

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

ที่ อว 78.016/2968

วันที่ 20 เมษายน 2566

เรื่อง ประชาสัมพันธ์การเปิดรับข้อเสนอโครงการ จากแหล่งทุน National Institutes of Health (NIH) ประเภท Research Project Grant หัวข้อ "International Research in Infectious Diseases (R01 Clinical Trial Not Allowed)" หมายเลขประกาศทุน RFA-AI-23-023

สิ่งที่ส่งมาด้วย

1. รายละเอียดประกาศทุน

2. ขั้นตอนการสมัครขอรับทุน

เรียน คณบดี / ผู้อำนวยการ

ด้วยแหล่งทุน National Institutes of Health (NIH) เปิดรับข้อเสนอโครงการ ประเภท Research Project Grant หัวข้อ "International Research in Infectious Diseases (R01 Clinical Trial Not Allowed)" หมายเลขประกาศทุน RFA-Al-23-023 โดยเปิดรับข้อเสนอโครงการ ตั้งแต่วันที่ 2 กรกฎาคม 2566 จนถึงวันที่ 2 สิงหาคม 2566 เวลา 17.00 น. ตามเวลาประเทศไทย ทั้งนี้ โครงการที่เสนอขอทุนให้ปฏิบัติตาม ประกาศมหาวิทยาลัยมหิดล เรื่องหลักเกณฑ์และอัตราเงินค่าธรรมเนียมพัฒนาการวิจัยของมหาวิทยาลัยและส่วนงาน ที่จัดเก็บจากโครงการวิจัยที่ได้รับเงินอุดหนุนจากแหล่งทุนภายนอกมหาวิทยาลัย พ.ศ. 2560 และขอให้ดำเนินการ ตามที่ระบุในหนังสือซักซ้อมแนวปฏิบัติ เรื่องมาตรฐานการวิจัยของโครงการวิจัย รายละเอียดดังเอกสารแนบมาด้วยนี้ ทั้งนี้ อาจารย์/นักวิจัยที่สนใจสามารถศึกษารายละเอียดเพิ่มเติมได้ตามเอกสารที่แนบมาด้วยนี้ หรือเว็บไซต์ของแหล่ง https://grants.nih.gov/grants/guide/rfa-files/RFA-Al-23-023.html

ในการนี้ กองบริหารงานวิจัย มหาวิทยาลัยมหิดล จึงขอแจ้งข่าวประกาศทุนมายังท่าน เพื่อ โปรดประชาสัมพันธ์ทุนวิจัยดังกล่าวให้บุคลากรในหน่วยงานของท่านทราบโดยทั่วกัน และขอให้อาจารย์/นักวิจัย โปรดแจ้งความประสงค์การจัดส่งข้อเสนอโครงการ ภายในวันที่ 3 กรกฎาคม 2566 และจัดส่งข้อเสนอโครงการวิจัยเพื่อตรวจสอบรายละเอียดข้อเสนอโครงการฉบับ สมบูรณ์ภายในวันที่ 24 กรกฎาคม 2566 ทั้งนี้ หากส่วนงานจัดส่งข้อเสนอโครงการวิจัยหลังจากวันที่ 24 กรกฎาคม 2566 ทั้งนี้ หากส่วนงานจัดส่งข้อเสนอโครงการวิจัยหลังจากวันที่ 24 กรกฎาคม 2566 มหาวิทยาลัยขอสงวนสิทธิ์ในการยื่นข้อเสนอโครงการวิจัยเพื่อขอรับทุนดังกล่าว

จึงเรียนมาเพื่อโปรดทราบและประชาสัมพันธ์ข่าวทุนวิจัยดังกล่าวต่อไปด้วย จักขอบคุณยิ่ง

(ศาสตราจารย์ ดร. นายแพทย์ภัทรชัย กีรติสิน)

รองอธิการบดีฝ่ายวิจัย

ผู้ประสานงาน : นางสาวจิตติพร นวลละออง

โทร 02-849-6252 อีเมล chittiporn.nua@mahidol.edu

Department of Health and Human Services

Part 1: Overview Information

Participating Organization(s)

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

Components of Participating Organizations

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

Funding Opportunity Title

International Research in Infectious Diseases (R01 Clinical Trial Not Allowed)

Activity Code

R01 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r01&Search.x=0&Search_y=0&Search_Type=Activity) Research Project Grant

Announcement Type

New

Related Notices

- August 5, 2022 Implementation Details for the NIH Data Management and Sharing Policy. See Notice NOT-OD-22-189 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-189.html).
- August 8, 2022 New NIH "FORMS-H" Grant Application Forms and Instructions Coming for Due Dates on or after January 25, 2023. See Notice NOT-OD-22-195 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-195.html).
- August 31, 2022 Implementation Changes for Genomic Data Sharing Plans Included with Applications Due on or after January 25, 2023. See Notice NOT-OD-22-198 (https://grants.nih.gov/grants/guide/notice-files/not-od-22-198.html).
- October 26, 2022 Reminder: FORMS-H Grant Application Forms & Instructions Must be Used for Due Dates On or After January 25, 2023 - New Grant Application Instructions Now Available. See Notice NOT-OD-23-012 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-012.html).

Funding Opportunity Announcement (FOA) Number

RFA-AI-23-023

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 purpose of this Funding Opportunity Announcement (FOA) is to support applications for high-priority, regionally relevant infectious diseases research by international investigators in resource-constrained countries. Applicant organizations must be headquartered in foreign (non-U.S.) resource-constrained countries (i.e. low-income economies, lower-middle-income economies, and upper-middle-income economies by World Bank Classification (https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups)). Applicant organizations headquartered in low- and lower-middle income economy countries are particularly encouraged to apply. Eligibility status of applicant organizations will be determined by the World Bank Classification list at the time of application submission.

Key Dates

Posted Date

April 14, 2023

Open Date (Earliest Submission Date)

July 02, 2023

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
August 02, 2023	August 02, 2023	August 02, 2023	November 2023	January 2024	March 2024
August 02, 2024	August 02, 2024	August 02, 2024	November 2024	January 2025	March 2025
August 01, 2025	August 01, 2025	August 01, 2025	November 2025	January 2026	March 2026

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

August 02, 2025

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 <u>SF424 (R&R) Application Guide</u> (https://grants.nih.gov/grants/guide/url redirect.htm?id=82400), except where instructed to do otherwise (in this FOA or in a Notice from NIH Guide for Grants and Contracts). (//grants.nih.gov/grants/guide/url 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 (//grants.nih.gov/grants/guide/url redirect.htm?id=11164)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 <u>eRA Commons</u> (https://public.era.nih.gov/commons/) to track your application. Check with your institutional officials regarding availability.
- 3. Use <u>Grants.gov (https://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=RFA-AI-23-023)</u> Workspace to prepare and submit your application and <u>eRA Commons (http://public.era.nih.gov/commons/)</u> 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 applications for research on infectious diseases in eligible (resource constrained) foreign countries. Applicant organizations must be headquartered in foreign (non-U.S.) resource-constrained countries (i.e. low-income economies, lower-middle-income economies, and upper-middle-income economies by World Bank Classification (https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups)). Applications from organizations in low- and lower-middle income economy countries are especially encouraged to apply. Eligibility status of applicant organizations will be determined by World Bank Classification at the time of application submission. The intent of the FOA is to foster, stimulate and/or expand basic, translational, and applied research that will advance scientific discovery and engage local scientists in areas of infectious diseases research. Research should reflect the highest possible scientific rigor and focus on infectious diseases, including HIV/AIDS, of interest to the local and/or regional public health needs and priorities, and important from a global health perspective. Collaborative projects involving investigators from international sites and the U.S. are encouraged. Collaborative projects involving investigators from underrepresented institutions, including those in low and lower-middle economy countries are particularly encouraged. These grants will serve to build independent research capacity by providing direct funding to investigators who do not currently have NIH-funded grant or contract awards for research projects. The intent of these activities is to advance the development of local scientific expertise.

Background

The NIAID has a long-standing interest in, and commitment to, global health and international research. Topics of interest for this program cover a broad range of infectious diseases research topics, including, but not limited to: tuberculosis, malaria, HIV/AIDS, parasitic diseases, vectors and vector-borne diseases, drug resistance (antimicrobial and/or insecticide), zoonoses with public health consequences, and other emerging and re-emerging infectious diseases that are of public health significance. Development of basic, immunological, microbiological, biostatistical, bioinformatics, genomics, epidemiological, data management, and clinical research capacity is encouraged.

Research Objectives and Scope

Studies may be proposed on any aspect of infectious disease research (except clinical trials), including but not limited to: basic biological studies of pathogens and vectors; the epidemiology, natural history, pathogenesis, immunopathogenesis of infectious diseases; epidemiologic studies to define the incidence, clinical presentations, and outcomes of diseases; identification of resistance mechanisms and patterns; characterization of susceptible cohorts for a particular pathogen; pilot and feasibility studies in preparation for larger studies; studies focused on the effects of climate change on the incidence, prevalence and severity of infectious diseases.

Note: HIV/AIDS studies must address NIAID priorities as described: https://www.niaid.nih.gov/about/division-aids-overview (https://www.niaid.nih.gov/about/division-aids-overview).

Collaborative projects involving investigators and institutions from international sites and the U.S. are encouraged; however, a U.S. partner is not required. Collaborative projects involving institutions in -low and -lower-middle economy countries are particularly encouraged. Applicants are encouraged to establish multi-institutional collaborations and to include activities that involve the transfer of technologies and research methods, sharing of core resources including the administration of research grant programs, and expansion of linkages to other sites via attendance at national and international meetings and other methods of communication. NIH supports several international research programs on infectious diseases, including HIV/AIDS. This International Research in Infectious Diseases (IRID) Program is intended to complement these programs by expanding the breadth of research supported at international sites and by providing support to new researchers. This may include sites where NIH or NIAID already has significant investment in research and/or infrastructure. However, previous NIH funding is not a requirement.

Programmatic Meetings:

An initial virtual Program kick-off and Annual Programmatic Meetings will be held to facilitate communication and collaboration. Annual meetings will be held to update NIAID on progress and future directions of the program. The meetings will be virtual.

Applicants are strongly encouraged to contact the Scientific/Research Contact(s) located at the end of this FOA to discuss NIAID's research priority areas.

Applications proposing the following will be considered non-responsive and will not be reviewed:

- Research involving Select Agents. Select Agents are biological agents or toxins listed in 42 CFR Part 73 (https://www.ecfr.gov/current/title-42/chapter-I/subchapter-F/part-73?toc=1), 7 CFR Part 331 (https://www.ecfr.gov/current/title-7/subtitle-B/chapter-III/part-331?toc=1) and 9 CFR Part 121 (https://www.ecfr.gov/current/title-9/chapter-I/subchapter-E/part-121), or the HHS and USDA Select Agents and Toxins List (http://www.cdc.gov/od/sap/docs/salist.pdf).
- · Clinical trials.

For more information about this FOA, see <u>Frequently Asked Questions (https://www.niaid.nih.gov/grants-contracts/questions-and-answers-fa-ai-23-023)</u>. NIAID plans to hold an informational webinar for this FOA. Details about the webinar will be available at this same link after FOA publication. Participation in the webinar is not required to submit an application in response to this FOA. See <u>Section VIII. Other Information</u> for award authorities and regulations.

Section II. Award Information

Funding Instrument

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

Application Types Allowed

New

Resubmission - Resubmission to RFA-Al-23-023

The OER Glossary (//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)

Funds Available and Anticipated Number of Awards

NIAID intends to commit \$1,360,000 in FY 2024 to fund 7-8 awards.

Award Budget

Application budgets should not exceed \$125,000 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 5 years.

NIH grants policies as described in the NIH Grants Policy Statement (//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

Non-domestic (non-U.S.) Entities (Foreign Institutions)

Applicant organizations must be headquartered in foreign (non-U.S.) resource-constrained (i.e. low-income economies, lower-middle-income economies) by World Bank Classification

(https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups) at the time of application submission. Applicant organizations headquartered in low- and lower-middle income economy countries are particularly encouraged to apply.

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 not eligible to apply.

Foreign components, as defined in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_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)) 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/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.
 - NATO Commercial and Government Entity (NCAGE) Code (//grants.nih.gov/grants/guide/url_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.
- <u>eRA Commons (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123)</u> Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their Grants.gov registration; 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.
- <u>Grants.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=82300)</u> Applicants must have an active SAM registration in order to complete the Grants.gov registration.

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

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

Eligible Individuals (Program Director/Principal Investigator)

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

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

PDs/PIs must have a primary appointment at an institution/organization in an eligible country. Investigators who currently serve or have served as PDs/PIs on R01-equivalent grants (other than an expiring/current IRID) or contracts funded by NIH are not eligible to apply.

For institutions/organizations proposing multiple PDs/PIs, all PDs/PIs must have primary appointment at an institution/organization in an eligible country.

2. Cost Sharing

This FOA does not require cost sharing as defined in the <u>NIH Grants Policy Statement. (//grants.nih.gov/grants/guide/url_redirect.htm?</u> 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 <u>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)</u>. 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 <u>2.3.9.4 Similar, Essentially Identical, or Identical Applications</u>
 (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 <u>SF424 (R&R) Application Guide</u> (https://grants.nih.gov/grants/guide/url_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 <u>Part 1. Overview Information</u>, 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:

Soheyla Saadi, Ph.D. Telephone: 240-669-5178

Email: saadisoh@nih.gov (mailto:saadisoh@nih.gov)

Page Limitations

All page limitations described in the SF424 Application Guide and the <u>Table of Page Limits (//grants.nih.gov/grants/guide/url_redirect.htm?</u> 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:

No more than 20% of the budget (direct costs) in any year may be subcontracted to an institution in a high-income economy country (World Bank Classification (https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups)). All subcontracts combined to such high-income economy countries should account for no more than 20% of the budget (direct costs). Subcontracts to eligible foreign institutions are not subject to this cap.

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: Provide evidence that the scientific question(s) addressed are important to the country/region in which the research will be conducted and important from a global health perspective. Explain how the proposed research team will increase scientific capacity related to the proposed subject area. If proposed, outline plans for collaboration and explain how the proposed research and collaborative

research team are likely to advance the development of local scientific expertise or increase collaborative research capacity at the foreign site.

Resource Sharing Plan:

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

Other Plan(s):

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

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

All applicants planning research (funded or conducted in whole or in part by NIH) that results in the generation of scientific data are
required to comply with the instructions for the Data Management and Sharing Plan. All applications, regardless of the amount of direct
costs requested for any one year, must address a Data Management and Sharing Plan.

Appendix:

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

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

PHS Human Subjects and Clinical Trials Information

When involving human subjects research, clinical research, and/or NIH-defined clinical trials (and when applicable, clinical trials research experience) follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with the following additional instructions:

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

Study Record: PHS Human Subjects and Clinical Trials Information

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

Delayed Onset Study

Note: <u>Delayed onset (https://grants.nih.gov/grants/glossary.htm#DelayedOnsetStudy)</u> 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), 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

<u>Part I. Overview Information</u> 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 <u>Federal holiday (https://grants.nih.gov/grants/guide/url_redirect.html?id=82380)</u>, the application deadline is automatically extended to the next business day.

Organizations must submit applications to <u>Grants.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=11128)</u> (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 <u>eRA Commons (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123)</u>, 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)

6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the <u>NIH Grants Policy Statement</u> (//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).

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. <u>Section III. Eligibility Information</u> 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). 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) guidance. For assistance with application submission Contacts in Section VII.

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field 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) 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)

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) 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: Does the application adequately demonstrate that the scientific question is of interest to the region in which the research will be conducted and important from a global health perspective?

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?

Specific to this FOA: Is the research team, as proposed, likely to increase scientific capacity in the county/region related to the proposed subject area?

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: If proposed, are plans for collaboration sufficiently developed? Is there likelihood that proposed collaborations will advance the development of local scientific expertise or increase collaborative research capacity at the local site?

Environment

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

Additional Review Criteria

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

Protections for Human Subjects

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

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

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 <a href="Guidelines for the Review of Inclusion in Clinical Research (//grants.nih.gov/grants/guide/url 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/url_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

For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewals

Not Applicable

Revisions

Not Applicable

Additional Review Considerations

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

Resource Sharing Plans

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

Authentication of Key Biological and/or Chemical Resources:

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

Budget and Period of Support

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

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by the National Institute of Allergy and Infectious Diseases, in accordance with NIH peer review policy and procedures (//grants.nih.gov/grants/guide/url 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). 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) of initial peer review will not be accepted for applications submitted in response to this FOA.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review by the appropriate national Advisory Council or Board. The following will be considered in making funding decisions:

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

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the <u>eRA Commons (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123)</u>. 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 <u>NIH Grants Policy Statement</u> (//grants.nih.gov/grants/guide/url_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).

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 <u>Award Conditions and Information for NIH Grants. (https://grants.nih.gov/grants/policy/nihgps/HTML5/part_ii_subpart_b.htm)</u> 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 (//grants.nih.gov/grants/guide/url 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 Grants Awards, Subpart A: General (//grants.nih.gov/grants/guide/url redirect.htm?id=11157) and Part II: Terms and Conditions of NIH Grants Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities (//grants.nih.gov/grants/guide/url redirect.htm?id=11159), including of note, but not limited to:

- Federal wide 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)
- <u>Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-041.html)</u>
- Acknowledgment of Federal Funding (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 will be required to complete an HHS Assurance of Compliance form (HHS 690) (https://ocrportal.hhs.gov/ocr/aoc/instruction.jsf) in which the recipient agrees, as a term and condition of receiving the grant, to administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, age, sex and disability, and agreeing to comply with federal conscience laws, where applicable. This includes ensuring that entities take meaningful steps to provide meaningful access to persons with limited English proficiency; and ensuring effective communication with persons with disabilities. Where applicable, Title XI and Section 1557 prohibit discrimination on the basis of sexual orientation, and gender identity. 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-provider-obligations/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) and
 https://www.lep.gov/).
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see https://www.hhs.gov/civil-rights/for-individuals/disability/index.html (https://www.hhs.gov/civil-rights/for-individuals/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 religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws see https://www.hhs.gov/conscience-protections/index.html (https://www.hhs.gov/conscience/protections/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 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 (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated

integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, 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

Not Applicable

3. Data Management and Sharing

Note: The NIH Policy for Data Management and Sharing is effective for due dates on or after January 25, 2023.

Consistent with the NIH Policy for Data Management and Sharing, when data management and sharing is applicable to the award, recipients will be required to adhere to the Data Management and Sharing requirements as outlined in the NIH Grants Policy Statement (https://grants.nih.gov/grants/policy/nihgps/HTML5/section-8/8.2.3 sharing research resources.htm#Data). Upon the approval of a Data Management and Sharing Plan, it is required for recipients to implement the plan as described.

4. Reporting

When multiple years are involved, recipients will be required to submit the <u>Research Performance Progress Report (RPPR)</u> (//grants.nih.gov/grants/rppr/index.htm) annually and financial statements as required in the <u>NIH Grants Policy Statement</u>. (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). 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.fsrs.gov (//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) 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 FAPIIS). 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: https://www.era.nih.gov/need-help (preferred method of contact) Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

General Grants Information (Questions regarding application instructions, application processes, and NIH grant resources) Email: <u>GrantsInfo@nih.gov</u> (mailto:<u>GrantsInfo@nih.gov</u>) (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)

Glen C. McGugan, Jr., Ph.D.

Division of Microbiology and Infectious Diseases

National Institute of Allergy and Infectious Diseases (NIAID)

Telephone: 240-627-3314

Email: gm233g@nih.gov (mailto:gm233g@nih.gov)

HIV/AIDS:

Melanie C. Bacon, RN, MPH

Division of AIDS

National Institute of Allergy and Infectious Diseases (NIAID)

Telephone: 240-627-3215

Email: mbacon@niaid.nih.gov (mailto:mbacon@niaid.nih.gov)

David McDonald, Ph.D.

Division of AIDS

National Institute of Allergy and Infectious Diseases (NIAID)

Telephone: 301-761-7815

Email: david.mcdonald@nih.gov (mailto:david.mcdonald@nih.gov)

Peer Review Contact(s)

Soheyla Saadi, Ph.D.

National Institute of Allergy and Infectious Diseases (NIAID)

Telephone: 240-669-5178

Email: saadisoh@nih.gov (mailto:saadisoh@nih.gov)

Financial/Grants Management Contact(s)

Vandhana Khurana

National Institute of Allergy and Infectious Diseases (NIAID)

Telephone: 240-669-2966

Email: khuranav@niaid.nih.gov (mailto:khuranav@niaid.nih.gov)

Section VIII. Other Information

Recently issued trans-NIH policy notices (//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 (//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 (//grants.nih.gov/grants/guide/url redirect.htm?id=11120).

Authority and Regulations

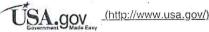
Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75 and 2 CFR Part 200.

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?04-14-23) NIH Funding Opportunities and Notices (/grants/guide/index.html)





(http://www.hhs.gov/) and Human Services (HHS)



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

ขั้นตอนการสมัครขอรับทุน National Institute of Health (NIH)

1. ผู้สมัครจะต้องแจ้งความประสงค์และนำส่งข้อมูลเข้ามายังกองบริหารงานวิจัย <u>ภายในกำหนดเวลาแจ้ง ความประสงค์การจัดส่งข้อเสนอในหนังสือประชาสัมพันธ์</u> โดยนำส่งข้อมูลทางอีเมล <u>chittiporn.nua@mahidol.edu</u> เพื่อขอเปิดบัญชี eRA commons และขอสร้างข้อเสนอโครงการใน ระบบออนไลน์ ASSIST ของแหล่งทุน NIH โดยแจ้งข้อมูลดังนี้

Name:

Surname:

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

Funding Opportunity Announcement (FOA) Number:

Application title:

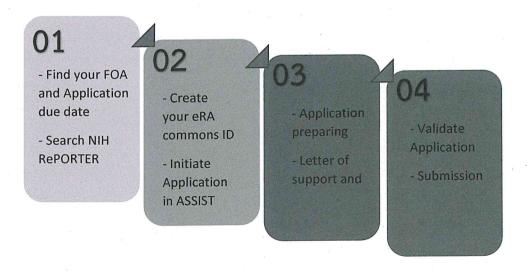
Application due date:

2. ผู้สมัครขอรับทุนศึกษาประกาศทุน (Funding opportunity announcements หรือ FOA) อย่างละเอียด ตรวจสอบกำหนดการส่งข้อเสนอของมหาวิทยาลัย และสืบค้นข้อมูลที่เกี่ยวข้องกับงานวิจัยของตนเองผ่าน NIH RePORTER https://reporter.nih.gov

3. มหาวิทยาลัยสร้างบัญชี eRA commons และสร้างข้อเสนอโครงการในระบบ ASSIST ให้ผู้สมัครขอรับ ทุน ผู้ขอรับทุนจัดทำข้อเสนอโครงการและเอกสารที่เกี่ยวข้องตามข้อกำหนดของแหล่งทุนร่วมกับ มหาวิทยาลัย

4. ผู้สมัครขอรับทุนนำส่งเอกสารข้อเสนอโครงการฉบับสมบูรณ์ผ่านหัวหน้าส่วนงานเพื่อขออนุมัติจัดส่ง ข้อเสนอโครงการผ่านระบบออนไลน์ ASSIST ตามกำหนดรับข้อเสนอของมหาวิทยาลัย** กองบริหาร งานวิจัยตรวจสอบข้อเสนอโครงการ เสนออนุมัตินำส่งข้อเสนอโครงการและจัดส่งข้อเสนอโครงการในนาม ของมหาวิทยาลัยไปยังแหล่งทุน

(**หากผู้สมัครขอรับทุนนำส่งข้อเสนอโครงการให้กองบริหารงานวิจัยตรวจสอบล่าช้ากว่ากำหนดของมหาวิทยาลัย มหาวิทยาลัยขอสงวนสิทธิ์ ในการรับข้อเสนอโครงการเพื่อนำส่งแหล่งทุนในรอบนั้นๆ)



สอบถามข้อมูลเพิ่มเติม คุณจิตติพร 02-8496252 <u>chittiporn.nua@mahidol.edu</u> หน่วยสนับสนุนการขอทุนวิจัยจากแหล่งทุนต่างประเทศ Mahidol University: Supporting Unit for International Research Funding (MU: SURF)