

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 of Allergy and Infectious Diseases ([NIAID \(https://www.niaid.nih.gov/\)](https://www.niaid.nih.gov/))

Funding Opportunity Title

Understanding Mechanisms and Outcomes of Trained Immunity (R21 Clinical Trial Not Allowed)

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)
Exploratory/Developmental Research Grant

Announcement Type

New

Related Notices

- **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).

Funding Opportunity Number (FON)

PAR-24-111

Companion Funding Opportunity

[PAR-24-112 \(https://grants.nih.gov/grants/guide/pa-files/PAR-24-112.html\)](https://grants.nih.gov/grants/guide/pa-files/PAR-24-112.html), R01
(https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=R01&&Search.x=0&&Search.y=0&&Search_Type=Activity)
Research Project

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)

93.855

Funding Opportunity Purpose

The purpose of this Notice of Funding Opportunity (NOFO) is to support research that improves understanding of basic mechanisms and biomarkers of trained immunity (*i.e.*, innate immune memory), plus the functional implications of trained immunity, related to 1) immune system development and function, 2) immunity to vaccines or natural infections, or 3) allergic diseases, autoimmunity, or rejection of organ/tissue/cell transplantation.

Key Dates

Posted Date

January 25, 2024

Open Date (Earliest Submission Date)

May 16, 2024

Letter of Intent Due Date(s)

30 days prior to the application due date

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
June 16, 2024 *	Not Applicable	Not Applicable	November 2024	January 2025	April 2025
October 16, 2024 *	Not Applicable	Not Applicable	March 2025	May 2025	July 2025
June 16, 2025 *	Not Applicable	Not Applicable	November 2025	January 2026	April 2026
October 16, 2025 *	Not Applicable	Not Applicable	March 2026	May 2026	July 2026
June 16, 2026 *	Not Applicable	Not Applicable	November 2026	January 2027	April 2027
October 16, 2026 *	Not Applicable	Not Applicable	March 2027	May 2027	July 2027

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

January 08, 2027

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 ([/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=PAR-24-111) (<https://grants.gov/search-grants?oppStatuses=closed|archived|posted|forecasted&fon=PAR-24-111>) 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.

Table of Contents

[Part 1. Overview Information](#)

[Key Dates](#)

[Part 2. Full Text of Announcement](#)

[Section I. Notice of Funding Opportunity Description](#)

[Section II. Award Information](#)

[Section III. Eligibility Information](#)

[Section IV. Application and Submission Information](#)

[Section V. Application Review Information](#)

[Section VI. Award Administration Information](#)

[Section VII. Agency Contacts](#)

[Section VIII. Other Information](#)

Part 2. Full Text of Announcement

Section I. Notice of Funding Opportunity Description

Background

While immunological memory is an integral feature of the immune system, it has traditionally been viewed as a unique aspect of adaptive immunity in which T cells and B cells remember specific antigens associated with pathogens or vaccines that have been encountered in the past. The idea of immune memory in the innate arm of the immune system, however, is a relatively recent concept within mammalian immunology. The term “trained immunity” refers to a nonspecific form of immune memory in innate immune cells in which an initial exposure to a pathogen, commensal, or vaccine “trains” innate immune cells so that their response to a variety of subsequent immune challenges differs from that of their naïve counterparts.

In support of this observation, investigators have identified epigenetic and metabolic changes that occur in innate immune cells following antigenic exposure and are preserved in daughter cells. A full mechanistic description of how exposure to immune training agents leads to epigenetic changes remains to be determined, as do functional characterizations of duration and plasticity of trained immunity phenotypes. Furthermore, the characteristics and mechanisms of trained immunity are likely distinct for different training agents. While trained immunity effects were originally described for myeloid-derived innate immune cells (*i.e.*, macrophages, neutrophils, and dendritic cells), recent findings demonstrate trained immunity in lymphoid derived innate immune cells, such as Natural Killer cells and Innate Lymphoid Cells.

Additional observations of non-specific forms of immune memory have existed for decades – predating the current concept of trained immunity. *Post-hoc* analyses of various vaccine trials and campaigns in countries with high rates of child mortality have shown that the administration of some vaccines caused a decrease in all-cause child mortality beyond what would be expected for protection against the vaccine-targeted disease alone. The biological mechanisms underlying these observations have yet to be uncovered and recent clinical trials directly testing the heterologous protection offered by vaccines such as BCG and MMR have failed to recapitulate the epidemiological

observations. Further research into the basic immunological features and mechanisms underlying heterologous immunity is needed to advance this field. At present, the concept of trained immunity offers the most compelling explanation for how heterologous immunity could be broadly induced by vaccines or infections; however, there is still much to be uncovered.

While the concept of trained immunity holds much promise for improving human health, many questions must be answered before it can be properly harnessed. An improved understanding of the molecular and cellular mechanisms, biomarkers, and functional significance of trained immunity is needed to advance understanding and future applications of this field.

Research Objectives and Scope

This Notice of Funding Opportunity (NOFO) solicits research projects that explore fundamental aspects of trained immunity. Such projects must align with NIAID's mission to advance knowledge of immune system development and function, and better understand, treat, and prevent infectious and immune-mediated (*i.e.*, allergic, autoimmune, cell/tissue/organ transplant rejection) diseases. Areas of high priority include, but are not limited to, the following:

- Identification of novel biomarkers associated with trained immunity induced by vaccines, vaccine adjuvants, and/or infectious pathogens
- Basic studies of trained immunity in immune-mediated diseases
- Elucidation of molecular and cellular mechanisms responsible for innate immune memory
- Characterization of the functional implications of trained immunity, including impact on adaptive immune responses and/or disease outcomes
- Determination of the duration and/or plasticity of trained immunity effects

Because basic characterizations of trained immunity are currently lacking, descriptive studies seeking to define immune signatures and phenotypes associated with trained immunity are allowed for applications submitted to this funding opportunity.

Applications Not Responsive to this NOFO

Applications that propose to conduct research in the following areas will be considered non-responsive and will not be reviewed:

- Studies of antigen-specific forms of immune memory (*i.e.*, adaptive immunity) in the absence of a connection to trained immunity.
- Projects focusing on applications of trained immunity without aims that improve understanding of basic aspects of trained immunity (*i.e.*, applications without novel characterizations of molecular mechanisms or biomarkers associated with trained immunity).
- Studies of innate immune memory in non-mammalian model systems without plans for how research findings will be translated to advance understanding of mammalian immunology.
- Applications proposing studies on HIV/AIDS
- Applications proposing clinical trials (all phases)

This NOFO is soliciting R21 applications that will support shorter term (up to two years) developmental/exploratory research activities, whereas the companion R01 ([PAR-24-112 \(https://grants.nih.gov/grants/guide/pa-files/PAR-24-112.html\)](https://grants.nih.gov/grants/guide/pa-files/PAR-24-112.html)) will support more developed (up to 5 years) applications.

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

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 SF424 (R&R) Application Guide provide details on these application types. Only those application types listed here are allowed for this NOFO.

Clinical Trial?

Not Allowed: Only accepting applications that do not propose clinical trials.

[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)

Funds Available and Anticipated Number of Awards

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

Award Budget

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 any single year.

Award Project Period

The total project period may not exceed 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

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

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

Nonprofits Other Than Institutions of Higher Education

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

For-Profit Organizations

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

Local Governments

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

Federal Governments

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

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations
- Non-domestic (non-U.S.) Entities (Foreign Organizations)

Foreign Organizations

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

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

Foreign components, as defined in the NIH Grants Policy Statement ([//grants.nih.gov/grants/guide/url_redirect.php?id=11118](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 SF 424 (R&R) 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 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) Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
 - NATO Commercial and Government Entity (NCAGE) Code ([//grants.nih.gov/grants/guide/url_redirect.php?id=11176](https://grants.nih.gov/grants/guide/url_redirect.php?id=11176)) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
 - Unique Entity Identifier (UEI) - A UEI is issued as part of the SAM.gov registration process. The same UEI must be used for all registrations, as well as on the grant application.
- eRA Commons (https://grants.nih.gov/grants/guide/url_redirect.php?id=11123) - Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their Grants.gov registrations; all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov ([//grants.nih.gov/grants/guide/url_redirect.php?id=82300](https://grants.nih.gov/grants/guide/url_redirect.php?id=82300)) – Applicants must have an active SAM registration in order to complete the Grants.gov registration.

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

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with their organization to develop an application for support. Individuals from diverse backgrounds, including underrepresented racial and ethnic groups, individuals with disabilities, and women are always encouraged to apply for NIH support. See, Reminder: Notice of NIH's Encouragement of Applications Supporting Individuals from Underrepresented Ethnic and Racial Groups as well as Individuals with Disabilities, (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-019.html>) NOT-OD-22-019 (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-019.html>).

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF424 (R&R) Application Guide.

2. Cost Sharing

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

3. Additional Information on Eligibility

Number of Applications

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

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

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.

- An application that has substantial overlap with another application pending appeal of initial peer review (see [NIH Grants Policy Statement 2.3.9.4 Similar, Essentially Identical, or Identical Applications](#) (https://grants.nih.gov/grants/guide/url_redirect.php?id=82423)).

Section IV. Application and Submission Information

1. Requesting an Application Package

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

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the Research (R) Instructions in the [How to Apply - Application Guide](#) (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400), except where instructed in this notice of funding opportunity to do otherwise. Conformance to the requirements in the 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/guide/url_redirect.php?id=82400) and the [Table of Page Limits](#) (https://grants.nih.gov/grants/guide/url_redirect.php?id=61134) must be followed.

Instructions for Application Submission

The following section supplements the instructions found in the [How to Apply – Application Guide](#) (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) and should be used for preparing an application to this NOFO.

SF424(R&R) Cover

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Project/Performance Site Locations

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Other Project Information

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Senior/Key Person Profile

All instructions in the SF424 (R&R) Application Guide must be followed.

R&R or Modular Budget

All instructions in the SF424 (R&R) Application Guide must be followed.

R&R Subaward Budget

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Cover Page Supplement

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Research Plan

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Research Strategy:

For all applications, explain the knowledge gaps to be filled, and how the proposed studies will advance understanding of trained immunity or its functional impact on adaptive immunity or other host processes.

Highlight the innovation within the studies as applied to trained immunity and its functional consequences on health and/or disease.

For applications that propose descriptive studies, explain why descriptive studies are needed.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide.

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

All instructions in the SF424 (R&R) 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 SF424 (R&R) 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 SF424 (R&R) 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 SF424 (R&R) Application Guide must be followed.

Delayed Onset Study

Note: Delayed onset (<https://grants.nih.gov/grants/glossary.htm#DelayedOnsetStudy>) does NOT apply to a study that can be described but will not start immediately (i.e., delayed start). All instructions in the SF424 (R&R) Application Guide must be followed.

PHS Assignment Request Form

All instructions in the SF424 (R&R) 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/url_redirect.php?id=11137), and procedures for foreign organizations described throughout the SF424 (R&R) Application Guide.

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

See Part 1. 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. Overview Information contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or Federal holiday (https://grants.nih.gov/grants/guide/url_redirect.php?id=82380), the application deadline is automatically extended to the next business day.

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

5. Intergovernmental Review (E.O. 12372)

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

6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url_redirect.php?id=11120\)](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 SF424 (R&R) 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 SF424 (R&R) 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 and responsiveness by NIAID, NIH. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

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

Scored Review Criteria

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

Significance

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

Specific to this NOFO: How effectively will the proposed studies advance our knowledge of trained immunity or its functional impact on adaptive immunity or other host processes?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance, and organizational structure appropriate for the project?

Innovation

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

Specific to this NOFO: How novel are the proposed studies as applied to trained immunity and its functional consequences on health and/or disease?

Approach

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

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

Environment

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

Additional Review Criteria

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

Protections for Human Subjects

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

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

Study Timeline

Inclusion of Women, Minorities, and Individuals Across the Lifespan

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of individuals of all ages (including children and older adults) to determine if it is justified in terms of the scientific goals and research

strategy proposed. For additional information on review of the Inclusion section, please refer to the [Guidelines for the Review of Inclusion in Clinical Research \(//grants.nih.gov/grants/guide/url_redirect.php?id=11174\)](https://grants.nih.gov/grants/guide/redirect.php?id=11174).

Vertebrate Animals

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

Biohazards

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

Resubmissions

Not Applicable

Renewals

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.

Applications from Foreign Organizations

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

Select Agent Research

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

Resource Sharing Plans

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

Authentication of Key Biological and/or Chemical Resources

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

Budget and Period of Support

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

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by the Center for Scientific Review, in accordance with [NIH peer review policies and practices \(//grants.nih.gov/grants/guide/redirect.php?id=11154\)](https://grants.nih.gov/grants/guide/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. Following initial peer review, recommended applications will receive a second level of review by the appropriate national Advisory Council or Board. The following will be considered in making funding decisions:

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

3. Anticipated Announcement and Award Dates

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

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

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the [NIH Grants Policy Statement](https://grants.nih.gov/grants/guide/url_redirect.php?id=82418) ([//grants.nih.gov/grants/guide/url_redirect.php?id=82418](https://grants.nih.gov/grants/guide/url_redirect.php?id=82418)).

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

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

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

Institutional Review Board or Independent Ethics Committee Approval: Recipient institutions must ensure that 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.

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the [NIH Grants Policy Statement](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)) as part of the NoA. For these terms of award, see the [NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General](https://grants.nih.gov/grants/guide/url_redirect.php?id=11157) ([//grants.nih.gov/grants/guide/url_redirect.php?id=11157](https://grants.nih.gov/grants/guide/url_redirect.php?id=11157)) and [Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities](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)), including of note, but not limited to:

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

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

If a recipient receives an award, the recipient must follow all applicable nondiscrimination laws. The recipient agrees to this when registering in SAM.gov. The recipient must also submit an Assurance of Compliance (HHS-690 (<https://www.hhs.gov/sites/default/files/form-hhs690.pdf>)). To learn more, see the [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.

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIS) requirements. FAPIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIS, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 2 CFR Part 200.206 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships.

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Data Management and Sharing

Consistent with the 2023 NIH Policy for Data Management and Sharing, when data management and sharing is applicable to the award, recipients will be required to adhere to the Data Management and Sharing requirements as outlined in the [NIH Grants Policy Statement \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2.3_sharing_research_resources.htm#Data\)](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 \(RPPR\) \(https://grants.nih.gov/grants/rppr/index.htm\)](https://grants.nih.gov/grants/rppr/index.htm) annually and financial statements as required in the [NIH Grants Policy Statement \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82419\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82419).

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 \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82420\)](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.

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

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

Section VII. Agency Contacts

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

Application Submission Contacts

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

Finding Help Online: <https://www.era.nih.gov/need-help> (<https://www.era.nih.gov/need-help>) (preferred method of contact)

Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

General Grants Information (Questions regarding application instructions, application processes, and NIH grant resources)

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

Telephone: 301-637-3015

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)

Contact Center Telephone: 800-518-4726

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

Scientific/Research Contact(s)

Ari Joffe, Ph.D.

National Institute of Allergy and Infectious Diseases (NIAID)

Telephone: 240-669-5084

Email: ari.joffe@nih.gov (<mailto:ari.joffe@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)

Tamia Powell

National Institute of Allergy and Infectious Diseases (NIAID)

Telephone: 240-669-2982

Email: tamia.powell@nih.gov (<mailto:tamia.powell@nih.gov>)

Section VIII. Other Information

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

[Weekly TOC for this Announcement](https://grants/guide/WeeklyIndex.cfm?01-26-24) ([/grants/guide/WeeklyIndex.cfm?01-26-24](https://grants/guide/WeeklyIndex.cfm?01-26-24))

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



National Institutes of Health ([/grants/oer.htm](https://grants/oer.htm))
Office of Extramural Research



(<http://www.hhs.gov/>) Department of Health
and Human Services (HHS)



(<http://www.usa.gov/>)

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Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see [Help Downloading Files](https://grants/edocs.htm) ([/grants/edocs.htm](https://grants/edocs.htm)).



Improve Understanding of Mechanisms, Biomarkers of Trained Immunity

Funding News Edition: **February 21, 2024**

See more articles in this edition

If your research project explores fundamental aspects of trained immunity, consider applying to either of the following notices of funding opportunities (NOFOs):

- [Understanding Mechanisms and Outcomes of Trained Immunity \(R01, Clinical Trial Not Allowed\) !\[\]\(0f48f43ebd21f231a458c96216dbf4d1_img.jpg\)](#)
- [Understanding Mechanisms and Outcomes of Trained Immunity \(R21, Clinical Trial Not Allowed\) !\[\]\(ba0878532603d6e0b20c60ffb7475d12_img.jpg\)](#)

The purpose of these NOFOs is to support research that improves understanding of basic mechanisms and biomarkers of trained immunity (i.e., innate immune memory), plus the functional implications of trained immunity, related to 1) immune system development and function, 2) immunity to vaccines or natural infections, or 3) allergic diseases, autoimmunity, or rejection of organ/tissue/cell transplantation.

Objectives

Your research project must align with NIAID's mission to advance knowledge of immune system development and function, and better understand, treat, and prevent infectious and immune-mediated diseases.

High-priority areas include:

- Identifying novel biomarkers associated with trained immunity induced by vaccines, vaccine adjuvants, or infectious pathogens.
- Basic studies of trained immunity in immune-mediated diseases.
- Elucidating molecular and cellular mechanisms responsible for innate immune memory.
- Characterizing the functional implications of trained immunity, including impact on adaptive immune responses and/or disease outcomes.
- Determining the duration or plasticity of trained immunity effects.

Since basic characterizations of trained immunity are currently lacking, we also invite descriptive studies seeking to define immune signatures and phenotypes associated with trained immunity.

Note that we will consider applications that propose to conduct research in the following areas to be nonresponsive and not review them:

- Studies of antigen-specific forms of immune memory (i.e., adaptive immunity) in the absence of a connection to trained immunity.
- Projects focusing on applications of trained immunity without aims that improve understanding of basic aspects of trained immunity (i.e., applications without novel characterizations of molecular mechanisms or biomarkers associated with trained immunity).
- Studies of innate immune memory in non-mammalian model systems without plans for how research findings will be translated to advance understanding of mammalian immunology.
- Applications proposing studies on HIV/AIDS.
- Applications proposing clinical trials (all phases).

In choosing between the R01 and R21 NOFOs, know that the R21 is designed for shorter term developmental/exploratory research activities whereas R01 applications should be more developed – providing preliminary data, including observational data, to support hypotheses or justify descriptive studies.

R01 Award and Budget Information

Application budgets are not limited but need to reflect the actual needs of the proposed project. The scope of the proposed project should determine the project period. The maximum project period is 5 years.

If you will request \$500,000 or more in direct costs in any one year, you must request prior approval from our scientific/research contact (listed below) at least 6 weeks before submitting the application. Refer to Big Grants for additional guidance.

Applications for the R01 NOFO are due twice annually through 2026, on June 5 or October 5, at 5 p.m. local time of the applicant organization.

R21 Award and Budget Information

For the R21 NOFO, your total project period may not exceed 2 years. The combined budget for direct costs for the 2-year project period may not exceed \$275,000. No more than \$200,000 may be requested in any single year.



Applications for the R21 NOFO are also due twice annually through 2026, on June 16 or October 16, at 5 p.m. local time of the applicant organization.

Direct inquiries for both the R01 and R21 NOFOs to Dr. Ari Joffe, NIAID's scientific/research contact, at ari.joffe@nih.gov or 240-669-5084.

Contact Us

Email us at deaweb@niaid.nih.gov for help navigating NIAID's grant and contract policies and procedures.

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Content last reviewed on February 21, 2024

ขั้นตอนการสมัครขอรับทุน National Institute of Health (NIH)

1. ผู้สมัครจะต้องแจ้งความประสงค์และนำส่งข้อมูลเข้ามายังกองบริหารงานวิจัย ภายในกำหนดเวลาแจ้งความประสงค์การจัดส่งข้อเสนอในหนังสือประชาสัมพันธ์ โดยนำส่งข้อมูลทางอีเมล chittiporn.nua@mahidol.edu เพื่อขอเปิดบัญชี eRA commons และขอสร้างข้อเสนอโครงการในระบบออนไลน์ ASSIST ของแหล่งทุน NIH โดยแจ้งข้อมูลดังนี้

Name: Surname:

Email (XXXX@mahidol.ac.th หรือ XXXX@mahidol.edu):

Funding Opportunity Announcement (FOA) Number:

Application title:

Application due date:

2. ผู้สมัครขอรับทุนศึกษาประกาศทุน (Funding opportunity announcements หรือ FOA) อย่างละเอียด ตรวจสอบกำหนดการส่งข้อเสนอของมหาวิทยาลัย และสืบค้นข้อมูลที่เกี่ยวข้องกับงานวิจัยของตนเองผ่าน NIH RePORTER <https://reporter.nih.gov>
3. มหาวิทยาลัยสร้างบัญชี eRA commons และสร้างข้อเสนอโครงการในระบบ ASSIST ให้ผู้สมัครขอรับทุน ผู้ขอรับทุนจัดทำข้อเสนอโครงการและเอกสารที่เกี่ยวข้องตามข้อกำหนดของแหล่งทุนร่วมกับมหาวิทยาลัย
4. ผู้สมัครขอรับทุนนำส่งเอกสารข้อเสนอโครงการฉบับสมบูรณ์ผ่านหัวหน้าส่วนงานเพื่อขออนุมัติจัดส่งข้อเสนอโครงการผ่านระบบออนไลน์ ASSIST ตามกำหนดรับข้อเสนอของมหาวิทยาลัย** กองบริหารงานวิจัยตรวจสอบข้อเสนอโครงการ เสนออนุมัตินำส่งข้อเสนอโครงการและจัดส่งข้อเสนอโครงการในนามของมหาวิทยาลัยไปยังแหล่งทุน

(*หากผู้สมัครขอรับทุนนำส่งข้อเสนอโครงการให้กองบริหารงานวิจัยตรวจสอบล่าช้ากว่ากำหนดของมหาวิทยาลัย มหาวิทยาลัยขอสงวนสิทธิ์ในการรับข้อเสนอโครงการเพื่อนำส่งแหล่งทุนในรอบนั้นๆ)

01

- Find your FOA and Application due date

- Search NIH RePORTER

02

- Create your eRA commons ID

- Initiate Application in ASSIST

03

- Application preparing

- Letter of support

04

- Validate Application

- Submission

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หน่วยสนับสนุนการขอทุนวิจัยจากแหล่งทุนต่างประเทศ

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