr/index.htm](https://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](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](https://grants.nih.gov/grants/guide/url_redirect.php?id=82428)).

A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the [NIH Grants Policy Statement Section 8.6 Closeout](https://grants.nih.gov/grants/guide/url_redirect.php?id=82420) ([//grants.nih.gov/grants/guide/url\\_redirect.php?id=82420](https://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.

## 5. Evaluation

Enter text here.

## 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) (<mailto:GrantsInfo@nih.gov>) (preferred method of contact)

Telephone: 301-480-7075

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) (<mailto:support@grants.gov>)

### Scientific/Research Contact(s)

**Mukesh Verma, Ph.D.**

National Cancer Institute (NCI)

Telephone: 240-276-6889

Email: [vermam@mail.nih.gov](mailto:vermam@mail.nih.gov) (<mailto:vermam@mail.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)

**Dawn Mitchum**

National Cancer Institute (NCI)

Telephone: 240-276-5699

Email: [dawn.mitchum@nih.gov](mailto:dawn.mitchum@nih.gov) (<mailto:dawn.mitchum@nih.gov>)

## Section VIII. Other Information

Recently issued trans-NIH [policy notices](https://grants.nih.gov/grants/guide/url_redirect.php?id=11163) ([https://grants.nih.gov/grants/guide/url\\_redirect.php?id=11163](https://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](https://grants.nih.gov/grants/guide/url_redirect.php?id=11164) ([https://grants.nih.gov/grants/guide/url\\_redirect.php?id=11164](https://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](https://grants.nih.gov/grants/guide/url_redirect.php?id=11120) ([https://grants.nih.gov/grants/guide/url\\_redirect.php?id=11120](https://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.

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[Weekly TOC for this Announcement](https://grants.nih.gov/grants/guide/WeeklyIndex.cfm?11-08-24) (<https://grants.nih.gov/grants/guide/WeeklyIndex.cfm?11-08-24>)

[NIH Funding Opportunities and Notices](https://grants.nih.gov/grants/guide/index.html) (<https://grants.nih.gov/grants/guide/index.html>)

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