

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 \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=82474\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82474))

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

Funding Opportunity Title
Accelerating Research and Development of Next Generation Vaccines against Malaria - a Model for Mosquito-Borne Diseases (R61/R33 Clinical Trial Not Allowed)

Activity Code
[R61 \(http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r61&Search.x=0&Search.y=0&Search_Type=Activity\)](http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r61&Search.x=0&Search.y=0&Search_Type=Activity)[/R33 \(http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r33&Search.x=0&Search.y=0&Search_Type=Activity\)](http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r33&Search.x=0&Search.y=0&Search_Type=Activity) Exploratory/Developmental Phased Award

Announcement Type
New

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

Funding Opportunity Number (FON)
RFA-AI-28-024

Companion Funding Opportunity
None

Number of Applications
Only one application per institution is allowed, as defined in Part 2, 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 and/or preclinical development of highly efficacious vaccines against malaria - one of the deadliest mosquito-borne diseases - by capitalizing on recent technological innovations, particularly in structure-based immunogen design, improved formulations, and combination vaccines. The goal is to achieve long-lasting, highly effective protection that can save lives, strengthen public health security in the United States, and serve as a model for, or are potentially effective against, other mosquito-borne diseases.

Funding Opportunity Goal(s)
To assist public and private nonprofit institutions and individuals to establish, expand and improve biomedical research and research training in infectious diseases and related areas; to conduct developmental research; to produce and test research materials. To assist public, private and commercial institutions to conduct developmental research, to produce and test research materials, to provide research services as required by the agency for programs in infectious diseases, and controlling disease caused by infectious or parasitic agents, allergic and immunologic diseases and related areas. Projects range from studies of microbial physiology and antigenic structure to collaborative trials of experimental drugs and vaccines, mechanisms of resistance to antibiotics as well as research dealing with epidemiological observations in hospitalized patients or community populations and progress in allergic and immunologic diseases. Because of this dual focus, the program encompasses both basic research and clinical research.

Key Dates

Posted Date
October 13, 2026

Open Date (Earliest Submission Date)
January 11, 2027

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS - New/Renewal/Resubmission/Revision, as allowed	Scientific Merit Review	Advisory Council Review	Earliest Start Date
February 11, 2027	Not Applicable	Not Applicable	July 2027	October 2027	December 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.

Due Dates for E.O. 12372
Not Applicable

Expiration Date
February 12, 2027

Required Application Instructions

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

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

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

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

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

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

Mosquito-borne illnesses remain a major public health concern in the United States and worldwide. Malaria causes the greatest number of deaths globally and poses a significant risk for U.S. citizens abroad. The two first-generation malaria vaccines only offer partial, short-term protection in reducing disease in children over five months of age living in endemic areas. Better vaccines are needed to achieve higher efficacy against infection, severe disease, and/or transmission, offer longer lasting immunity, and protect across broader populations of all ages.

Research Objectives

This notice of funding opportunity (NOFO) uses a R61/R33 Exploratory/Developmental Phased Award activity code to support discovery, proof-of concept, and/or preclinical development activities that are exploratory and developmental in nature, and to enable and accelerate the generation of highly efficacious malaria vaccines directed principally against two major human parasites, *Plasmodium falciparum* and *Plasmodium vivax*. The NOFO seeks product candidates or concepts that are highly effective in preventing infection, reducing disease burden, and/or blocking transmission of malaria and potentially other mosquito-borne diseases.

Specific Areas of Research Interest

The initiative will support activities that include, but are not limited to, the following topics:

For discovery and proof of concept for vaccine candidate features:

- Design and/or construction of novel vaccine concepts utilizing improved immunogen design or new antigen(s), formulation, novel innovative or modern technology platforms [e.g., Artificial Intelligence (AI)-guided vaccine design] intended to lead to significant prevention of infection, reduction of disease, or blocking of transmission.
- Exploration of combination vaccine concepts:
 - Combination of different vaccine platforms to elicit a broader range of protective immune responses,
 - Combination of multiple protein subunit immunogens to target one or more functional biological pathways,
 - Multi-stage vaccines targeting different life cycle stages of the parasites, for example, pre-erythrocytic, blood, and/or sexual stages of the parasite,
 - Vaccine concepts that target mosquito vector products (e.g., salivary gland proteins) or processes that may help to reduce pathogen infection, transmission or disease.
- Demonstration of favorable vaccine features by confirming immunogenicity and efficacy of candidates using new approach methodologies (NAMs) or appropriate animal models [Note: for this NOFO, efficacy is defined as prevention of infection, disease, or relapse (e.g., for *P. vivax*)]. Examples of NAMs include novel functional assays, model systems, *in vitro* or *ex vivo* culture systems, or computational and AI-based approaches.

For preclinical development:

- Critical assay and process development,
- Formulation improvement,
- Current Good Manufacturing Practices (cGMP) pilot lot production and release,
- Investigational New Drug (IND)-enabling activities,
- Regulatory support required for initiation of Phase I trial (clinical protocol development or implementation of clinical trial excluded).

Applications Not Responsive to this NOFO

The following types of applications are not responsive to this NOFO and will not be reviewed:

- Applications that propose malaria vaccine concepts principally focused on *Plasmodium* parasites other than *P. falciparum* or *P. vivax*
- Applications that propose Good Laboratory Practice (GLP) toxicology studies in animals
- Applications that propose clinical trial protocol development

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

Clinical Trial?

Not Allowed: This NOFO only accepts applications that do not propose clinical trials. Note: Applications may propose activities involving human subjects that are not deemed 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 \$4M in FY28 to fund 5-7 awards.

Award Budget

Budgets for the R61 phase are not expected to exceed \$400,000 direct costs annually. Budgets for the R33 phase are not expected to exceed \$750,000 direct costs annually.

Award Project Period

Applicants may request up to 3 years of support for the R61 phase, and up to 2 years of support for the R33 phase. The maximum project period is 5 years total.

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

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions - Includes all types

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

Nonprofits Other Than Institutions of Higher Education

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

For-Profit Organizations

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

Local Governments

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

Federal Governments

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

Other

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

Foreign Organizations/International Collaborations

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 \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11118\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11118), **are** allowed.

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

Applications involving foreign subawards/subcontracts submitted in response to this NOFO will be deemed noncompliant and will not be considered for funding. This policy applies to all monetary international collaborations resulting in foreign subawards/subcontracts, however, it does not preclude unfunded international collaborations or [foreign components \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section_1/1.2_definition_of_terms.htm\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_1/1.2_definition_of_terms.htm), funding for foreign consultants, or procurement of unique equipment or supplies from foreign vendors.

Required Registrations**Applicant Organizations**

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

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

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

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

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

Eligible Individuals (Program Director/Principal Investigator)

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

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

2. Cost Sharing

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

3. Additional Information on Eligibility**Number of Applications**

Only one application per institution (normally identified by having a unique UEL or NIH IPF number) is allowed. The NIH will not accept duplicate or highly overlapping applications under review at the same time, per [NIH Grants Policy Statement Section 2.3.7.4 Submission of Resubmission Application](http://grants.nih.gov/grants/guide/redirect.htm?id=82415) (<http://grants.nih.gov/grants/guide/redirect.htm?id=82415>). This means that the NIH will not accept:

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

Section IV. Application and Submission Information

1. Requesting an Application Package

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

2. Content and Form of Application Submission

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

Page Limitations

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

Instructions for Application Submission

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

SF424(R&R) Cover

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

SF424(R&R) Project/Performance Site Locations

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

SF424(R&R) Other Project Information

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

Other Attachment:

Applicants are **required** to provide the following additional material: Upload a separate PDF attachment with indicated filename "Product Development Plan.pdf".

Within the Product Development Plan, outline how the project will support the overall vaccine development pipeline and how the anticipated outcome will inform future development considerations. Describe key features of the proposed vaccine candidate or relevant development process including product indication, route of administration and dosing, duration of protection, product release profile and other product attributes (i.e., Preferred Product Characteristics). While the plan does not need to be comprehensive, describe how it will encourage product development-oriented thinking and demonstrate awareness of the steps needed to advance the candidate along a development pathway toward real-world implementation.

- For discovery focused applications, a high-level strategy for future research and development beyond discovery, especially preclinical development and IND-enabling considerations.
- For preclinical development focused applications, an IND-directed product development strategy and a plan beyond a Phase I clinical trial. The plan should also include ownership or intellectual property rights to ensure freedom to operate.

This attachment is limited to 4 pages and cannot be used to extend the 12-page limit of the Research Strategy.

SF424(R&R) Senior/Key Person Profile

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

R&R Budget

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

R&R Subaward Budget

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

PHS 398 Cover Page Supplement

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

PHS 398 Research Plan

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

Specific Aims: Describe and clearly demarcate the specific aims for each of the two phases (R61 and R33) on the single Specific Aims attachment.

For the R61 phase, focus the specific aims on discovery and/or preclinical development to establish and test key research or development concepts, with strategies designed to enable proof-of-concept studies for a novel or improved vaccine candidate(s) and to generate data to support the underlying hypothesis and feasibility of advancement.

For the subsequent R33 phase, contingent upon successful completion of R61 milestones, outline the plan to conduct more advanced research and preclinical development activities to further validate and advance the lead candidate(s) or concepts based on R61 outcomes.

Research Strategy:

Describe a single research strategy that includes both the R61 and R33 phases, with clearly labeled sections for the research proposed in the R61 and R33 phases. For each phase, describe the research or development approach, objectives, and how they will achieve the specific aims. Provide preliminary data or other information to support or justify the hypothesis, rationale, and overall plan. Avoid duplicating information or experimental details in the R33 section that are already provided in the R61 section. Although the research plans for the R33 phase may be broad and somewhat speculative due to the uncertain outcomes of the R61 phase, they should be described in sufficient detail to allow reviewers to assess their scientific merit based on anticipated results. Include the following information in the appropriate R61 or R33 section:

- Describe how the project will significantly advance the knowledge and understanding of vaccine design, testing and/or development for malaria and other mosquito-borne diseases.
- Describe how the proposed project has the potential of leading to the discovery and/or development of a new or improved, promising vaccine with significantly higher efficacy over currently available vaccine strategies in preventing infection, reducing disease, and interrupting transmission.
- Describe how the research plan represents the best use of current knowledge or emerging technologies to explore, design, identify, and/or evaluate the proposed candidate vaccines; or address significant preclinical development hurdles.
- Identify translational Go/No-go criteria for selection of vaccine candidates for final performance confirmation versus continued design and screening efforts, or for decision-making for continued preclinical development effort such as stepwise process scale up or vaccine production.
- Describe the composition of the multidisciplinary research team and highlight how translational science or product development expertise is integrated to demonstrate a clear understanding of the product development process.

Note that the proposed vaccine products or concepts should take into consideration downstream implementation feasibility, such as favorable product features (e.g., easily deployable formulation and straightforward immunization regimen) to address real world implementation demands. Collaboration of a multidisciplinary team across different scientific disciplines including translational science or product development experts or with a Product Development Partner are highly encouraged.

Timelines and Transition Milestones:

Within the application provide clear timelines for project activities to address the proposed specific aims for both the R61 and R33 phases, as well as transition milestones to move from R61 to R33. These specific aims and transition milestones will guide Go/No-go decisions and include success criteria, and be specific, measurable, achievable, relevant and time-bound (SMART) and scientifically justified. A Gantt chart or similar tool may be used to show timelines and how project activities relate to each other and to the overall goals.

Applicants are **required** to include:

- Detailed project timelines to address specific aims for both R61 and R33 phases.
- A clear set of transition milestones to assess readiness to move from R61 to R33.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the [How to Apply - Application Guide](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400).

Other Plan(s):

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

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

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

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

PHS Human Subjects and Clinical Trials Information

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

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

Study Record: PHS Human Subjects and Clinical Trials Information

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

Delayed Onset Study

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

PHS Assignment Request Form

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

Foreign Organizations

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

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

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

4. Submission Dates and Times

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

Organizations must submit applications to [Grants.gov](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11128) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11128) (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the [eRA Commons](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11128) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11128).

[id=11123](#)), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the [NIH Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications](#) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=82423).

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

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

5. Intergovernmental Review (E.O. 12372)

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

6. Funding Restrictions

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

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

7. Other Submission Requirements and Information

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

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

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

Important reminders:

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

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

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

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

Mandatory Disclosure

Recipients or subrecipients must submit any information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. See Mandatory Disclosures, [2 CFR 200.113](https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-B/section-200.113) (<https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-B/section-200.113>) and [NIH Grants Policy Statement Section 4.1.36](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1.36_mandatory_disclosures.htm). (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1.36_mandatory_disclosures.htm)

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

Post Submission Materials

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

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. Applications submitted to the NIH in support of the [NIH mission](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11149) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11149) are evaluated for scientific and technical merit through the NIH peer review system.

Overall Impact

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

Scored Review Criteria

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

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

Significance

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

Innovation

- Evaluate the extent to which innovation influences the importance of undertaking the proposed research. Note that while technical or conceptual innovation can influence the importance of the proposed research, a project that is not applying novel concepts or approaches may be of critical importance for the field.

- Evaluate whether the proposed work applies novel concepts, methods or technologies or uses existing concepts, methods, technologies in novel ways, to enhance the overall impact of the project.

Factor 2. Rigor and Feasibility (Approach)

Approach

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

Rigor:

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

Feasibility:

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

Specific to this NOFO:

- Evaluate the clarity and appropriateness of the criteria to support translational Go/No-go decisions in selection of vaccine candidates for final performance or for continued development efforts.
- Evaluate whether the R61 transition milestones are appropriately described, quantifiable, and achievable, and whether the timelines proposed to achieve the aims of the R61 and R33 phases of the project are appropriate and feasible.

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

Investigator(s)

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

Environment

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

Specific to this NOFO:

- Evaluate whether the proposed research team leverage translational science or product development expertise to accelerate discovery or development of promising malaria vaccines.

Additional Review Criteria

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

Protections for Human Subjects

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

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

This NOFO only accepts applications that do not propose clinical trials. Note: Applications may propose activities involving human subjects that are not deemed clinical trials.

Vertebrate Animals

When the proposed research includes Vertebrate Animals, evaluate the involvement of live vertebrate animals according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. For additional information on review of the Vertebrate Animals section, please refer to the [Worksheet for Review of the Vertebrate Animals Section \(http://grants.nih.gov/grants/guide/redirect.htm?id=11150\)](http://grants.nih.gov/grants/guide/redirect.htm?id=11150).

Biohazards

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

Resubmissions

As applicable, evaluate the full application as now presented.

Renewals

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

Revisions

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

Additional Review Considerations

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

Authentication of Key Biological and/or Chemical Resources

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

Budget and Period of Support

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

Product Development Plan

Evaluate whether the Product Development Plan adequately describes the summary of critical product features important for downstream product development considerations, and/or a product development strategy aligned with the goal of a highly efficacious and safe vaccine for real world implementation including product ownership or intellectual property position, as applicable.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s), convened by CSR, in accordance with [NIH peer review policies and practices \(https://grants.nih.gov/policy-and-compliance/policy-topics/peer-review\)](https://grants.nih.gov/policy-and-compliance/policy-topics/peer-review), 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.

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

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

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

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

3. Anticipated Announcement and Award Dates

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

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

Section VI. Award Administration Information**1. Award Notices**

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

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

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

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

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

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

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

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

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

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

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

Successful recipients under this NOFO agree that:

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

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

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

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

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

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

For applications involving funding Medication-Assisted Treatment (MAT) or medications for opioid use disorder (MOUD), this funding should be used to provide comprehensive treatment and recovery support services rather than medication-only models for opioid use disorder. Services should include medications, where clinically indicated, in conjunction with psychosocial and other treatment and recovery support services. Funding can also be used to support individualized tapering and discontinuation of medications when clinically indicated. Please see [Updated Funding Guidance for Recipients on MAT/MOUD](https://gcc02.safelinks.protection.outlook.com/?) (<https://gcc02.safelinks.protection.outlook.com/?>)

[url=https%3A%2F%2Fwww.samhsa.gov%2Fsites%2Fdefault%2Ffiles%2Fdear-colleague-letter-mat-moud-guidance.pdf&data=05%7C02%7Cchelsey.hughes%40nih.gov%7C725bb62d1f94a2b9ff908dec0bc5a25%7C14b77578977342d58507251ca2dc2b06%7C0%7C0%7C63916011238415](https://www.samhsa.gov/sites/default/files/dear-colleague-letter-mat-moud-guidance.pdf&data=05%7C02%7Cchelsey.hughes%40nih.gov%7C725bb62d1f94a2b9ff908dec0bc5a25%7C14b77578977342d58507251ca2dc2b06%7C0%7C0%7C63916011238415)

As of October 1, 2025, HHS has adopted [2 CFR Part 200](https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200) (<https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200>), with some modifications included in 2 CFR Part 300. These regulations replace those in 45 CFR Part 75. However, for NIH, under the Consolidated Appropriations Act for FY 2026, ([P.L. 119-75](https://www.congress.gov/bills/119/75) (<https://www.congress.gov/bills/119/75>), the provisions relating to indirect costs in 45 CFR 75 continue to apply to NIH awards. Consistent with the statute, NIH will not apply updated thresholds outlined within 2 CFR Part 200, at this time.

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

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

Cooperative Agreement Terms and Conditions of Award

Not Applicable.

3. Data Management and Sharing

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

4. Reporting

When multiple years are involved, recipients will be required to submit the [Research Performance Progress Report \(RPPR\)](https://grants.nih.gov/grants/rppr/index.htm) ([http://grants.nih.gov/grants/rppr/index.htm](https://grants.nih.gov/grants/rppr/index.htm)) annually and financial statements as required in the [NIH Grants Policy Statement Section 8.4.1 Reporting](https://grants.nih.gov/grants/policy/nihgps/html5/section_8/8.4.1_reporting.htm), (https://grants.nih.gov/grants/policy/nihgps/html5/section_8/8.4.1_reporting.htm). To learn more about post-award monitoring and reporting, see the NIH Grants & Funding website, see [Post-Award Monitoring and Reporting](https://grants.nih.gov/grants/guide/url_redirect.php?id=82428) (https://grants.nih.gov/grants/guide/url_redirect.php?id=82428).

A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the [NIH Grants Policy Statement Section 8.6 Closeout](https://grants.nih.gov/grants/policy/nihgps/html5/section_8/8.4.1_reporting.htm) ([http://grants.nih.gov/grants/guide/url_redirect.php?id=82420](https://grants.nih.gov/grants/guide/url_redirect.php?id=82420)). NIH NOFOs outline intended research goals and objectives. Post award, NIH will review and measure performance based on the details and outcomes that are shared within the RPPR, as described at 2 CFR Part 200.301.

5. Evaluation

For transition to the R33 phase, recipients must submit the transition package no less than 75 days before the proposed start of the R33 phase. The transition plan should include the R61 progress report describing in detail the progress towards the R61 milestones and a description of how research proposed for the R33 phase will be supported by the completion of the R61 phase milestones. These materials will be evaluated by NIH Program staff. It is understood that the proposed goals and/or benchmarks for the R33 phase may be revised based on activities during the R61 planning phase. In the event of an award for the R33 phase, the PD(s)/PI(s) and NIH staff will negotiate a list of benchmarks for each year of R33 support. Transition to the R33 phase is neither automatic nor guaranteed. R33 funding decisions will be based on the original R61/R33 peer review recommendations, successful completion of R61 milestones, program priorities, and availability of funds. Given the risky nature of the R61 phase, it is expected that approximately 50% of grants funded in the R61 phase will transition to the R33 phase.

Section VII. Agency Contacts

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

Application Submission Contacts

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

[Grants.gov Support Center](https://grants.nih.gov/grants/guide/url_redirect.php?id=11163) (https://grants.nih.gov/grants/guide/url_redirect.php?id=11163)

[url=https%3A%2F%2Fgrants.nih.gov%2Fsupport&data=05%7C02%7Cantoinette.caliman%40nih.gov%7Caf6dde64d644478d4e8b08dde6700581%7C14b77578977342d58507251ca2dc2b](https://grants.nih.gov/grants/guide/url_redirect.php?id=11164)
- Questions regarding Grants.gov registration and services (e.g., Workspace, subscriptions).

Scientific/Research Contact(s)

National Institute of Allergy and Infectious Diseases (NIAID)

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

Peer Review Contact(s)

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

Financial/Grants Management Contact(s)

National Institute of Allergy and Infectious Diseases (NIAID)

Email: NIAIDFinancial-GrantsContact@mail.nih.gov (<mailto:NIAIDFinancial-GrantsContact@mail.nih.gov>)

Section VIII. Other Information

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