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

ที่ อว 78.016/ ๗๖๕๓
วันที่ 25 ตุลาคม 2566
เรื่อง ประชาสัมพันธ์การเปิดรับข้อเสนอโครงการ จากแหล่งทุน National Institutes of Health (NIH) หมายเลขประกาศทุน RFA-AI-23-057

สิ่งที่ส่งมาด้วย 1. รายละเอียดประกาศทุน
2. ขั้นตอนการสมัครขอรับทุน

เรียน คณบดี / ผู้อำนวยการ

ด้วยแหล่งทุน National Institutes of Health (NIH) เปิดรับข้อเสนอโครงการ ประเภท U19 Research Program – Cooperative Agreements หัวข้อ “Multidisciplinary Research to Accelerate Hepatitis B Cure in Persons Living with HIV and HBV (U19 Clinical Trial Not Allowed)” หมายเลขประกาศทุน RFA-AI-23-057 โดยเปิดรับข้อเสนอโครงการ ตั้งแต่วันที่ 13 กุมภาพันธ์ 2567 จนถึงวันที่ 13 มีนาคม 2567 เวลา 17.00 น. ตามเวลาประเทศไทย ทั้งนี้ โครงการที่เสนอขอทุนให้ปฏิบัติตามประกาศมหาวิทยาลัยมหิดล เรื่อง หลักเกณฑ์และอัตราเงินค่าธรรมเนียมพัฒนาการวิจัยของมหาวิทยาลัยและส่วนงานที่จัดเก็บจากโครงการวิจัยที่ได้รับเงินอุดหนุนจากแหล่งทุนภายนอกมหาวิทยาลัย พ.ศ. 2560 และขอให้ดำเนินการตามที่ระบุในหนังสือชักชวนแนวปฏิบัติ เรื่องมาตรฐานการวิจัยของโครงการวิจัย รายละเอียดดังเอกสารแนบมาด้วยนี้ ทั้งนี้ อาจารย์/นักวิจัยที่สนใจสามารถศึกษารายละเอียดเพิ่มเติมได้ตามเอกสารที่แนบมาด้วยนี้ หรือเว็บไซต์ของแหล่ง https://grants.nih.gov/grants/guide/rfa-files/RFA-AI-23-057.html

ในการนี้ กองบริหารงานวิจัย มหาวิทยาลัยมหิดล จึงขอแจ้งข่าวประกาศทุนมายังท่าน เพื่อโปรดประชาสัมพันธ์ทุนวิจัยดังกล่าวให้บุคลากรในหน่วยงานของท่านทราบโดยทั่วกัน และขอให้อาจารย์/นักวิจัย **โปรดแจ้งความประสงค์การจัดส่งข้อเสนอโครงการไปยังกองบริหารงานวิจัยทางอีเมล chittiporn.nua@mahidol.edu ภายในวันที่ 13 กุมภาพันธ์ 2567** ตามขั้นตอนการสมัครขอรับทุน ดังสิ่งที่ส่งมาด้วย 2 และจัดส่งข้อเสนอโครงการวิจัยผ่านส่วนงานต้นสังกัดมายังกองบริหารงานวิจัยเพื่อตรวจสอบรายละเอียดข้อเสนอโครงการฉบับสมบูรณ์ ภายใน 5 วันทำการก่อนปิดรับสมัครทุน ทั้งนี้ หากส่วนงานจัดส่งข้อเสนอโครงการวิจัยหลังจากวันที่กำหนด มหาวิทยาลัยขอสงวนสิทธิ์ในการยื่นข้อเสนอโครงการวิจัยเพื่อขอรับทุนดังกล่าว

จึงเรียนมาเพื่อโปรดทราบและประชาสัมพันธ์ข่าวทุนวิจัยดังกล่าวต่อไป จักขอบพระคุณยิ่ง

(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

Multidisciplinary Research to Accelerate Hepatitis B Cure in Persons Living with HIV and HBV (U19 Clinical Trial Not Allowed)

Activity Code

U19 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=u19&Search.x=0&Search.y=0&sort=ac&Search_Type=Activity&text_prev=) Research Program – Cooperative Agreements

Announcement Type

New

Related Notices

- **August 31, 2022**- Implementation Changes for Genomic Data Sharing Plans Included with Applications Due on or after January 25, 2023. See Notice NOT-OD-22-198 (https://grants.nih.gov/grants/guide/notice-files/not-od-22-198.html).
- **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).

Notice of Funding Opportunity (NOFO) Number

RFA-AI-23-057

Companion Notice of Funding Opportunity

None

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)

93.855

Notice of Funding Opportunity Purpose

The purpose of this Notice of Funding Opportunity (NOFO) is to support research to better understand the impact of host and viral heterogeneity on pathogenesis of disease, viral persistence, and immunopathology of Hepatitis B (HBV) and inform cure strategies for HBV in people living with HIV (PLWH). Applicants will establish multidisciplinary teams that span the clinical and basic/translational research arenas and establish an observational cohort to accelerate discovery and increase clinical impact.

Key Dates

Posted Date

October 10, 2023

Open Date (Earliest Submission Date)

February 13, 2024

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 - New/Renewal/Resubmission/Revision, as allowed	Scientific Merit Review	Advisory Council Review	Earliest Start Date
Not Applicable	Not Applicable	March 13, 2024	July 2024	October 2024	December 2024

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

March 14, 2024

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the Multi-Project (M) Instructions in the How to Apply - Application Guide (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 the *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 NOFO) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

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

1. Use the NIH ASSIST system to prepare, submit and track your application online.
   Apply Online Using ASSIST
2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA Commons (https://public.era.nih.gov/commons/) to track your application. Check with your institutional officials regarding availability.

Table of Contents

Part 2. Full Text of Announcement

Section I. Notice of Funding Opportunity Description

Background

Hepatitis B virus (HBV) is a global public health threat with an estimated 300 million people chronically infected, resulting in nearly 1 million deaths annually. Considered a silent epidemic, the World Health Organization (WHO) estimates only ten percent of persons living with HBV know they are infected, highlighting a need to increase awareness, develop treatments, and accelerate scientific discovery. Deaths attributed to viral hepatitis have increased 22 percent since 2000, highlighting an urgent and unmet need for research to cure HBV.

WHO estimates nearly eight percent of persons living with HIV (PLWH) are also living with chronic HBV and are at an eight to ten percent risk of developing HBV related complications, including cirrhosis, fibrosis, and hepatocellular carcinoma (HCC). The rate of chronic HBV for PLWH ranges from 5% to 20% depending on the population studied and the geographical region. To date, the highest rates of chronic HBV coinfection with HIV have been reported in areas where HBV is highly endemic, such as sub-Saharan Africa and parts of Asia. The risks of progressing to chronic HBV is multifactorial and includes age at infection, immune status, and the individual variation in the immune response.

The National Institutes of Health (NIH) recognized HBV as a priority pathogen causing significant morbidity and mortality and developed a strategic plan dedicated to accelerating preclinical and clinical research for a HBV cure (https://www.niaid.nih.gov/sites/default/files/Trans-NIH-Hep-B-Strategic-Plan-2022.pdf (https://www.niaid.nih.gov/sites/default/files/Trans-NIH-Hep-B-Strategic-Plan-2022.pdf)). There is an unmet need to elucidate the mechanisms of HBV persistence, pathogenesis, and immune dysfunction that drive different stages of chronic HBV disease and how host immune responses impact disease outcome. This understanding will provide a platform for identifying clinically relevant biomarkers, targets for new immunotherapies and antiviral drugs for the development of novel treatment strategies that promote clearance of HBV. In addition, the development of non-invasive diagnostics that accurately measure different stages of chronic HBV and elucidate the extent of liver injury are of critical importance. These diagnostics would reduce the need for invasive procedures, allowing for frequent monitoring, accurate measures of disease progression and an indication of treatment success or failure.

This Notice of Funding Opportunity (NOFO) supports the establishment of observational patient cohorts of people living with HBV with the goal of facilitating multidisciplinary research that spans the clinical and basic/translational arenas to advance our understanding of HBV in PLWH, which is crucial to stimulate relevant research discoveries to drive HBV cure. Each observational cohort will support research in different geographical regions with endemic patient populations living with HBV and HIV. Advancements in biomarker discovery, host immunotherapies, viral drug targets, and non-invasive diagnostics can significantly enhance our ability to characterize the disease, predict treatment outcomes, and guide new therapeutic interventions for people living with HIV and HBV, improving health outcomes, and reducing morbidity and mortality attributed to HBV.

Research Objectives and Scope

Each application will include a cross-disciplinary team of investigators that engages preclinical and clinical researchers in HBV and in HIV as expertise requires. Applicants are highly encouraged to include early career scientists (e.g., research track investigators, staff scientists, and Assistant level professors). Research applications are strongly encouraged to focus on the study of primary viral isolates from different genotypes and include objectives that address multiple stages of the natural life cycle of HBV in PLWH. Investigators are encouraged to develop multi-omics strategies to identify novel host and viral factors that underly disease mechanisms with an emphasis on identifying drug targets and biomarkers for HBV cure. Applications will combine at least one clinical research project and one basic or translational research project to accelerate discovery and increase clinical impact.

Examples of research areas of interest include, but are not limited to:

- Determine the impact of host and viral heterogeneity on disease progression, persistence, immunopathology, and the impact on therapeutic outcomes including HBV and/or HIV drug resistance.
- Elucidate the liver microenvironment in distinct stages of chronic HBV and the impact of HBV viral infection on the immunological response.
- Measure the size of the latent HBV reservoir and design targeted approaches to eradicate the persistent reservoir (e.g., cccDNA, iDNA)
- Evaluate the impact of HIV and HIV treatment on cccDNA and iDNA.
- Determine the clinical impact of HBV iDNA on the immune response.
- Discover and develop new surrogate markers that predict progression through the different stages of chronic HBV, including the immune response, inflammation (e.g., hepatic flares), liver injury and indicators and predictors of treatment response.
- Develop non-invasive diagnostic tools to assess stages of HBV disease progression, liver injury, and hepatic flares.

Each application will provide expertise, infrastructure, and capacity to conduct international clinical studies (either at the PD(s)/PI(s) organization or through collaborations and sub-contracts). Clinical site(s) must be in locations with high incidence and/or prevalence of chronic HBV in PLWH. Clinical sites must have an established infrastructure, including experienced local investigators capable of conducting multi-disciplinary clinical studies that meet US regulatory requirements for the protection of human subjects; adequate laboratory facilities and personnel to perform protocol-specific tests; access to patient populations that are suitable to study people living with HBV and HIV; track record of successful enrollment of volunteers (with HBV presenting with disease, with HBV and HIV presenting with disease, and appropriate comparison groups) in clinical studies; expertise in virology and immunology.

Applicants are strongly encouraged to leverage existing clinical data and sample repositories from previously funded cohort studies, to include, but not limited to: Multicenter AIDS Cohort Study and the Women's Interagency HIV Study (MACS/WIHS) Combined Cohort Study; African Cohort Study (AFRICOS); Hepatitis B Research Network (HBRN); AIDS Clinical Trials Group Longitudinal Linked Randomized Trials (ALLRT); D.C. Cohort Longitudinal HIV Study (DC cohort); CFAR Network of Integrated Clinical Systems (CNICS).

Applications on the following research topics will be considered non-responsive and will not be reviewed:

- Clinical trials (all phases)
- Adding patients to an already established cohort
- Hepatitis viruses other than HBV
- Applications that do not include patients living with HIV
- Applications that do not include both HBV clinical research and basic or translational projects
- Applications that do not include a biorepository Shared Resource Core
- Applications that focus on epidemiologic studies

Program Components:

Administrative Core:
Each application will include an Administrative Core, led by the PD(s)/PI(s), to manage and coordinate all activities to ensure project timelines and objectives are met. The Administrative Core will include a Program Management Plan that will guide its operations and activities as well. The Core will also be responsible for carrying out activities described in the Data Management and Sharing Plan. The Administrative Core will also be responsible for organizing an annual programmatic meeting for all investigators and NIAID staff.

After award, applicants, in collaboration with NIAID Program Staff, will establish a Scientific Advisory Board (SAB). The SAB will assist in review of research productivity, progress toward the proposed goals, adherence to timelines, and the continued relevance of the research approach. The SAB may recommend new scientific directions or re-prioritization of research as appropriate. Please do not include names of potential members of the SAB in the application or contact them prior to the award and without consultation of NIAID Program Staff.

Scientific Core:
Each Scientific Core will provide shared support services and is required to be utilized by two Research Projects. Scientific Cores in virology, immunology and multi-omics are strongly encouraged. Other examples include, but are not limited, specialized services (e.g., metabolomics, bioinformatics, statistics), and molecular or microbiology laboratories. Scientific Cores may not conduct research independent of the proposed Research Projects.

Shared Resource Core(s):
Each application must include one Shared Resource Core that is required to establish a biorepository for the observational cohort and will provide for the long-term storage of quality clinical samples (e.g., serum, plasma, blood, tissue etc.) generated by each Research Project and ensure future access to these samples. Applicants may propose, but are not required to, up to one more Shared Resource Core to meet the needs of the Research Projects. Examples of other Shared Resource Cores include, but are not limited to, image databases (e.g., Fibroscan), compound libraries, chemical synthesis, immunology, and microbiology support. Each Shared Resource Core proposed will provide scientific or clinical services to at least two Research Projects and should not duplicate services provided by Scientific Cores.

Statistical and Data Management Center:
Each application will include a Statistical and Data Management Center providing support for all proposed Research Projects. The Statistical and Data Management Center will collect, manage, and store data generated at all Clinical Sites and Laboratories, ensuring uniformity of procedures and statistical measurements. The Statistical and Data Management Center will be responsible for the release of datasets, in adherence to the requirements and timelines described in the Final NIH Policy for Data Management and Sharing (NOT-OD-21-013 (https://grants.nih.gov/grants/guide/notice-files/not-od-21-013.html)). The Center will also be responsible for the release of analytical tools and other resources that impact the broader scientific community.

Research Projects
Applications will propose at least two synergistic Research Projects (at least one clinical and one basic or translational) that meet the goals of the initiative to develop HBV cure strategies:

- Elucidate mechanisms of persistence and pathogenesis
- Discover and develop clinically relevant biomarkers
- Discover and/or validate host and/or new viral drug targets
- Develop non-invasive diagnostics

Please refer to the NIH Glossary (https://grants.nih.gov/grants/glossary.htm) for the definitions of Basic Research, Clinical Research, and Translational Research

Applicants are highly encouraged to contact the Scientific/Research Contacts to discuss their application and arrange a pre-application meeting prior to submission of their application.

Plan for Enhancing Diverse Perspectives (PEDP)

This NOFO requires a Plan for Enhancing Diverse Perspectives (PEDP) as part of the application (see further below). Applicants are strongly encouraged to read the NOFO instructions carefully and view the available PEDP guidance material (https://braininitiative.nih.gov/about/plan-enhancing-diverse-perspectives-pedp). Applications must include a Plan for Enhancing Diverse Perspectives (PEDP) submitted as Other Project Information as an attachment (see Section IV). The PEDP will be assessed as part of the scientific and technical peer review evaluation, as well as considered among programmatic matters with respect to funding decisions.
See Section VIII. Other Information for award authorities and regulations.

Section II. Award Information

Funding Instrument

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

Application Types Allowed

New

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 NOFO.

Clinical Trial?

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

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

Funds Available and Anticipated Number of Awards

NIAID intends to commit $6 million in FY 2025 to fund 1-3 awards.

Award Budget

Application budgets are not limited but need to reflect the actual needs of the proposed 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 NOFO.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

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

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

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

Nonprofits Other Than Institutions of Higher Education

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

For-Profit Organizations

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

Local Governments

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

Federal Governments

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

Foreign Institutions

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

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

Foreign components, as defined in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/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 Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications (//grants.nih.gov/grants/guide/url_redirect.htm?id=82423) 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.
- eRA Commons (https://era.nih.gov/) - 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.
- Grants.gov (//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. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support. Individuals from diverse backgrounds, including underrepresented racial and ethnic groups, individuals with disabilities, and women are always encouraged to apply for NIH support. 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.

2. Cost Sharing

This NOFO does not require cost sharing as defined in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11126).

3. Additional Information on Eligibility

Number of Applications

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

NIH will not accept duplicate or highly overlapping applications under review at the same time per NIH Grants Policy Statement Section 2.3.7.4 Submission of Resubmission Application (//grants.nih.gov/grants/guide/url_redirect.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 (//grants.nih.gov/grants/guide/url_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 or an institutional system-to-system solution. A button to apply using ASSIST is available in Part 1 of this NOFO. See the administrative office for instructions if planning to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the Multi-Project (M) Instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400), except where instructed in this notice of funding opportunity to do otherwise and where instructions in the Application Guide are directly related to the Grants.gov downloadable forms currently used with most NIH opportunities. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Letter of Intent

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

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

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

The letter of intent should be sent to:

Kristina Wickham, PhD
Telephone: 301-761-5390
Email: kristina.wickham@nih.gov (mailto:kristina.wickham@nih.gov)

Page Limitations

All page limitations described in the SF424 Application Guide and the Table of Page Limits (https://grants.nih.gov/grants/guide/url_redirect.htm?id=61134) must be followed.

Component	Component Type for Submission	Page Limit	Required/Optional	Minimum	Maximum
Overall	Overall	12	Required	1	1
Administrative Core	Admin Core	12	Required	1	1
Scientific Cores	Core	12	Required	2	4
Shared Resource Core(s)	Shared Resource	12	Required	1	2
Statistical and Data Management Center	Data Center	6	Required	1	1
Research Projects	Project	12	Required	2	3

Instructions for the Submission of Multi-Component Applications

The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing a multi-component application.

The application should consist of the following components:

- Overall: Required
- Administrative Core: required (maximum 1)
- Scientific Cores: required (minimum 2, maximum 4)
- Shared Resource Core(s): required (minimum 1, has to be a biorepository, maximum 2)
- Statistical and Data Management Center: required (maximum 1)
- Research Projects: Required (minimum of 2, one clinical and one basic or translational, maximum 3)

Overall Component

When preparing the application, use Component Type 'Overall'.

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

SF424(R&R) Cover (Overall)

Complete entire form.

PHS 398 Cover Page Supplement (Overall)

Note: Human Embryonic Stem Cell lines from other components should be repeated in cell line table in Overall component.

Research & Related Other Project Information (Overall)

Follow standard instructions, with the following additional instructions:

Other Attachments

Plan for Enhancing Diverse Perspectives (PEDP)

In an "Other Attachment" entitled "Plan for Enhancing Diverse Perspectives," all applicants must include a summary of strategies to advance the scientific and technical merit of the proposed project through expanded inclusivity. The PEDP should provide a holistic and integrated view of how enhancing diverse perspectives is viewed and supported throughout the application and can incorporate elements with relevance to any review criteria (significance, investigator(s), innovation, approach, and environment) as appropriate. Where possible, applicant(s) should align their description with these required elements within the research strategy section. The PEDP will vary depending on the scientific aims, expertise required, the environment and performance site(s), as well as how the project aims are structured. The PEDP may be no more than 1-page in length and should include a timeline and milestones for relevant components that will be considered as part of the review. Examples of items that advance inclusivity in research and may be part of the PEDP can include, but are not limited to:

- Discussion of engagement with different types of institutions and organizations (e.g., research-intensive, undergraduate-focused, minority-serving, community-based).
- Description of any planned partnerships that may enhance geographic and regional diversity.
- Plan to enhance recruiting of women and individuals from groups historically under-represented in the biomedical, behavioral, and clinical research workforce.
- Proposed monitoring activities to identify and measure PEDP progress benchmarks.
- Plan to utilize the project infrastructure (i.e., research and structure) to support career-enhancing research opportunities for diverse junior, early- and mid-career researchers.
- Description of any training and/or mentoring opportunities available to encourage participation of students, postdoctoral researchers, and co-investigators from diverse backgrounds.
- Plan to develop transdisciplinary collaboration(s) that require unique expertise and/or solicit diverse perspectives to address research question(s).
- Publication plan that enumerates planned manuscripts and proposed lead authorship.
- Outreach and planned engagement activities to enhance recruitment of individuals from diverse groups as research participants including those from under-represented backgrounds.

For further information on the Plan for Enhancing Diverse Perspectives (PEDP), please see https://braininitiative.nih.gov/about/plan-enhancing-diverse-perspectives-pedp (https://braininitiative.nih.gov/about/plan-enhancing-diverse-perspectives-pedp).

Project/Performance Site Locations (Overall)

Enter primary site only.

A summary of Project/Performance Sites in the Overall section of the assembled application image in eRA Commons compiled from data collected in the other components will be generated upon submission.

Research and Related Senior/Key Person Profile (Overall)

Include only the Project Director/Principal Investigator (PD/PI) and any multi-PDs/PIs (if applicable to this NOFO) for the entire application.

The biosketch(es) should include a description of the PD(s)/PI(s) prior leadership and management experience with complex, multidisciplinary international collaborations, including development of clinical cohorts, that demonstrate their ability to accomplish the proposed work and advance research.

A summary of Senior/Key Persons followed by their Biographical Sketches in the Overall section of the assembled application image in eRA Commons will be generated upon submission.

Budget (Overall)

The only budget information included in the Overall component is the Estimated Project Funding section of the SF424 (R&R) Cover.

A budget summary in the Overall section of the assembled application image in eRA Commons compiled from detailed budget data collected in the other components will be generated upon submission.

PHS 398 Research Plan (Overall)

Specific Aims:

Describe the overall objectives of the proposed research and how the specific aims and hypotheses will drive the research program. When applicable designate which specific aims or projects will be conducted by each Institution.

Research Strategy:

- Summarize the overarching theme of the proposed observational cohort and explain how the work proposed advances the understanding of HBV virology, immunology, and/or cure strategies, addresses longstanding obstacles, or key biomedical questions in HBV and HIV co-infection research, while highlighting the innovation, significance, and emerging concepts of the proposed research and technology development.
- Describe the incidence and/or prevalence of chronic HBV in PLWH for the population to be enrolled at the proposed clinical sites and evaluated at associated laboratories. Provide the location, including country and region, for each site and associated laboratory. Describe the capacity to conduct international clinical studies at the site, including the track record of successful enrollment (with HBV presenting with disease, with HBV and HIV presenting with disease, and appropriate comparison groups) and the capacity to evaluate clinical samples from international clinical studies at the associated laboratory.
- Describe the primary viral isolates to be collected and the impact of different geographical areas on the host response in persons living with HBV or HBV and HIV.
- Describe how the individual projects (at least one basic or translational research project and at least one clinical research project) and cores synergize to achieve the overall goals of the application.
- Describe the overall scope of the research program and how the research team will leverage existing cohort samples and/or clinical data and specimens to address research hypotheses.
- Describe how the established infrastructure and expertise will support the proposed Research Projects.
- Describe how the biological specimens and clinical data collected from individuals will be obtained and used to address the proposed hypotheses of the research.
- Provide a timeline for implementation of the proposed research that includes all research partners included in the application.
- Describe how the partnerships and collaborations involved will lead to critical new knowledge about HBV cure in people living with HIV.

Letters of Support:

Applicants should provide letters of support from relevant organizations and collaborators who are lending their expertise or resources to all components (e.g., Research Projects, Cores) of the program.

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. If required, the Data Management and Sharing (DMS) Plan must be provided in the Overall component.

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 items are allowed in the Appendix. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide; any instructions provided here are in addition to the SF424 (R&R) Application Guide instructions.

PHS Human Subjects and Clinical Trials Information (Overall)

When involving human subjects research, clinical research, and/or NIH-defined clinical trials 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, there must be at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or a **Delayed Onset Study** record within the application. The study record(s) must be included in the component(s) where the work is being done, unless the same study spans multiple components. To avoid the creation of duplicate study records, a single study record with sufficient information for all involved components must be included in the Overall component when the same study spans multiple components.

Study Record: PHS Human Subjects and Clinical Trials Information

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

Delayed Onset Study

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

PHS Assignment Request Form (Overall)

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

Administrative Core

When preparing your application, use Component Type 'Admin Core'.

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

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. If required, the Data Management and Sharing (DMS) Plan must be provided in the Overall component.

SF424 (R&R) Cover (Administrative Core)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Administrative Core)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Administrative Core)

Human Subjects: Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

Vertebrate Animals: Answer only the 'Are Vertebrate Animals Used?' question.

Project Narrative: Do not complete. Note: ASSIST screens will show an asterisk for this attachment indicating it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components.

Project /Performance Site Location(s) (Administrative Core)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites. prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Administrative Core)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Core Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

Budget (Administrative Core)

Budget forms appropriate for the specific component will be included in the application package.

PEDP implementation costs: Applicants may include allowable costs associated with PEDP implementation (as outlined in the Grants Policy Statement section 7 (https://grants.nih.gov/grants/policy/nihgps/html5/section_7/7.1_general.htm)).

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Administrative Core)

Specific Aims: List in priority order, the broad, long-range objectives and goals of the proposed Administrative Core

Research Strategy:

- Describe the organizational structure of the Administrative Core.
- Describe plans and procedures for establishing and managing an Administrative Core that provides the organizational capacity for the following:
  - Coordinating, supervising, and managing all observational cohort activities.
  - Establishing and monitoring overall progress of Shared Resource Core(s) (e.g., biorepository) and Data Management and Sharing Plan.
  - Assisting Core and Research Project Leaders with administrative aspects of their projects, such as gathering of annual progress reports, and monitoring progress.
  - Organizing annual programmatic meetings, site visits, and teleconference calls.
- Describe the plan for how the research team will incorporate early-stage investigators, including research track investigators, staff scientists, and Assistant Professors.
- Describe the overall administrative and management plan as it applies to fiscal accountability, and communication plans.
- Describe processes for coordination and making decisions on scientific direction, procedures for problem identification/resolution and resolving conflicts, contingency plans related to potential setbacks and delays, and approach to establishing a strong collaborative environment for the Program.
- Describe how resources, including access to clinical samples and data, will be managed and organized.
- Describe plan to hold annual SAB meeting (including NIH Program representatives) to review progress, plan and design activities and establish priorities, and update implementation of PEDP.

Resources Sharing Plan:

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

Appendix:

Only limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide; any instructions provided here are in addition to the SF424 (R&R) Application Guide instructions.

PHS Human Subjects and Clinical Trials Information (Administrative Core)

When involving human subjects research, clinical research, and/or NIH-defined clinical trials 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 a **Delayed Onset Study** record.

Study Record: PHS Human Subjects and Clinical Trials Information

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

Delayed Onset Study

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

Scientific Cores

When preparing your application, use Component Type 'Core'.

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

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. If required, the Data Management and Sharing (DMS) Plan must be provided in the Overall component.

SF424 (R&R) Cover (Scientific Cores)

Complete only the following fields:

- Applicant Information

- Type of Applicant (optional)
- Descriptive Title of Applicant's Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Scientific Cores)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Scientific Cores)

Human Subjects: Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

Vertebrate Animals: Answer only the 'Are Vertebrate Animals Used?' question.

Project Narrative: Do not complete. Note: ASSIST screens will show an asterisk for this attachment indicating it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components.

Project /Performance Site Location(s) (Scientific Cores)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Scientific Cores)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Core Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

Budget (Scientific Cores)

Budget forms appropriate for the specific component will be included in the application package.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Scientific Cores)

Specific Aims: List in priority order, the broad, long-range objectives and goals of the proposed Scientific Core.

Research Strategy:

Provide details of the services or resources provided by the scientific core to support at least two Research Projects, and how the core is relevant to the primary theme of the application. Scientific Cores in virology, immunology and/or multi-omics are strongly encouraged.

- Describe the relationship of the Scientific Core(s) to the central focus of the overall Program and clarify how the Scientific Core(s) is/are not duplicative of other services or facilities provided by the other cores and synergize(s) with the research projects to maximize research efficiency.
- Describe how the provision of resources and proposed core services and activities are critical to meeting the objectives of the Research Projects and the overall Program.
- For each technology and/or multi-omics approach, explain the rationale for selection of the general methods and approaches proposed to accomplish the specific aims. Include quality control measures and criteria for prioritization and usage of the proposed Scientific Core resources.

Resources Sharing Plan:

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

Appendix:

Only limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide; any instructions provided here are in addition to the SF424 (R&R) Application Guide instructions.

PHS Human Subjects and Clinical Trials Information (Scientific Cores)

When involving human subjects research, clinical research, and/or NIH-defined clinical trials 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 a **Delayed Onset Study** record.

Study Record: PHS Human Subjects and Clinical Trials Information

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

Delayed Onset Study

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

Shared Resource Core(s)

When preparing your application, use Component Type 'Shared Resource'.

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

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. If required, the Data Management and Sharing (DMS) Plan must be provided in the Overall component.

SF424 (R&R) Cover (Shared Resource Core(s))

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Shared Resource Core(s))

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Shared Resource Core(s))

Human Subjects: Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

Vertebrate Animals: Answer only the 'Are Vertebrate Animals Used?' question.

Project Narrative: Do not complete. Note: ASSIST screens will show an asterisk for this attachment indicating it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components.

Project /Performance Site Location(s) (Shared Resource Core(s))

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Shared Resource Core(s))

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Core Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

Budget (Shared Resource Core(s))

Budget forms appropriate for the specific component will be included in the application package.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Shared Resource Core(s))

Specific Aims: List in priority order the timeline, structure, and goals of the proposed Shared Resource Core(s).

Research Strategy:

Describe how the activities of the Shared Resource Core(s) contribute to meeting the Program's goals and objectives.

Biorepository Shared Resource Core (required)

- Describe how participants will be recruited and enrolled either by providing evidence of a collaboration/partnership or by utilizing existing infrastructure in the region (e.g., clinical research sites and laboratories) and strictly follow international standards for human sample collection.
- Discuss how the clinical samples and data will be collected, managed, analyzed, and shared to be compliant with international standards when establishing the biorepository. Include process for specimen labeling, coding, tracking, archiving and quality assurance.
- Describe the infrastructure of the biorepository, including, but not limited to, the following:
    - dedicated space and room details
    - maintenance, including heating, air conditioning, water purification systems and any other specialized electrical or mechanical services required
    - electrical set-up, including voltage, surge-protection, and back-up requirements
    - capacity for storage, maintenance, quality control, and distribution of samples based upon the informed consent and policy
    - equipment, including but not limited to, mechanical and nitrogen vapor freezers, liquid nitrogen tanks, laminar flow hoods, incubators, and specialized equipment
    - back-up plans to ensure continued biorepository function at all times.
- Describe the plan for biospecimen receipt, processing, storage, and distribution.
- Describe quality control and assurance approaches that certify the integrity and authenticity of each sample and how the biorepository will test, monitor, and ensure the continuous safekeeping of the collected specimens.
- Describe the plan for integration of human clinical specimens from each observational cohort and clinical site proposed, including considerations for import/export of specimens across international borders and all regulatory and material transfer agreements required for each clinical site.
- Discuss the plan for long-term sustainability of the biorepository for future research use.

Non-biorepository Shared Resource Core (optional)

If a non-biorepository Shared Resource Core is proposed (e.g., image databases (e.g., Fibroscan), compound libraries, chemical synthesis, immunology, and microbiology support):

- Clarify how the Shared Resource Core is not duplicative of other services or facilities provided by the other cores and synergizes with the Research Projects to maximize research efficiency.
- Describe how the proposed Core activities will contribute to meeting the Research Project objectives, including rationale for use of methodologies, technologies, and approaches

Resources Sharing Plan:

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

Appendix:

Only limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide; any instructions provided here are in addition to the SF424 (R&R) Application Guide instructions.

PHS Human Subjects and Clinical Trials Information (Shared Resource Core(s))

When involving human subjects research, clinical research, and/or NIH-defined clinical trials 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 a **Delayed Onset Study** record.

Study Record: PHS Human Subjects and Clinical Trials Information

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

Delayed Onset Study

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

Statistical and Data Management Center

When preparing your application, use Component Type 'Data Center'.

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

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. If required, the Data Management and Sharing (DMS) Plan must be provided in the Overall component.

SF424 (R&R) Cover (Statistical and Data Management Center)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Statistical and Data Management Center)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Statistical and Data Management Center)

Human Subjects: Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

Vertebrate Animals: Answer only the 'Are Vertebrate Animals Used?' question.

Project Narrative: Do not complete. Note: ASSIST screens will show an asterisk for this attachment indicating it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components.

Project /Performance Site Location(s) (Statistical and Data Management Center)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites. prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Statistical and Data Management Center)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Core Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

Budget (Statistical and Data Management Center)

Budget forms appropriate for the specific component will be included in the application package.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Statistical and Data Management Center)

Specific Aims: List in priority order the objectives and goals of the proposed Statistical and Data Management Center, the relationship to the Administrative Core, and how the Center supports the individual Research Projects or other Cores in the application.

Research Strategy:

- Describe the organizational structure and role of the Statistical and Data Management Center in research activities.
- Describe the plans for implementation of the data management system, as well as the time frame to achieve a fully operational data management system with appropriately qualified personnel.
- Describe the Strategy for Management of Data Activities Plan that describes internal and external data acquisition strategies and procedures for data management, data quality, data analyses, and dissemination for all data and data-related materials generated by the Center.
- Describe the integration of data for each independent cohort, cores, and research projects, including considerations for international data sharing (without duplicating what is in the Data Management Sharing Plan), collaboration and adherence to ethical and regulatory requirements that ensure uniformity of procedures and statistical measurements.
- Describe the quality control procedures for the data, and how to identify and resolve issues with quality control that maintains data integrity.
- Describe plans to provide biostatistical support to meet the Program's objectives.

Resources Sharing Plan:

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

Appendix:

Only limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide; any instructions provided here are in addition to the SF424 (R&R) Application Guide instructions.

PHS Human Subjects and Clinical Trials Information (Statistical and Data Management Center)

When involving human subjects research, clinical research, and/or NIH-defined clinical trials 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 a **Delayed Onset Study** record.

Study Record: PHS Human Subjects and Clinical Trials Information

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

Delayed Onset Study

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

Research Projects:

When preparing your application, use Component Type 'Project'.

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

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. If required, the Data Management and Sharing (DMS) Plan must be provided in the Overall component.

SF424 (R&R) Cover (Research Projects)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Research Projects)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Research Projects)

Human Subjects: Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

Vertebrate Animals: Answer only the 'Are Vertebrate Animals Used?' question.

Project Narrative: Do not complete. Note: ASSIST screens will show an asterisk for this attachment indicating it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components.

Project /Performance Site Location(s) (Research Projects)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Research Projects)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Project Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

Budget (Research Projects)

Budget forms appropriate for the specific component will be included in the application package.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Research Projects)

Specific Aims: Describe the broad objectives and goals of the proposed Research Project. Concisely and realistically describe the hypothesis or hypotheses to be tested. State the Project's relationship to the overall research program's goals and how they synergize with other Research Projects.

Research Strategy:

- Discuss relevant knowledge gaps and include a description of how the research will advance scientific knowledge, technical capabilities, or how it might influence clinical practices.
- Discuss the availability of and the rationale for selecting samples, methods, and technologies for accomplishing the project's aims. As applicable, include descriptions of new methodologies, their advantages, and limitations over existing ones, including alternative approaches.
- Include a description of the prior research that serves as the key support for the proposed project.
- Describe how the research projects incorporate new technologies, including state-of-the-art multi-omics platforms and bioinformatics analyses tools and pipelines.
- Include timelines for each Research Project that address all research activities and include data generation, analysis, integration, and timelines for receiving samples from collaborators.

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.

Appendix:

Only limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide; any instructions provided here are in addition to the SF424 (R&R) Application Guide instructions.

PHS Human Subjects and Clinical Trials Information (Research Projects)

When involving human subjects research, clinical research, and/or NIH-defined clinical trials 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 a **Delayed Onset Study** record.

Study Record: PHS Human Subjects and Clinical Trials Information

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

Delayed Onset Study

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

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

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

Organizations must submit applications to Grants.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=11128) (the online portal to find and apply for grants across all Federal agencies) using ASSIST or other electronic submission systems. Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications (//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 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 *NIH Grants Policy Statement* (//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.

For information on how applications will be automatically assembled for review and funding consideration after submission, refer to: http://grants.nih.gov/grants/ElectronicReceipt/files/Electronic_Multi-project_Application_Image_Assembly.pdf (//grants.nih.gov/grants/ElectronicReceipt/files/Electronic_Multi-project_Application_Image_Assembly.pdf).

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). 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, contact the Application Submission Contacts in Section VII.

Important reminders:

All PD(s)/PI(s) and component Project Leads 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.

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 (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400).

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

Applications must include a PEDP submitted as Other Project Information as an attachment. Applications that fail to include a PEDP will be considered incomplete and will be withdrawn before review.

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 - Overall

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 - Overall

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

Significance

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

Specific to this NOFO:

To what extent do the efforts described in the Plan for Enhancing Diverse Perspectives further the significance of the project?

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 NOFO:

- To what extent does the PD(s)/PI(s) have prior leadership and management experience with complex, multidisciplinary international collaborations, including development of clinical cohorts, that demonstrate their ability to accomplish the proposed work and advance research?
- To what extent will the efforts described in the Plan for Enhancing Diverse Perspectives strengthen and enhance the expertise required for the project?

Innovation

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

Specific to this NOFO:

- If included, how well do the research projects incorporate new technologies and/or state of the art multi-omics strategies to address the proposed hypotheses?
- To what extent will the efforts described in the Plan for Enhancing Diverse Perspectives meaningfully contribute to innovation?

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 NOFO:

- To what extent do the clinical Research Project(s) and basic/translational Research Project(s) synergize to support the overall goal of the cohort?
- If the use of existing clinical data and sample repositories are included, how well has the applicant described plans to leverage these data from previously funded cohort studies and how adequate is the provided documentation that these resources will be available to investigators?
- Are the timeline and milestones associated with the Plan for Enhancing Diverse Perspectives well-developed and feasible?

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?

Specific to this NOFO:

- To what extent will features of the environment described in the Plan for Enhancing Diverse Perspectives (e.g., collaborative arrangements, geographic diversity, institutional support) contribute to the success of the project?

Overall Impact – Research Projects

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 – Research Projects

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?

Investigator(s)

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

Innovation

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

Approach

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

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address:

1. the protection of human subjects from research risks, and
2. inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of individuals of all ages (including children and older adults), justified in terms of the scientific goals and research strategy proposed?

Environment

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

Overall Impact – Individual Cores and Center

Reviewers will provide an overall impact score for each Core or Center to reflect their assessment of the likelihood for the Core or Center to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria.

Review Criteria – Individual Cores and Center

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the Core or Center activities to meet the needs of individual Research Projects or other Cores, and to contribute to Program goals and objectives, in consideration of the following points (as applicable to the Core or Center proposed).

Administrative Core

- How appropriate and adequate is the administrative and organizational structure of the Administrative Core to the attainment of the objective(s) of the proposed Program?
- How appropriate is the management plan for fiscal accountability and communication within the Program?
- How appropriate are the plans for coordination, problem identification and resolution, and the establishment of a strong collaborative environment for the Program?
- How adequate are the experience and availability of the Administrative Core Leader and administrative staff to manage the Program?

Scientific Core(s)

- To what extent are provision of resources and Core services for the individual Research Projects critical and justified for inclusion in the Program?
- How strong is the relationship of the Scientific Core(s) to the central focus of the overall Program?
- How well will the provided facilities or services of the Scientific Core serve the objectives of the overall program? How well will these services be prioritized and utilized?
- How adequate are the qualifications and expertise of the Core Leader(s) and key personnel to manage and advance the aims of the Core?

Shared Resource Core(s)

- How adequate are the qualifications and expertise of the Core Leader(s) and key personnel to manage and advance the aims of the Core?
- To what degree will the Core activities contribute to meeting the Program's goals and objectives?
- How appropriate is the rationale for selecting methodologies, technologies, and approaches to support the Research Projects?
- How adequate is the description for long-term sustainability and use of the biorepository?
- How adequate is the description of the data collection procedures, including specimen labeling, coding, tracking, archiving and quality assurance?
- How feasible is the plan for integration of human clinical specimens from each observational cohort and clinical site proposed, including considerations for import/export of specimens across international borders and all regulatory and material transfer agreements required for each clinical site?

Statistical and Data Management Center

- To what degree does the application provide evidence of qualified personnel to collaborate on the design, development, and testing of databases and data management software, validation, maintenance of systems, and documentation of changes and preparations of standard operating procedures?
- How clear and appropriate is the description of planning and implementation of the data management system, as well as the time frame to achieve a fully operational data management system with appropriately qualified personnel?
- How adequate is the evidence presented to show biostatistical support to meet the Program's objectives?

Additional Review Criteria - Overall, Projects, Cores, and Center

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

Protections for Human Subjects

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

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

Inclusion of Women, Minorities, and Individuals Across the Lifespan

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of individuals of all ages (including children and older adults) to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research (//grants.nih.gov/grants/guide/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

Not Applicable

Renewals

Not Applicable

Revisions

Not Applicable

Additional Review Considerations - Overall, Projects, Cores, and Center

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

Applications from Foreign Organizations

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

Select Agent Research

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

Resource Sharing Plans

Reviewers will comment on whether the Resource Sharing Plan(s) (e.g., Sharing Model Organisms (https://sharing.nih.gov/other-sharing-policies/model-organism-sharing-policy#policy-overview)) 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 policies and practices (//grants.nih.gov/grants/guide/url_redirect.htm?id=11154), using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

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

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

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 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, including the PEDP.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the eRA Commons (//grants.nih.gov/grants/guide/url_redirect.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 (//grants.nih.gov/grants/guide/url_redirect.htm?id=82416).

Section VI. Award Administration Information

1. Award Notices

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

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

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

Any application awarded in response to this NOFO will be subject to terms and conditions found on the Award Conditions and Information for NIH Grants (https://grants.nih.gov/grants/policy/nihgps/HTML5/part_ii_subpart_b.htm) 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: Grantee 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 Grant Awards, Subpart A: General (//grants.nih.gov/grants/guide/url_redirect.htm?id=11157) and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities (//grants.nih.gov/grants/guide/url_redirect.htm?id=11159), including of note, but not limited to:

- Federal-wide Standard Terms and Conditions for Research Grants (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_3/3.1_federalwide_standard_terms_and_conditions_for_research_grants.htm)
- Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment (//grants.nih.gov/grants/guide/url_redirect.htm?id=82417)
- 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 Assurance of Compliance form (HHS 690) (https://ocrportal.hhs.gov/ocr/aoc/instruction.jsf)) in which the recipient agrees, as a condition of receiving the grant, to administer 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. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html (https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.hhs.gov%2Fcivil-rights%2Ffor-providers%2Fprovider-obligations%2Findex.html&data=05%7C01%7Ccarrie.mitchell%40nih.gov%7Ce8bc304bfdb644bb556e08dac343ad36%7C14b77578977342d58507251ca2dc2b06%7C0%7C0%7C63803699

and https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html (https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.hhs.gov%2Fcivil-rights%2For-individuals%2Fnondiscrimination%2Findex.html&data=05%7C01%7Ccarrie.mitchell%40nih.gov%7Ce8bc304bfdb644bb556e08dac343ad36%7C14b77578977342d58507251ca2dc2b06%7C

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 NOFO.

- For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html (https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html)andhttps://www.lep.gov (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/conscience-protections/index.html (https://www.hhs.gov/conscience/conscience-protections/index.html) and https://www.hhs.gov/conscience/religious-freedom/index.html (https://www.hhs.gov/conscience/religious-freedom/index.html).

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

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (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

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

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

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

- Planning, directing, and executing the proposed research in accordance with the proposed timeline
- Communication with the NIH Project Scientist regarding the status of ongoing research
- Communication with the NIH Program Officer regarding changes in key personnel, changes in research plans, etc.
- Timely presentation/publication of work supported in part or whole by this Cooperative Agreement and appropriate acknowledgement of NIH support
- Holding an annual SAB meeting to review progress, plan and design activities, and establish priorities, to include NIH Program representatives
- Integrating and implementing the recommendations from the SAB into the research plan
- Timely acquisition of any proprietary rights, including intellectual property rights, and all materials appropriate for performing the project(s)
- As part of the annual progress report, providing a summary outlining interaction among the group members and with the NIH Project Scientist(s)
- Providing updates at least annually on implementation of the PEDP
- Recipients will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and NIH policies

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

- The Project Scientist will advise on the scientific and technical performance of the program, will provide guidance for the scientific areas of the research project, and coordinate with other appropriate NIH staff to provide advice or assistance to the awardee on specific scientific or technical issues
- The Project Scientist will facilitate interactions between the awardee and other groups of importance to the awardee. Examples include, but are not limited to, NIAID Clinical Trial Networks, pharmaceutical and/or biotechnology companies
- Additionally, an agency Program Official or IC program director will serve as the NIAID Program Officer, responsible for the normal scientific and programmatic stewardship of the award, and will be named in the award notice
- Both the NIAID Project Scientist and Program Officer will participate in the kick-off meeting, annual SAB meetings, webinars, teleconferences, and other meetings as appropriate
- The NIAID Program Officer and Project Scientist will not participate as a co-author on any publications resulting from the research

Areas of Joint Responsibility include:

- Scientific Advisory Board (SAB): Within six months of award, the PD/PI, in consultation with the NIAID Project Scientist, will establish the Scientific Advisory Board (SAB). The PD/PI and the NIAID Project Scientist will share the responsibility for establishing the membership of the SAB. Members of the SAB are expected to attend the annual SAB meeting. For each SAB meeting, a chairperson of the SAB will be selected to provide the PD(s)/PI(s) with a comprehensive written evaluation of research progress and activities, including the Board's recommendations, within 30 days of the annual meeting.

Dispute Resolution:

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

3. 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). Upon the approval of a Data Management and Sharing Plan, it is required for recipients to implement the plan as described.

4. Reporting

When multiple years are involved, recipients will be required to submit the Research Performance Progress Report (RPPR) (//grants.nih.gov/grants/rppr/index.htm) annually and financial statements as required in the NIH Grants Policy Statement. (//grants.nih.gov/grants/guide/url_redirect.htm?id=82419)

A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the NIH Grants Policy Statement (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.6_closeout.htm). 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 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 the threshold. See the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=82420) for additional information on this reporting requirement.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and 2 CFR Part 200.113 and Appendix XII to 45 CFR Part 75 and 2 CFR Part 200, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than $10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently 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 75and 2 CFR Part 200 – Award Term and Condition for Recipient Integrity and Performance Matters.

Section VII. Agency Contacts

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

Application Submission Contacts

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

Finding Help Online: https://www.era.nih.gov/need-help (https://www.era.nih.gov/need-help) (preferred method of contact)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

General Grants Information (Questions regarding application instructions, application processes, and NIH grant resources)
Email: GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov) (preferred method of contact)
Telephone: 301-637-3015

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)
Contact Center Telephone: 800-518-4726
Email: support@grants.gov (mailto:support@grants.gov)

Scientific/Research Contact(s)

Josh Radke, PhD
National Institute of Allergy and Infectious Disease (NIAID)
Telephone: 301-761-6525
Email: josh.radke@nih.gov (mailto:josh.radke@nih.gov)

Peer Review Contact(s)

Kristina S. Wickham, Ph.D.
National Institute of Allergy and Infectious Diseases (NIAID)
Telephone: 301-761-5390
Email: kristina.wickham@nih.gov (mailto:kristina.wickham@nih.gov)

Financial/Grants Management Contact(s)

Svetlana Alperovich
National Institute of Allergy and Infectious Diseases (NIAID)
Telephone: 301-761-6895
Email: svetlana.alperovich@nih.gov (mailto:svetlana.alperovich@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?10-13-23)
NIH Funding Opportunities and Notices (/grants/guide/index.html)

National Institutes of Health (//grants/oer.htm)
Office of Extramural Research
(http://www.hhs.gov/) Department of Health and Human Services (HHS)
USA.gov (http://www.usa.gov/)

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

ขั้นตอนการสมัครขอรับทุน National Institute of Health (NIH)

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

   Name: Surname:

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

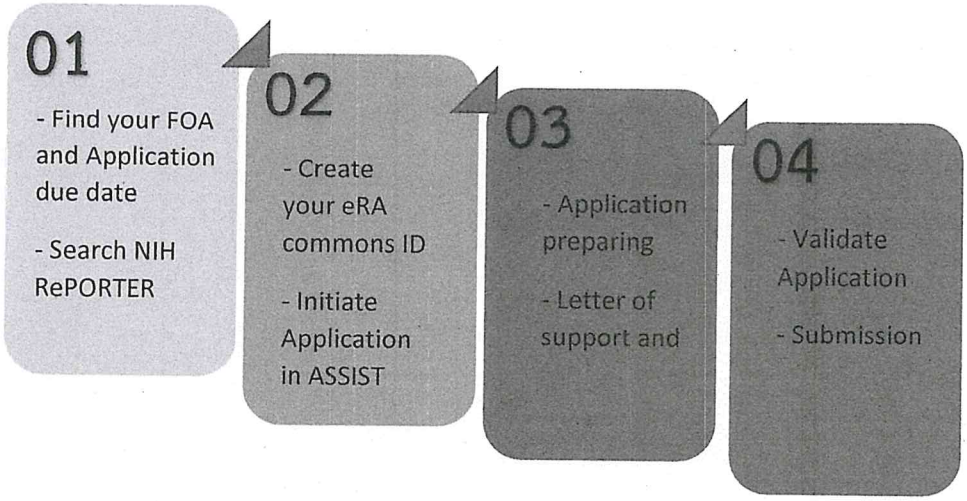
   Funding Opportunity Announcement (FOA) Number:

   Application title:

   Application due date:

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

(**หากผู้สมัครขอรับทุนนำส่งข้อเสนอโครงการให้กองบริหารงานวิจัยตรวจสอบล่าช้ากว่ากำหนดของมหาวิทยาลัย มหาวิทยาลัยขอสงวนสิทธิ์ในการรับข้อเสนอโครงการเพื่อนำส่งแหล่งทุนในรอบนั้นๆ)



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