



งานบริหารและส่งเสริมการวิจัย
กองบริหารงานวิจัย มหาวิทยาลัยมหิดล
โทร. 02-849-6252 โทรสาร. 02-849-6247

ที่ อว 78.016/ ๐๐๘๒

วันที่ ๑๑ ตุลาคม 2565

เรื่อง ประชาสัมพันธ์การเปิดรับข้อเสนอโครงการจากแหล่งทุน National Institutes of Health (NIH) ประเภท Research Project – Cooperative Agreements หัวข้อ “Maintaining Immunity after Immunization (U01 Clinical Trial Not Allowed)” หมายเลขประกาศทุน RFA-AI-22-055

สิ่งที่ส่งมาด้วย 1. รายละเอียดประกาศทุน RFA-AI-22-055
2. ขั้นตอนการสมัครขอรับทุน

เรียน คณบดี / ผู้อำนวยการ

ด้วยแหล่งทุน National Institutes of Health (NIH) ประเภท Research Project – Cooperative Agreements หัวข้อ “Maintaining Immunity after Immunization (U01 Clinical Trial Not Allowed)” หมายเลขประกาศทุน RFA-AI-22-055 โดยเปิดรับข้อเสนอโครงการตั้งแต่วันที่ 13 ธันวาคม 2565 จนถึงวันที่ 13 มกราคม 2566 เวลา 17.00 น. ตามเวลาประเทศไทย ทั้งนี้ โครงการที่เสนอขอทุนให้ปฏิบัติตามประกาศมหาวิทยาลัยมหิดล เรื่องหลักเกณฑ์และอัตราเงินค่าธรรมเนียมพัฒนาการวิจัยของมหาวิทยาลัยและส่วนงานที่จัดเก็บจากโครงการวิจัยที่ได้รับเงินอุดหนุนจากแหล่งทุนภายนอกมหาวิทยาลัย พ.ศ. 2560 และขอให้ดำเนินการตามที่ระบุในหนังสือชักชวนแนวปฏิบัติ เรื่องมาตรฐานการวิจัยของโครงการวิจัย รายละเอียดดังเอกสารแนบมาด้วยนี้ ทั้งนี้ อาจารย์/นักวิจัยที่สนใจสามารถศึกษารายละเอียดเพิ่มเติมได้ตามเอกสารที่แนบมาด้วยนี้ หรือเว็บไซต์ของแหล่งทุนที่ <https://grants.nih.gov/grants/guide/rfa-files/RFA-AI-22-055.html>

ในการนี้ กองบริหารงานวิจัย มหาวิทยาลัยมหิดล จึงขอแจ้งข่าวประกาศทุนมายังท่าน เพื่อโปรดประชาสัมพันธ์ทุนวิจัยดังกล่าวให้บุคลากรในหน่วยงานของท่านทราบโดยทั่วกัน และขอให้อาจารย์/นักวิจัยโปรดแจ้งความประสงค์การจัดส่งข้อเสนอ ภายในวันที่ 13 ธันวาคม 2565 และจัดส่งข้อเสนอโครงการวิจัยผ่านส่วนงานต้นสังกัดมายังกองบริหารงานวิจัยเพื่อตรวจสอบรายละเอียดข้อเสนอโครงการฉบับสมบูรณ์ภายในวันที่ 6 มกราคม 2566 ทั้งนี้ หากส่วนงานแจ้งความประสงค์การจัดส่งข้อเสนอโครงการวิจัยหลังจากวันที่ 13 ธันวาคม 2565 มหาวิทยาลัยขอสงวนสิทธิ์ในการยื่นข้อเสนอโครงการวิจัยเพื่อขอรับทุนดังกล่าว

จึงเรียนมาเพื่อโปรดทราบและประชาสัมพันธ์ข่าวทุนวิจัยดังกล่าวต่อไปด้วย จักขอบคุณยิ่ง

(ศาสตราจารย์ ดร. นายแพทย์ ภัทรชัย กิรติสิน)

รองอธิการบดีฝ่ายวิจัย

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

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

Components of Participating Organizations

National Institute of Allergy and Infectious Diseases (<https://www.niaid.nih.gov/>)

Funding Opportunity Title

Maintaining Immunity after Immunization (U01 Clinical Trial Not Allowed)

Activity Code

[U01 \(http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=u01&Search.x=0&Search.y=0&Search_Type=Activity\)](http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=u01&Search.x=0&Search.y=0&Search_Type=Activity) Research Project – Cooperative Agreements

Announcement Type

Reissue of [RFA-AI-17-034 \(https://grants.nih.gov/grants/guide/rfa-files/RFA-AI-17-034.html\)](https://grants.nih.gov/grants/guide/rfa-files/RFA-AI-17-034.html).

Related Notices

[NOT-OD-22-190 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-190.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-190.html) - Adjustments to NIH and AHRQ Grant Application Due Dates Between September 22 and September 30, 2022

Funding Opportunity Announcement (FOA) Number

RFA-AI-22-055

Companion Funding Opportunity

None

Number of Applications

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

Assistance Listing Number(s)

93.855

Funding Opportunity Purpose

The goal of this Funding Opportunity Announcement (FOA) is to promote research to improve our understanding of how vaccines against infectious agents lead to durable protective immunity. This initiative will support studies that define components and mechanisms of the immune system that determine such durability. Applications must propose the use of human cells/tissues to decipher the human response elicited through vaccination. Animal studies also may be included to elucidate mechanistic pathways not easily accomplished with human samples.

Key Dates

Posted Date

August 22, 2022

Open Date (Earliest Submission Date)

December 13, 2022

Letter of Intent Due Date(s)

30 days prior to the application due date

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS	Scientific Merit Review	Advisory Council Review	Earliest Start Date

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS	Scientific Merit Review	Advisory Council Review	Earliest Start Date
January 13, 2023	January 13, 2023	Not Applicable	July 2023	October 2023	December 2023

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 14, 2023

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 [SF424 \(R&R\) Application Guide \(https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400), except where instructed to do otherwise (in this FOA or in a Notice from [NIH Guide for Grants and Contracts \(https://grants.nih.gov/grants/guide/uri_redirect.htm?id=11164\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=11164)).

Conformance to all requirements (both in the Application Guide and the FOA) 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 \(http://public.era.nih.gov/commons/\)](http://public.era.nih.gov/commons/) to track your application. Check with your institutional officials regarding availability.
3. Use [Grants.gov \(https://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=RFA-AI-22-055\)](https://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=RFA-AI-22-055) 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. Funding Opportunity Description

Purpose

The purpose of this Funding Opportunity Announcement (FOA) is to support individual single-project cooperative agreements that undertake research to identify the requirements for induction and maintenance of durable protective immunity following vaccination against infectious agents. Applications are sought that propose to (1) define the immune mechanisms and components that lead to sustained immunity, and/or (2) identify common versus distinct durable immune mechanisms triggered by vaccines compared to natural infection. Findings from this research will contribute to a more complete understanding of the requirements for vaccine-induced durable protection.

Projects supported under this program will define and characterize the components of the immune response that are stimulated and how these components interact to induce an effective, durable immune response, such as that seen in vaccines against hepatitis B, varicella, or yellow fever, for example. Identification of determinants of *protective* durable immunity relies on long-term efficacy or challenge studies. This FOA will support analyses of human samples from such studies in addition to the studies mentioned above, which focus on durable immunogenicity.

Background

While vaccines against infectious diseases have saved countless lives and improved the overall health of the global population, many vaccines require multiple boosts to induce protective immunity, and this immunity often does not persist over long time periods. The recent COVID-19 pandemic has highlighted the importance of this issue. While the historically rapid development and distribution of the SARS-CoV-2 vaccines have been a public health success, the waning of immunity after vaccination and the need for additional booster vaccinations have complicated immunization efforts. Waning immunity after SARS-CoV-2 vaccination is not unique. Another example of waning immunity became evident with the transition from the whole cell pertussis vaccine (wP) to the acellular vaccine (aP) leading to the resurgence of *Bordetella pertussis* infection among adolescents. Recent studies have indicated that the aP vaccine resulted in a less persistent immune response and induced mainly Th2 immune responses, while the wP vaccine induced mainly Th1 and Th17 responses. Importantly, individuals naturally infected with *Bordetella pertussis* developed life-long immunity to re-infection. These observations suggest that comparative analysis of immunity to some natural infections versus those triggered by vaccination may identify immune parameters regulating the induction of durable protective immunity. In the case of *Salmonella typhi* vaccines, the live attenuated vaccine provides a longer duration of protection (5 years) than the polysaccharide vaccine (2 years). However, the relatively short duration of protection of both vaccines creates practical difficulties in maintaining immunity in endemic regions. Recent studies have indicated that a balance between effector memory T cells and regulatory T cells may be essential for a more durable response to the *S. typhi* vaccine.

Although these examples illustrate waning immunity in response to immunization, many vaccines produce long-lasting and perhaps life-long immunity. In addition to the wP vaccine mentioned above, attenuated vaccines against smallpox and yellow fever viruses produce a persistent, high quality immune response. Over the last fifteen years, studies of the immune response to the YF-17D yellow fever vaccine have indicated that it activates multiple dendritic cell subsets through a diverse array of Toll-like receptors. This combination of receptors induces a set of proinflammatory cytokines that affect the Th1/Th2 helper cell balance and provides a strong stimulus for CD8 T cell memory. All of these immune elements act together to produce a durable immune response. These findings illustrate how understanding the complex interaction of immune system components that are triggered by effective vaccines may lead to elucidating the key components of durable immunity. A comparison of the immune mechanisms triggered by these vaccines with those that induce less durable responses may lead to strategies for developing safer, more effective vaccines.

In the last four years of the Maintaining Immunity after Immunization program, investigators have made important progress on understanding how certain components of the immune response are engaged and activated after vaccination and infection. For example, to generate a protective memory response to influenza vaccination, studies have shown that both naive and memory human B cells need to enter vaccine-induced germinal-center structures in lymph nodes. This new finding suggests that both types of cells may be needed to generate humoral memory from vaccination. In a mouse model of malaria, B cells, rather than dendritic cells, were shown to be the predominant mechanism for antigen-driven T helper cell activation and thus for durable responses. In another study, the T cells produced after vaccination against early SARS-CoV-2 variants were found to be cross reactive against the Omicron and other SARS-CoV-2 variants, indicating that the T cell component of cellular immunity may be a critical factor in determining durable immunity to this vaccine.

NIAID also has supported several programs to characterize the immune response to vaccination, such as the [Human Immunology Project Consortium \(https://grants.nih.gov/grants/guide/rfa-files/RFA-AI-20-079.html\)](https://grants.nih.gov/grants/guide/rfa-files/RFA-AI-20-079.html), the [Cooperative Centers on Human Immunology \(https://grants.nih.gov/grants/guide/rfa-files/rfa-ai-17-040.html#:~:text=The%20Cooperative%20Centers%20on%20Human%20Immunology%20\(CCHI\)%20program%20was%20initiated,in%20the%20area%20of%20biodefense,\)](https://grants.nih.gov/grants/guide/rfa-files/rfa-ai-17-040.html#:~:text=The%20Cooperative%20Centers%20on%20Human%20Immunology%20(CCHI)%20program%20was%20initiated,in%20the%20area%20of%20biodefense,), and [Protective Immunity in Special Populations \(https://sam.gov/opp/ffd13619ac28958005e978b95d00c10/view\)](https://sam.gov/opp/ffd13619ac28958005e978b95d00c10/view); and [adjunct science programs that seek to boost the immune response to vaccination through discovery/development of novel targeted adjuvants, such as the Adjuvant Discovery Program \(https://sam.gov/opp/c53907364d7a0fc881d7f82f84475cab/view\)](https://sam.gov/opp/c53907364d7a0fc881d7f82f84475cab/view), the [Adjuvant Development Program \(https://sam.gov/opp/a2a72d93698c43f5a00d69da478c484a/view\)](https://sam.gov/opp/a2a72d93698c43f5a00d69da478c484a/view), and the [Molecular Mechanisms of Combination Adjuvants Program \(https://grants.nih.gov/grants/guide/notice-files/NOT-AI-20-047.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-AI-20-047.html). Together, these programs have yielded important new discoveries about the immune response to different adjuvants and vaccines. Data generated by these programs are available through the [ImmPort \(http://www.immport.org/\)](http://www.immport.org/) database supported by DAIT. With this reissue, the Maintaining Immunity after Immunization program seeks to extend upon this work and continue to identify the immune components/pathways needed to elicit and sustain a protective immune response following vaccination.

Specific Areas of Research Interest

While many of the components of the immune response triggered by vaccination are known, those immune components needed to *sustain* a protective immune response are not fully understood. This FOA invites applications to define the immune mechanisms mediating durable immunity from vaccination. Since the main objective of this initiative is to identify the factors governing the induction and maintenance of durable immunity in humans, applicants must use human cells and/or tissues, such as those that can be obtained from human subjects given licensed vaccines, or samples from independently supported clinical trials, (e.g., challenge studies, or clinical trials of vaccine candidates). The variability of the human immune response should be considered, especially as it relates to immunocompromised or underrepresented populations. Animal studies also may be included to extend observations in humans or for mechanistic studies that cannot be conducted easily in humans, including pathogen challenge studies to elucidate durable protective immune mechanisms induced by vaccines. Studies involving live vertebrate animals are required to comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals ([Policy \(https://olaw.nih.gov/sites/default/files/PHSPolicyLabAnimals.pdf\)](https://olaw.nih.gov/sites/default/files/PHSPolicyLabAnimals.pdf)), and with all applicable provisions of the [Animal Welfare Act \(http://www.nal.usda.gov/awic/legislat/awa.htm\)](http://www.nal.usda.gov/awic/legislat/awa.htm) and other Federal statutes and regulations relating to animals. Applicants awarded under this FOA will be required to submit their data to [ImmPort \(http://www.immport.org/\)](http://www.immport.org/) or another publicly available data repository identified by NIAID.

Areas of research interest include, but are not limited to:

- Identification of the molecular components of innate and adaptive immune responses, such as immune receptors, metabolic changes, epigenetic modifications, or signaling molecules that must be activated to maintain durable protective immunity.
- Understanding of the crosstalk between components of innate and adaptive immunity leading to the induction/maintenance of durable immunity.
- Comparison of immune mechanisms/components that lead to protective immunity and are differentially elicited by natural infection versus by vaccination.
- Characterization of immune mechanisms that contribute to reduction in durable immunity after vaccination in immunocompromised individuals (e.g., transplant recipients, individuals with autoimmune disorders).
- Determination of the impact of race, ethnicity or other factors that could be related to genetic determinants of durable immunity to vaccination.
- Elucidation of the role of "trained" innate immunity as an initiator of durable protective immunity.
- Understanding the effect of external factors (e.g., nutrition, circadian rhythm, age) on durable protective immunity, and the components of immune activation that are affected by these factors.
- Understanding the mechanisms regulating localization of immune cell types to tissues or organs, and how these mechanisms affect the formation of durable protective immunity, for example, the determination of the role of mucosal immune elements in durable immunity.
- Determination of the effect of boosting (vaccines or natural infection/exposure) on maintenance/evolution of durable protective immune responses.
- Comparison of the immune mechanisms that are engaged by vaccines that induce durable immunity versus those that induce short-term protective immunity.

The following research areas are non-responsive and applications proposing such studies will **not** be reviewed:

- Projects that examine the efficacy of vaccine or adjuvant formulation without focusing on immune mechanisms triggered by these vaccines or adjuvants.
- Studies on AIDS, HIV, cancer, or SIV.
- Studies to perform clinical trials; however, studies proposing the use of human samples collected from independently funded clinical trials are responsive and will be reviewed.
- Projects that focus on vaccine and/or vaccine technology development.
- Projects that only study the immune response to infection, outside the context of vaccination.
- Projects that focus on adjuvant discovery and/or adjuvant development.
- Projects that do not propose the use of human cells and/or tissues.

Note: Renewal applications may not propose clinical trials, nor can they use funds from this FOA, if awarded, to continue ongoing clinical trials from the previous award.

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

Section II. Award Information

Funding Instrument

Cooperative Agreement: A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, NIH scientific or program staff will assist, guide, coordinate, or participate in project activities. See Section VI.2 for additional information about the substantial involvement for this FOA.

Application Types Allowed

New
Renewal

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

Clinical Trial?

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

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

Funds Available and Anticipated Number of Awards

NIAID intends to commit \$4.8 M in FY 2024 to fund 5-8 awards.

Award Budget

Application budgets are not expected to exceed \$450,000 in direct costs per year, and should reflect the actual needs of the project.

Award Project Period

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

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

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 Government

- 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 Institutions)

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **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 \(//grants.nih.gov/grants/guide/redirect.htm?id=11118\)](https://grants.nih.gov/grants/guide/redirect.htm?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. The [NIH Policy on Late Submission of Grant Applications \(//grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html) states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- **System for Award Management (SAM)**– (<https://grants.nih.gov/grants/guide/redirect.htm?id=82390>) Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
 - [NATO Commercial and Government Entity \(NCAGE\) Code \(//grants.nih.gov/grants/guide/redirect.htm?id=11176\)](https://grants.nih.gov/grants/guide/redirect.htm?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 \(https://grants.nih.gov/grants/guide/redirect.htm?id=11123\)](https://grants.nih.gov/grants/guide/redirect.htm?id=11123) - Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their full SAM and 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 \(//grants.nih.gov/grants/guide/redirect.htm?id=82300\)](https://grants.nih.gov/grants/guide/redirect.htm?id=82300) – Applicants must have an active SAM registration in order to complete the Grants.gov registration.

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

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

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 FOA does not require cost sharing as defined in the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/redirect.htm?id=11126\)](https://grants.nih.gov/grants/guide/redirect.htm?id=11126)

3. Additional Information on Eligibility

Number of Applications

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

The NIH will not accept duplicate or highly overlapping applications under review at the same time, per [2.3.7.4 Submission of Resubmission Application \(https://grants.nih.gov/grants/policy/nihgps/html5/section_2/2.3.7_policies_affecting_applications.htm#Submissi\)](https://grants.nih.gov/grants/policy/nihgps/html5/section_2/2.3.7_policies_affecting_applications.htm#Submissi). 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 [2.3.9.4 Similar, Essentially Identical, or Identical Applications \(https://grants.nih.gov/grants/policy/nihgps/html5/section_2/2.3.9_application_receipt_information_and_deadlines.htm#Similar\)](https://grants.nih.gov/grants/policy/nihgps/html5/section_2/2.3.9_application_receipt_information_and_deadlines.htm#Similar).)

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 FOA. 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 [SF424 \(R&R\) Application Guide \(https://grants.nih.gov/grants/guide/redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/redirect.htm?id=82400) except where instructed in this funding opportunity announcement 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.

Letter of Intent

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

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

- Descriptive title of proposed activity

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

The letter of intent should be sent to:

James T. Snyder, Ph.D.

Telephone: 240-669-5060

Email: James.Snyder@nih.gov (<mailto:James.Snyder@nih.gov>)

Page Limitations

All page limitations described in the SF424 Application Guide and the [Table of Page Limits \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11133\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11133) must be followed.

Instructions for Application Submission

The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this FOA.

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

, with the following additional instructions:

Applicants should budget sufficient funds for travel to Rockville, MD for (a) a kickoff meeting with NIH and other awardees shortly after awards are made, and (b) an annual program progress meeting with the NIH and other awardees thereafter. Anticipate a 2-day meeting and 2-night stay for the PD/PI and up to 3 key personnel. In the budget justification section, provide a justification for the travel funds needed to attend these meetings.

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: Summarize the scientific problem being addressed and how the proposed research fulfills the purpose and objectives of this FOA. Include the following:

- Describe the expected gain in fundamental knowledge of immune mechanisms that prolong immunity. Describe how findings from the proposed research will lead to a clearer understanding of the requirements for inducing and maintaining durable protective immunity.
- Provide a plan for data management and quality control within the proposed study. Describe data collection procedures, quality control methods, data curation and methods for data deposition.
- Describe the feasibility of the proposed approach; describe access to proposed human samples/biospecimens and/or non-commercial or unique reagents needed to conduct the studies.
- Timelines should address the time needed to acquire samples from independently funded clinical research or clinical trials.
- If the proposed approach uses an animal model, applicants must include a justification for the use of the proposed animal model with respect to how it will be used to determine immune mechanisms, identify correlates of protection, or test for prolonged protective immunity, as they apply to the human immune system.

Letter of Support: For projects obtaining samples from independently-funded clinical trials, include a letter of collaboration/support from the clinical trial director agreeing to provide samples according to the timeline established by the applicant.

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.

The following modifications also apply:

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.
- All investigators funded under this FOA will be expected to share their data publicly through [ImmPort \(http://www.immport.org/\)](http://www.immport.org/) or other public portals approved by NIAID. Therefore, the Data Sharing plan should include a summary of how the applicant will manage data submission and interactions with [ImmPort \(http://www.immport.org/\)](http://www.immport.org/).

Appendix:

Only limited Appendix materials are allowed. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide

, with the following additional instructions:

Copies of the informed consent form(s) or draft informed consent form(s) for any proposed additional independent studies, if different from those of the parent clinical trial(s), must also be included.

It is also recommended that the following items be clarified in the consent form or draft informed consent form(s): (1) additional blood or tissue that will be collected as part of the proposed study; (2) the right of the subjects to refuse to participate in the proposed study and still participate in the parent clinical trial; (3) that no charges to the subject for participation in the proposed study are incurred; and (4) agreement to share the subject's de-identified data obtained from the proposed study as well as the parent trial. Any incentives provided to subjects to participate in the proposed study, if in addition to those under the parent clinical trial, should be clearly described and justified; (5) indication that the samples can be used for third party analyses and proposed immune studies.

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 \(https://grants.nih.gov/grants/glossary.htm#DelayedOnsetStudy\)](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 Institutions

Foreign (non-U.S.) institutions must follow policies described in the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11137\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11137), and procedures for foreign institutions 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 \(https://grants.nih.gov/grants/guide/url_redirect.html?id=82380\)](#), the application deadline is automatically extended to the next business day.

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

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 SF424 (R&R) 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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11120\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

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

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the 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 \(https://grants.nih.gov/grants/how-to-apply-application-guide.html\)](https://grants.nih.gov/grants/how-to-apply-application-guide.html). 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 FOA 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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11146\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11146) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review 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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=82299\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82299). Any instructions provided here are in addition to the instructions in the policy.

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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11149\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11149) are evaluated for scientific and technical merit through the NIH peer review system.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following 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 FOA:

Are the mechanism(s) or component(s) being studied within the proposed project important for induction and maintenance of durable protective immunity?

Will this project provide new insight into the immune mechanisms that are needed for induction and maintenance of durable protective immunity?

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?

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?

Specific to this FOA:

Is the experimental plan adequate and feasible to determine whether the putative immune component(s) or mechanism(s) is/are essential to maintain durable protective immunity to infection following vaccination and/or natural infection?

Are the sources, consent forms, procedures, collection, documentation, and use of all human samples/biospecimens clearly described, and are all the logistics and feasibility issues addressed and adequately justified?

Are the descriptions of project feasibility adequate? Are the plans for data management for the proposed study described and feasible?

Do the plans adequately describe data collection procedures, quality control methods, data curation and methods for data deposition?

For projects involving animal models, is the animal model justified in terms of its relevance to human responses?

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.

Specific to this FOA:

In those studies using identifiable human biospecimens collected from independently funded clinical research or clinical trials, are the timeline and documentation necessary to successfully obtain the samples and implement the proposed project(s) adequately addressed?

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 \(https://grants.nih.gov/grants/guide/redirect.htm?id=11175\)](https://grants.nih.gov/grants/guide/redirect.htm?id=11175).

Inclusion of Women, Minorities, and Individuals Across the Lifespan

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

determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the [Guidelines for the Review of Inclusion in Clinical Research \(//grants.nih.gov/grants/guide/redirect.htm?id=11174\)](https://grants.nih.gov/grants/guide/redirect.htm?id=11174).

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment 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. Reviewers will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals. For additional information on review of the Vertebrate Animals section, please refer to the [Worksheet for Review of the Vertebrate Animals Section \(//grants.nih.gov/grants/guide/redirect.htm?id=11150\)](https://grants.nih.gov/grants/guide/redirect.htm?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

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

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 following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: (1) [Data Sharing Plan \(//grants.nih.gov/grants/guide/redirect.htm?id=11151\)](https://grants.nih.gov/grants/guide/redirect.htm?id=11151); (2) [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); and (3) [Genomic Data Sharing Plan \(GDS\) \(https://sharing.nih.gov/genomic-data-sharing-policy\)](https://sharing.nih.gov/genomic-data-sharing-policy).

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 National Institute of Allergy and Infectious Diseases, in accordance with [NIH peer review policy and procedures \(//grants.nih.gov/grants/guide/redirect.htm?id=11154\)](https://grants.nih.gov/grants/guide/redirect.htm?id=11154), using the stated [review criteria \(file:///C:/Users/mckenziene/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/13V4QPZR/Research%20Draft.doc# 1. Criteria\)](file:///C:/Users/mckenziene/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/13V4QPZR/Research%20Draft.doc# 1. Criteria). Assignment to a Scientific Review Group will be shown in the eRA Commons.

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

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

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

Applications will be assigned to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review by the National Advisory Allergy and Infectious Diseases Council. 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 \(https://grants.nih.gov/grants/guide/redirect.htm?id=11123\)](https://grants.nih.gov/grants/guide/redirect.htm?id=11123). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

Information regarding the disposition of applications is available in the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/redirect.htm?id=11120\)](https://grants.nih.gov/grants/guide/redirect.htm?id=11120).

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 \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.5.1_just-in-time_procedures.htm\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.5.1_just-in-time_procedures.htm).

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.5. 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 FOA 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 \(https://grants.nih.gov/grants/guide/uri_redirect.htm?id=11120\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?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 \(https://grants.nih.gov/grants/guide/uri_redirect.htm?id=11157\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?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 \(https://grants.nih.gov/grants/guide/uri_redirect.htm?id=11159\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=11159), including of note, but not limited to:

- [Federalwide Research Terms and Conditions \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section_3/3.1_federalwide_standard_terms_and_conditions_for_research_grants.htm\)](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 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-041.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-041.html)
- [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.

Should the applicant organization successfully compete for an award, recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identify, sexual orientation, and pregnancy). This includes ensuring programs are accessible to persons with limited English proficiency and persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please see <https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html> (<https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html>) and <https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html> (<https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html>).

HHS recognizes that 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 FOA.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals see <https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html> (<https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html>) and <https://www.lep.gov> (<https://www.lep.gov>).
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including reasonable accommodations and making services accessible to them, see <http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html> (<http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html>).
- HHS funded health and education programs must be administered in an environment free of sexual harassment, see <https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html> (<https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html>). For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see <https://grants.nih.gov/grants/policy/harassment.htm> (<https://grants.nih.gov/grants/policy/harassment.htm>).
- For guidance on administering programs in compliance with applicable federal conscience protection and associated anti-discrimination laws see <https://www.hhs.gov/conscience/conscience-protections/index.html> (<https://www.hhs.gov/conscience/conscience-protections/index.html>) and <https://www.hhs.gov/conscience/religious-freedom/index.html> (<https://www.hhs.gov/conscience/religious-freedom/index.html>).

Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at <https://www.hhs.gov/ocr/about-us/contact-us/index.html> (<https://www.hhs.gov/ocr/about-us/contact-us/index.html>) or call 1-800-368-1019 or TDD 1-800-537-7697.

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 45 CFR Part 75.205 and 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

The following special terms of the award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Part 75 and 2 CFR Part 200, and other HHS, PHS, and NIH grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial NIH programmatic involvement with the recipients is anticipated during the performance of the activities. Under the cooperative agreement, the NIH's purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility reside with the recipients for the project as a whole, although specific tasks and activities may be shared among the recipients and the NIH as defined below.

The PD(s)/PI(s) will have the primary responsibility for:

- Ensure data from individual projects are made publicly available, following the timeline, data set definitions, and procedures negotiated at the time of Award and included as a Term and Condition of Award, as appropriate and consistent with achieving the goals of the program. Data set definitions will be negotiated with NIH as part of the data-sharing plan for the program.
- Share reagents and resources with other investigators funded under this FOA as appropriate and consistent with achieving the goals of the program.
- Share all data generated under this FOA publicly through ImmPort or other public portals designated by NIH as appropriate. Data submission and release plans will be negotiated prior to award. The PD/PI will establish procedures within the project to ensure that all members of the program support and conform to the data-sharing and other resource-sharing plans. The final versions of NIH-approved sharing plans will become a Term and Condition of the award.
- Recipients will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and NIH policies.

NIH staff have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

- The role of the NIAID/NIH Project Scientist in the cooperative agreement is to support and encourage the recipient's activities by substantial involvement as a partner and facilitator in the process without assuming responsibilities that remain with the PDs/Pis. The NIAID Project Scientist will work closely with the PD/PI and other Program member scientists to facilitate collaborations and to leverage the resources available to the Program.
- The NIAID Project Scientist will monitor the progress of the recipients, help coordinate research approaches among all Programs funded through the FOA, and contribute to the shaping of research projects or approaches as warranted. The Project Scientist will support and facilitate this process but will not direct it.
- An NIAID Program Officer will be assigned to each award and will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice. The Project Scientist may also serve as a Program Officer.

Areas of Joint Responsibility include:

- Prior to award, annual milestones for the entire project period will be requested from all projects being considered for funding. These milestones will be negotiated with the NIAID Program Officer and updated annually. Subsequent annual funding will depend on progress in meeting these milestones.

Dispute Resolution:

Any disagreements that may arise in scientific or programmatic matters (within the scope of the award) between award recipients and the NIH may be brought to Dispute Resolution. A Dispute Resolution Panel composed of three members will be convened. It will have three members: a designee of the Steering Committee chosen without NIH staff voting, one NIH designee, and a third designee with expertise in the relevant area who is chosen by the other two; in the case of individual disagreement, the first member may be chosen by the individual recipient. This special dispute resolution procedure does not alter the recipient's right to appeal an adverse action that is otherwise appealable in accordance with PHS regulation 42 CFR Part 50, Subpart D and DHHS regulation 45 CFR Part 16.

3. 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/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).

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/policy/nihgps/HTML5/section_8/8.6_closeout.htm) (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.6_closeout.htm). NIH FOAs 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 45 CFR Part 75.301 and 2 CFR Part 200.301.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), 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.fsr.gov (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11170) on all subawards over \$25,000. See the [NIH Grants Policy Statement](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1.8_federal_funding_accountability_and_transparency_act_ffata.htm) (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1.8_federal_funding_accountability_and_transparency_act_ffata.htm) for additional information on this reporting requirement.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, 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 45 CFR Part 75 – Award Term and Conditions 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: <http://grants.nih.gov/support/> (<http://grants.nih.gov/support/>) (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)

Conrad Mallia, Ph.D.

National Institute of Allergy and Infectious Diseases (NIAID)

Telephone: 240-627-3491

Email: cmallia@niaid.nih.gov (<mailto:cmallia@niaid.nih.gov>)

Peer Review Contact(s)

James T. Snyder, Ph.D.
National Institute of Allergy and Infectious Diseases (NIAID)
Telephone: 240-669-5060
Email: James.Snyder@nih.gov (<mailto:James.Snyder@nih.gov>)

Financial/Grants Management Contact(s)

Fabiola Chacon
National Institute of Allergy and Infectious Diseases (NIAID)
Telephone: (301) 761-7938
Email: fabiola.chacon@nih.gov (<mailto:fabiola.chacon@nih.gov>)

Section VIII. Other Information

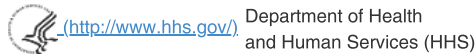
Recently issued trans-NIH [policy notices](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11163) (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11163) may affect your application submission. A full list of policy notices published by NIH is provided in the [NIH Guide for Grants and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

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 2 CFR 200, 42 CFR Part 52 and 45 CFR Part 75.

[Weekly TOC for this Announcement](https://grants.nih.gov/grants/guide/WeeklyIndex.cfm?08-26-22) (<https://grants.nih.gov/grants/guide/WeeklyIndex.cfm?08-26-22>)

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

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 and

04

- Validate Application
- Submission

สอบถามข้อมูลเพิ่มเติม คุณจิตติพร 02-8496252 chittiporn.nua@mahidol.edu

หน่วยสนับสนุนการขอทุนวิจัยจากแหล่งทุนต่างประเทศ

Mahidol University: Supporting Unit for International Research Funding (MU: SURF)