



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

ที่ อว 78.016/๗1825

วันที่ 12 มีนาคม 2567

เรื่อง ประชาสัมพันธ์การเปิดรับข้อเสนอโครงการ จากแหล่งทุน National Institutes of Health (NIH) ประเภท Research Project Grant หัวข้อ “Impact of Comorbidities and Co-Infections on HIV Reservoirs (R01 Clinical Trial Not Allowed)” หมายเลขประกาศทุน RFA-DK-25-013

- สิ่งที่ส่งมาด้วย
1. รายละเอียดประกาศทุน
  2. ขั้นตอนการสมัครขอรับทุน

เรียน คณบดี / ผู้อำนวยการ

ด้วยแหล่งทุน National Institutes of Health (NIH) เปิดรับข้อเสนอโครงการ ประเภท Research Project Grant หัวข้อ “Impact of Comorbidities and Co-Infections on HIV Reservoirs (R01 Clinical Trial Not Allowed)” หมายเลขประกาศทุน RFA-DK-25-013 โดยเปิดรับข้อเสนอโครงการ ตั้งแต่ วันที่ 30 มิถุนายน 2567 จนถึงวันที่ 30 กรกฎาคม 2567 เวลา 17.00 น. ตามเวลาประเทศไทย ทั้งนี้ โครงการที่เสนอขอทุนให้ปฏิบัติตามประกาศมหาวิทยาลัยมหิดล เรื่องหลักเกณฑ์และอัตราเงินค่าธรรมเนียมพัฒนาการวิจัยของมหาวิทยาลัยและส่วนงานที่จัดเก็บจากโครงการวิจัยที่ได้รับเงินอุดหนุนจากแหล่งทุนภายนอกมหาวิทยาลัย พ.ศ. 2560 และขอให้ดำเนินการตามที่ระบุในหนังสือชักซ้อมแนวปฏิบัติ เรื่องมาตรฐานการวิจัยของโครงการวิจัย รายละเอียดตั้งเอกสารแนบมาด้วยนี้ ทั้งนี้ อาจารย์/นักวิจัยที่สนใจสามารถศึกษารายละเอียดเพิ่มเติมได้ตามเอกสารที่แนบมาด้วยนี้ หรือเว็บไซต์ของแหล่ง <https://grants.nih.gov/grants/guide/rfa-files/rfa-dk-25-013.html>

ในการนี้ กองบริหารงานวิจัย มหาวิทยาลัยมหิดล จึงขอแจ้งข่าวประกาศทุนมายังท่าน เพื่อโปรดประชาสัมพันธ์ทุนวิจัยดังกล่าวให้บุคลากรในหน่วยงานของท่านทราบโดยทั่วกัน และขอให้อาจารย์/นักวิจัยโปรดแจ้งความประสงค์การจัดส่งข้อเสนอโครงการ ภายในวันที่ 28 มิถุนายน 2567 และจัดส่งข้อเสนอโครงการวิจัยผ่านส่วนงานต้นสังกัดมายังกองบริหารงานวิจัยเพื่อตรวจสอบรายละเอียดข้อเสนอโครงการฉบับสมบูรณ์ภายในวันที่ 23 กรกฎาคม 2567 ทั้งนี้ หากส่วนงานจัดส่งข้อเสนอโครงการวิจัยหลังจากวันที่ 23 กรกฎาคม 2567 มหาวิทยาลัยขอสงวนสิทธิ์ในการยื่นข้อเสนอโครงการวิจัยเพื่อขอรับทุนดังกล่าว

จึงเรียนมาเพื่อโปรดทราบและประชาสัมพันธ์ข่าวทุนวิจัยดังกล่าวต่อไปด้วย จักขอบพระคุณยิ่ง

(ศาสตราจารย์ ดร. นายแพทย์ภัทรชัย กีรติสิน)

รองอธิการบดีฝ่ายวิจัย

# Department of Health and Human Services

## Part 1. Overview Information

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### Participating Organization(s)

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

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### Components of Participating Organizations

National Institute of Diabetes and Digestive and Kidney Diseases ([NIDDK \(https://www.niddk.nih.gov/\)](https://www.niddk.nih.gov/))

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

All applications to this funding opportunity announcement should fall within the mission of the Institutes/Centers. The following NIH Offices may co-fund applications assigned to those Institutes/Centers.

Office of Research on Women's Health ([ORWH \(https://orwh.od.nih.gov/\)](https://orwh.od.nih.gov/))

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### Funding Opportunity Title

Impact of Comorbidities and Co-Infections on HIV Reservoirs (R01 Clinical Trial Not Allowed)

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### Activity Code

R01 ([https://grants.nih.gov/grants/funding/ac\\_search\\_results.htm?text\\_curr=r01&Search.x=0&Search.y=0&Search\\_Type=Activity](https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r01&Search.x=0&Search.y=0&Search_Type=Activity)) Research Project Grant

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### Announcement Type

New

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### Related Notices

- **August 31, 2022-** Implementation Changes for Genomic Data Sharing Plans Included with Applications Due on or after January 25, 2023. See Notice [NOT-OD-22-198 \(https://grants.nih.gov/grants/guide/notice-files/not-od-22-198.html\)](https://grants.nih.gov/grants/guide/notice-files/not-od-22-198.html).
- **August 5, 2022-** Implementation Details for the NIH Data Management and Sharing Policy. See Notice [NOT-OD-22-189 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-189.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-189.html).

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### Funding Opportunity Number (FON)

RFA-DK-25-013

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### Companion Funding Opportunity

None

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### Number of Applications

See Section III. 3. Additional Information on Eligibility.

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### Assistance Listing Number(s)

93.847, 93.313, 93.855

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### Funding Opportunity Purpose

This Notice of Funding Opportunity (NOFO) seeks to foster new multi-disciplinary teams to address how HIV Comorbidities and co-infections within the missions of NIDDK and NIAID interact with viral reservoirs, potentially confounding cure strategies aimed at either sustained viral suppression or elimination from the body. These teams will mechanistically interrogate the impact of inflammation, metabolic perturbations,

or other pathophysiological processes associated with these comorbidities or co-infections on reservoir dynamics, and/or the interplay of these conditions and co-infections on HIV reservoir biology in ways that are likely to interact with potential cure strategies.

## Key Dates

### Posted Date

February 29, 2024

### Open Date (Earliest Submission Date)

June 30, 2024

### Letter of Intent Due Date(s)

May 30, 2024

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	July 30, 2024	November 2024	January 2025	April 2025

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

July 31, 2024

### Due Dates for E.O. 12372

Not Applicable

## Required Application Instructions

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

Conformance to all requirements (both in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) and the NOFO) is required and strictly enforced. Applicants must read and follow all application instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400), follow the program-specific instructions.

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

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

1. Use the NIH ASSIST system to prepare, submit and track your application online.

[Apply Online Using ASSIST](#)

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and [eRA Commons \(https://public.era.nih.gov/commons/\)](https://public.era.nih.gov/commons/) to track your application. Check with your institutional officials regarding availability.



3. Use [Grants.gov \(https://grants.gov/search-grants?oppStatuses=closed|archived|posted|forecasted&fon=rfa-dk-25-013\)](https://grants.gov/search-grants?oppStatuses=closed|archived|posted|forecasted&fon=rfa-dk-25-013) Workspace to prepare and submit your application and [eRA Commons \(http://public.era.nih.gov/commons/\)](http://public.era.nih.gov/commons/) to track your application.

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## Part 2. Full Text of Announcement

### Section I. Notice of Funding Opportunity Description

#### Background

Because of the effectiveness of antiretroviral therapy (ART), HIV has become a manageable chronic disease in people with access to healthcare. As people age with HIV, they are developing various comorbidities and coinfections that significantly impact their health and quality of life. Currently, over half of people with HIV (PWH) living in the United States are aged 50 or older, and co-infections and comorbidities within NIDDK's mission are becoming more prevalent within this growing population. These include enteropathy and loss of gastrointestinal homeostasis; noncommunicable liver diseases; hepatitis virus infections; kidney, urologic, and hematologic diseases; and metabolic perturbations, obesity, diabetes, and associated complications; and polypharmacy.

Several anatomical sites within the mission of NIDDK harbor important HIV reservoirs. These include the gastrointestinal mucosa, adipose tissue, kidneys, the genital tract and the liver. Inflammation, metabolic perturbations, and pathophysiological processes associated with NIDDK-relevant co-occurring conditions impact HIV reservoir dynamics and decay and post-treatment control of viremia in affected anatomical sites. In addition, NIDDK-relevant pathogenic processes might impact reservoirs in other tissues and organ systems throughout the body in addition to the diseased organ. For example, loss of intestinal epithelial barrier function associated with HIV-associated enteropathy may result in systemic inflammation that may impact multiple tissue reservoirs. Reservoir dynamics need to be rigorously studied in the context of these mechanisms for cure strategies to be effective in people aging with HIV and comorbidities and co-infections. Current strategies to achieve either ART-free remission or eradication of HIV from the body need to account specifically for a variety of comorbid noncommunicable diseases and co-infections to be effective in PWH that are aging and living with these conditions. Moreover, co-infections such as tuberculosis and hepatitis are more prevalent in populations outside of the United States. However, most current research on HIV cure does not include a focus on the contribution of prevalent comorbidities and co-infections.

Likewise, most cure-related research on HIV has been limited to subtype B viruses despite the higher prevalence of non-subtype B viruses world-wide and their increasing prevalence in the United States. There is some evidence that there are differences in viremic control and reservoir sizes among different subtypes. Therefore, understanding comorbidities and co-infections in the context of diverse HIV subtypes is also an area of need.

Research to address this problem will require synergistic, collaborative interactions between experts in HIV science and researchers with primary expertise in the pathobiology of the comorbidities or co-infections being investigated. This initiative will therefore foster new multi-disciplinary teams to address how comorbidities and co-infections prevalent in PWH interact with viral reservoirs in ways that could confound cure strategies aimed at sustained viral suppression or elimination from the body.

#### Objectives and Scope

In-depth mechanistic interrogations into this problem would benefit from synergistic partnership between Multiple Program Directors/Principal Investigators (PDs/Pis). Therefore, applications submitted to this NOFO must have a multiple PD/PI structure, with at least one PD/PI who has expertise in HIV science and one PD/PI who has expertise in the physiology, pathophysiology, or metabolism of the relevant tissue(s) or process(es). One or more additional PD/PI may also be included if their expertise is key to the success of the project. Because this NOFO is being issued to address the need to develop greater interdisciplinary communication between research communities, there is no expectation that teams necessarily have previous publications with each other or otherwise have a history of extensive previous collaboration.

Appropriate evidence of a strong and dedicated PD/PI team can be provided in the development of the project itself, as reflected in the quality of the preliminary data, the rigor of the approach, and the Multiple PD/PI leadership plan. Studies must use "wet lab" approaches.



Epidemiological research will not be supported by this NOFO. Studies may use animal models or human subjects, specimens, or data. All aspects of the approach must be aligned with the guidelines outlined in [NOT-OD-20-018, UPDATE: NIH HIV/AIDS Research Priorities and Guidelines for Determining HIV/AIDS Funding.](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-018.html) (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-018.html) In other words, all of the proposed research must be undertaken in the context of HIV/AIDS. For example, a project that included a component studying mechanisms of inflammation associated with a comorbidity in people without HIV or animal models without an HIV or SIV component would not be supported by this NOFO.

Comorbidities and co-infections of interest to NIDDK include enteropathy and loss of gastrointestinal homeostasis; noncommunicable liver diseases and viral hepatitis co-infections; kidney, urologic, and hematologic diseases; and obesity, diabetes, and associated complications. Viral reservoirs of particular interest include those in the gastrointestinal mucosa, kidney, liver, genital tract, and adipose tissue. Because NIDDK-relevant pathogenic processes may contribute to inflammation or metabolic perturbations in other tissues and organ systems, projects that include the impact of NIDDK-relevant pathogenic processes on reservoirs located in other anatomical sites might also be appropriate for this NOFO. For example, either obesity or loss of intestinal epithelial barrier function associated with HIV-associated enteropathy may result in systemic inflammation.

Applications proposing studies of HIV reservoirs or post-treatment control that involve co-infections or comorbidities outside of the mission of NIDDK will be considered for funding by NIAID.

NIDDK strongly encourages Research on Sex/Gender Differences, Sexual and Gender Minority-Related Research and Race/Ethnic Diversity (see [NOT-DK-22-003](https://grants.nih.gov/grants/guide/notice-files/NOT-DK-22-003.html) (https://grants.nih.gov/grants/guide/notice-files/NOT-DK-22-003.html)).

*This NOFO aligns with the Mission and Vision of the [NIDDK Strategic Plan for Research](https://www.niddk.nih.gov/about-niddk/strategic-plans-reports/niddk-strategic-plan-for-research) (https://www.niddk.nih.gov/about-niddk/strategic-plans-reports/niddk-strategic-plan-for-research), including the theme of empowering a multidisciplinary workforce, engaging diverse stakeholders, and pursuing pathways to health for all. Specifically, this NOFO aligns with Scientific Goal 1 of the Strategic Plan.*

**Topics of particular interest to NIDDK** (<https://www.niddk.nih.gov/>) include, but are not limited to:

- Pathophysiological and metabolic pathways whereby comorbidities and co-infections within NIDDK's mission contribute to the establishment, dynamics, persistence, and post-treatment control of viral reservoirs in the affected anatomical sites and throughout the body.
- Impact of systemic inflammation or metabolic perturbation resulting from NIDDK-relevant comorbidities and co-infections on establishment, dynamics, persistence, and post-treatment control.
- Post-treatment control in PWH and NIDDK-relevant comorbidities and co-infections or animal models of NIDDK-relevant HIV comorbidities and co-infections.
- Reactivation potential of latent HIV in various tissues affected by NIDDK-relevant comorbidities and co-infections, utilizing existing and/or novel latency reversing agents (LRAs).
- Response of non-subtype B reservoirs to comorbidities and co-infections within NIDDK's mission.
- Longitudinal HIV reservoir dynamics, including decay rates, distributions of persistent, actively expressing and latent reservoirs, viral integration sites within the genome, and mechanisms of clonal expansion of diverse HIV subtypes in tissues affected by NIDDK-relevant comorbidities and co-infections.
- Reactivation potential of latent, non-subtype B HIV in the context of NIDDK-relevant comorbidity or co-infections utilizing existing and/or novel LRAs.

**NIAID** (<https://www.niaid.nih.gov/>) is interested in how co-infections and comorbidities outside the mission of NIDDK, including tuberculosis, impact the topics above.

**ORWH** (<https://orwh.od.nih.gov/>) is part of the NIH Office of the Director. ORWH works with the 27 NIH Institutes and Centers to advance rigorous research of relevance to the health of women. ORWH does not award grants but co-funds women's health-related applications and research projects that have received an award from one of the participating NIH Institutes and Centers (ICs) listed in this NOFO. Applications seeking ORWH co-funding, in response to this NOFO, should ensure that the proposed work is aligned with at least one goal and objective outlined in the [Trans-NIH Strategic Plan for Women's Health Research](https://orwh.od.nih.gov/about/trans-nih-strategic-plan-womens-health-research) (https://orwh.od.nih.gov/about/trans-nih-strategic-plan-womens-health-research).

ORWH supports research projects that address topics of relevance to women - including cisgender and transgender women – as well as gender-diverse people assigned female sex at birth. Intersectional approaches are strongly encouraged. For this NOFO, areas of particular interest include:

1. Projects focused on the female genital tract;
2. Projects designed and powered to explore comorbidities and co-infections among women, particularly around the menopausal transition.

**Topics that are NOT responsive to this NOFO:**

- Projects that interrogate HIV reservoirs outside of the context of comorbidities, co-infections, and complications (CCCs).
- Studies that primarily use epidemiological approaches.
- Projects that have one or more components that pursue diseases, conditions, or co-infections outside of the context of HIV/AIDS and therefore are ineligible for the use of HIV/AIDS-designated funds. The guidelines for allocation of HIV funding have been described

most recently in [NOT-OD-20-018](#), [UPDATE: NIH HIV/AIDS Research Priorities and Guidelines for Determining HIV/AIDS Funding](#). (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-018.html>)

Non-responsive applications **will be administratively withdrawn and not be reviewed** for this NOFO. Projects without a proposed Multiple PD/PI structure will be considered non-compliant and will not be reviewed.

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

## Section II. Award Information

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### Funding Instrument

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

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### Application Types Allowed

New

New

The [OER Glossary](#) ([https://grants.nih.gov/grants/guide/url\\_redirect.php?id=11116](https://grants.nih.gov/grants/guide/url_redirect.php?id=11116)) and the [How to Apply - Application Guide](#) ([https://grants.nih.gov/grants/guide/url\\_redirect.php?id=82400](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400)) provide details on these application types. Only those application types listed here are allowed for this NOFO.

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### Clinical Trial?

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

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

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### Funds Available and Anticipated Number of Awards

The following NIH components intend to commit the following amounts in FY 2025:

NIDDK, \$2,800,000 to fund 3 - 5 awards.

NIAID, \$1,000,000 to fund 1 - 2 awards.

Funds available for ORWH co-funding are dependent upon appropriations.

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### Award Budget

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

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### 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](#) ([https://grants.nih.gov/grants/guide/url\\_redirect.php?id=11120](https://grants.nih.gov/grants/guide/url_redirect.php?id=11120)) will apply to the applications submitted and awards made from this NOFO.

## Section III. Eligibility Information

### 1. Eligible Applicants

#### Eligible Organizations

Higher Education Institutions

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

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

- Hispanic-serving Institutions



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

#### Nonprofits Other Than Institutions of Higher Education

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

#### For-Profit Organizations

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

#### Local Governments

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

#### Federal Governments

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

#### Other

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

### Foreign Organizations

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

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

Foreign components, as defined in the *NIH Grants Policy Statement* ([//grants.nih.gov/grants/guide/url\\_redirect.php?id=11118](https://grants.nih.gov/grants/guide/url_redirect.php?id=11118)), **are** allowed.

### Required Registrations

#### Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the [How to Apply - Application Guide](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) ([https://grants.nih.gov/grants/guide/url\\_redirect.php?id=82400](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400)) to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. Failure to complete registrations in advance of a due date is not a valid reason for a late submission, please reference [NIH Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications](https://grants.nih.gov/grants/guide/url_redirect.php?id=82423) ([//grants.nih.gov/grants/guide/url\\_redirect.php?id=82423](https://grants.nih.gov/grants/guide/url_redirect.php?id=82423)) for additional information

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

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

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

### **Eligible Individuals (Program Director/Principal Investigator)**

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

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the [How to Apply - Application Guide](https://grants.nih.gov/grants/guide/uri_redirect.php?id=82400) ([https://grants.nih.gov/grants/guide/uri\\_redirect.php?id=82400](https://grants.nih.gov/grants/guide/uri_redirect.php?id=82400)).

## **2. Cost Sharing**

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

## **3. Additional Information on Eligibility**

### **Number of Applications**

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

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

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

Projects submitted to this NOFO must propose multiple-PDs/PIs and must include at least one PD/PI whose expertise is primarily in HIV science and at least one other PD/PI with expertise in physiology, pathophysiology, pathobiology, or metabolism.

## **Section IV. Application and Submission Information**

### **1. Requesting an Application Package**

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

### **2. Content and Form of Application Submission**

It is critical that applicants follow the instructions in the Research (R) Instructions in the [How to Apply - Application Guide](https://grants.nih.gov/grants/guide/uri_redirect.php?id=82400) ([https://grants.nih.gov/grants/guide/uri\\_redirect.php?id=82400](https://grants.nih.gov/grants/guide/uri_redirect.php?id=82400)) except where instructed in this notice of funding opportunity to do otherwise. Conformance to the requirements in the [How to Apply - Application Guide](https://grants.nih.gov/grants/guide/uri_redirect.php?id=82400) ([https://grants.nih.gov/grants/guide/uri\\_redirect.php?id=82400](https://grants.nih.gov/grants/guide/uri_redirect.php?id=82400)) 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:



John Connaughton, Ph.D.

Chief, Scientific Review Branch

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

Telephone: 301-594-7797

Email: [NIDDKletterofintent@mail.nih.gov](mailto:NIDDKletterofintent@mail.nih.gov) (<mailto:NIDDKletterofintent@mail.nih.gov>)

## Page Limitations

All page limitations described in the [How to Apply – Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) and the [Table of Page Limits \(https://grants.nih.gov/grants/guide/url\\_redirect.php?id=61134\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=61134) must be followed.

## Instructions for Application Submission

The following section supplements the instructions found in the [How to Apply – Application Guide](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400)

([https://grants.nih.gov/grants/guide/url\\_redirect.php?id=82400](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400)) and should be used for preparing an application to this NOFO.

### SF424(R&R) Cover

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

### SF424(R&R) Project/Performance Site Locations

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

### SF424(R&R) Other Project Information

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

### SF424(R&R) Senior/Key Person Profile

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

### R&R or Modular Budget

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

### R&R Subaward Budget

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

### PHS 398 Cover Page Supplement

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

### PHS 398 Research Plan

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

#### Research Strategy:

The presentation of the research strategy should include a brief description of each PD/PI's contribution to its development, including the overall strategy, methodology and analytical approaches. The presentation of preliminary data should include a brief description of each PD/PI's contribution to it, which may be related to experimental design, execution, and/or interpretation.

#### Multiple PD/PI Leadership Plan:

The application must include a Multiple PD/PI Leadership Plan. The Multiple PD/PI Leadership Plan must describe how the Multiple PD/PI structure is necessary to achieve the aims of this project and brings together at least one PD/PI with primary expertise in HIV science with at least one other PD/PI with primary expertise in the relevant NIDDK-related comorbidity, co-infection, or complication being addressed. The plan should include one or more examples of how development of specific aspects of the research plan benefited from interactions between the PDs/Pis, including enhanced innovation and a strengthened, more rigorous approach. The plan should describe how each PD/PI will participate in aspects of the project primarily led by the other PD(s)/PI(s) in order to leverage the full combined expertise of the Multiple PD/PI team. It is important to describe plans for the leadership approach, governance and organizational structure that includes specific plans to facilitate collaboration and communication among team members (e.g., virtual team meetings, teleconferences, and websites).

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

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

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

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

**Appendix:** Only limited Appendix materials are allowed. Follow all instructions for the Appendix as described in the [How to Apply - Application Guide](#), with the following modifications: ([https://grants.nih.gov/grants/guide/url\\_redirect.php?id=82400](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400))

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

## PHS Human Subjects and Clinical Trials Information

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

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

### Study Record: PHS Human Subjects and Clinical Trials Information

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

## PHS Assignment Request Form

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

## Foreign Organizations

Foreign (non-U.S.) organizations must follow policies described in the [NIH Grants Policy Statement](#) ([https://grants.nih.gov/grants/guide/url\\_redirect.php?id=11137](https://grants.nih.gov/grants/guide/url_redirect.php?id=11137)), and procedures for foreign organizations.

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

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

## 4. Submission Dates and Times

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

Organizations must submit applications to [Grants.gov](#) ([https://grants.nih.gov/grants/guide/url\\_redirect.php?id=11128](https://grants.nih.gov/grants/guide/url_redirect.php?id=11128)) (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the [eRA Commons](#) ([https://grants.nih.gov/grants/guide/url\\_redirect.php?id=11123](https://grants.nih.gov/grants/guide/url_redirect.php?id=11123)), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the [NIH Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications](#) ([https://grants.nih.gov/grants/guide/url\\_redirect.php?id=82423](https://grants.nih.gov/grants/guide/url_redirect.php?id=82423)).

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

Information on the submission process and a definition of on-time submission are provided in the [How to Apply - Application Guide](#) ([https://grants.nih.gov/grants/guide/url\\_redirect.php?id=82400](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400)).

## 5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to [intergovernmental review](#). ([https://grants.nih.gov/grants/policy/nihgps/html5/section\\_10/10.10.1\\_executive\\_orders.htm](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 \(//grants.nih.gov/grants/guide/uri\\_redirect.php?id=11120\)](https://grants.nih.gov/grants/guide/uri_redirect.php?id=11120).

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

## 7. Other Submission Requirements and Information

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

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

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

### Important reminders:

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

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

See [more tips \(//grants.nih.gov/grants/guide/uri\\_redirect.php?id=11146\)](https://grants.nih.gov/grants/guide/uri_redirect.php?id=11146) for avoiding common errors.

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

### Use of Common Data Elements in NIH-funded Research

Many NIH ICs encourage the use of common data elements (CDEs) in basic, clinical, and applied research, patient registries, and other human subject research to facilitate broader and more effective use of data and advance research across studies. CDEs are data elements that have been identified and defined for use in multiple data sets across different studies. Use of CDEs can facilitate data sharing and standardization to improve data quality and enable data integration from multiple studies and sources, including electronic health records. NIH ICs have identified CDEs for many clinical domains (e.g., neurological disease), types of studies (e.g. genome-wide association studies (GWAS)), types of outcomes (e.g., patient-reported outcomes), and patient registries (e.g., the Global Rare Diseases Patient Registry and Data Repository). NIH has established a "Common Data Element (CDE) Resource Portal" (<http://cde.nih.gov/>) to assist investigators in identifying NIH-supported CDEs when developing protocols, case report forms, and other instruments for data collection. The Portal provides guidance about and access to NIH-supported CDE initiatives and other tools and resources for the appropriate use of CDEs and data standards in NIH-funded research. Investigators are encouraged to consult the Portal and describe in their applications any use they will make of NIH-supported CDEs in their projects.

### Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in [the policy \(//grants.nih.gov/grants/guide/uri\\_redirect.php?id=82299\)](https://grants.nih.gov/grants/guide/uri_redirect.php?id=82299).

## Section V. Application Review Information

### 1. Criteria

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

For this particular NOFO, note the following: this NOFO requires a multiple PD/PI structure, with at least one PD/PI who has expertise in HIV science and one PD/PI who has expertise in the physiology, pathophysiology, or metabolism of the relevant to the relevant tissue(s) or process(es). Because this NOFO is being issued to address the need to develop greater interdisciplinary communication between research communities, there is no expectation that teams necessarily have previous publications with each other or otherwise have a history of extensive previous collaboration. Appropriate evidence of a strong and dedicated PD/PI team can be provided in the development of the project itself, as reflected in the quality of the preliminary data, the rigor of the approach, and the Multiple PD/PI leadership plan.

### Overall Impact



Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

## Scored Review Criteria

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

### Significance

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

### Investigator(s)

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

### Innovation

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

### Approach

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

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

### Environment

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

## Additional Review Criteria

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

### Protections for Human Subjects

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

For research that involves human subjects and meets the criteria for one or more of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the [Guidelines for the Review of Human Subjects \(//grants.nih.gov/grants/guide/redirect.php?id=11175\)](https://grants.nih.gov/grants/guide/redirect.php?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 \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=11174\)](https://grants.nih.gov/grants/guide/redirect.php?id=11174).

### **Vertebrate Animals**

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

### **Biohazards**

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

### **Resubmissions**

Not applicable.

### **Renewals**

Not applicable.

### **Revisions**

Not applicable.

## **Additional Review Considerations**

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

### **Applications from Foreign Organizations**

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

### **Select Agent Research**

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

### **Resource Sharing Plans**

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

### **Authentication of Key Biological and/or Chemical Resources**

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

### **Budget and Period of Support**

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

## **2. Review and Selection Process**

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by NIDDK, in accordance with [NIH peer review policies and practices \(//grants.nih.gov/grants/guide/redirect.php?id=11154\)](https://grants.nih.gov/grants/guide/redirect.php?id=11154), using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

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

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

[Appeals \(https://grants.nih.gov/grants/policy/nihgps/html5/section\\_2/2.4.2\\_appeals\\_of\\_initial\\_scientific\\_review.htm\)](https://grants.nih.gov/grants/policy/nihgps/html5/section_2/2.4.2_appeals_of_initial_scientific_review.htm) of initial peer review will not be accepted for applications submitted in response to this NOFO.



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

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

### 3. Anticipated Announcement and Award Dates

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

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

## Section VI. Award Administration Information

### 1. Award Notices

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

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

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

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

Institutional Review Board or Independent Ethics Committee Approval: Recipient institutions must ensure that protocols are reviewed by their IRB or IEC. To help ensure the safety of participants enrolled in NIH-funded studies, the recipient must provide NIH copies of documents related to all major changes in the status of ongoing protocols.

### 2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=11120\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11120) as part of the NoA. For these terms of award, see the [NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=11157\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11157) and [Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=11159\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11159), including of note, but not limited to:

- [Federalwide Standard Terms and Conditions for Research Grants \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section\\_3/3.1\\_federalwide\\_standard\\_terms\\_and\\_conditions\\_for\\_research\\_grants.htm\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_3/3.1_federalwide_standard_terms_and_conditions_for_research_grants.htm)
- [Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=82417\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82417)
- [Acknowledgment of Federal Funding \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section\\_4/4.2.1\\_acknowledgement\\_of\\_federal\\_funding.htm\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.2.1_acknowledgement_of_federal_funding.htm)

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

If a recipient receives an award, the recipient must follow all applicable nondiscrimination laws. The recipient agrees to this when registering in SAM.gov. The recipient must also submit an Assurance of Compliance ([HHS-690 \(https://www.hhs.gov/sites/default/files/form-hhs690.pdf\)](https://www.hhs.gov/sites/default/files/form-hhs690.pdf)). To learn more, see the [Laws and Regulations Enforced by the HHS Office for Civil Rights website \(https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/laws/index.html\)](https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/laws/index.html).

HHS recognizes that NIH research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research. For additional guidance regarding



how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this NOFO.

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to System for Award Management (SAM.gov) requirements. SAM.gov requires Federal agencies to review and consider information about an applicant in the designated integrity and performance system (currently SAM.gov) prior to making an award. An applicant can review and comment on any information in the responsibility/qualification records available in SAM.gov. NIH will consider any comments by the applicant, in addition to the information available in the responsibility/qualification records in SAM.gov, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 2 CFR Part 200.206 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships.

### **Cooperative Agreement Terms and Conditions of Award**

Not Applicable

### **3. Data Management and Sharing**

Consistent with the 2023 NIH Policy for Data Management and Sharing, when data management and sharing is applicable to the award, recipients will be required to adhere to the Data Management and Sharing requirements as outlined in the [NIH Grants Policy Statement \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section\\_8/8.2.3\\_sharing\\_research\\_resources.htm#Data\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2.3_sharing_research_resources.htm#Data). Upon the approval of a Data Management and Sharing Plan, it is required for recipients to implement the plan as described.

### **4. Reporting**

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

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

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

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

### **Scientific/Research Contact(s)**

#### ***For Division of Digestive Diseases and Nutrition-related inquiries:***

Peter J. Perrin, Ph.D.

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

Telephone: 301-451-3759

Email: [Peter.Perrin@nih.gov](mailto:Peter.Perrin@nih.gov) ([mailto:Peter.Perrin@nih.gov?subject=Inquiry%20into%20RFA-DK-20-022%20\(Pathogenesis%20TEAMS\)\)](mailto:Peter.Perrin@nih.gov?subject=Inquiry%20into%20RFA-DK-20-022%20(Pathogenesis%20TEAMS))))

#### ***For Division of Kidney, Urologic and Hematologic Diseases-related inquiries:***

Deepak Nihalani, Ph.D.

Division of Kidney, Urologic, and Hematologic Diseases

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

Telephone: 301-594-6417

Email: [Deepak.Nihalani@nih.gov](mailto:Deepak.Nihalani@nih.gov) (<mailto:Deepak.Nihalani@nih.gov>)

#### ***For Division of Diabetes, Endocrinology and Metabolic Diseases-related inquiries:***

Saul Malozowski, M.D., Ph.D., M.B.A.

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

Telephone: 301 451-4683

Email: [sm007@nih.gov](mailto:sm007@nih.gov) ([mailto:sm007@nih.gov?subject=Inquiry%20into%20RFA-DK-20-022%20\(Pathogenesis%20TEAMS\)\)](mailto:sm007@nih.gov?subject=Inquiry%20into%20RFA-DK-20-022%20(Pathogenesis%20TEAMS))))

Elizabeth Anne Barr, Ph.D.

ORWH - Office of Research on Women's Health

Phone: 301-402-7895

E-mail: [elizabeth.barr@nih.gov](mailto:elizabeth.barr@nih.gov) (<mailto:elizabeth.barr@nih.gov>)

Leia Novak, PhD

National Institute of Allergy and Infectious Diseases (NIAID)

Telephone: 301-761-7825

Email: [Leia.Novak@nih.gov](mailto:Leia.Novak@nih.gov) (<mailto:Leia.Novak@nih.gov>)

### **Peer Review Contact(s)**

Maria Davila-Bloom, Ph.D

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

Telephone: 301-594-7637

Email: [davilabloomm@mail.nih.gov](mailto:davilabloomm@mail.nih.gov) (<mailto:davilabloomm@mail.nih.gov>)

### **Financial/Grants Management Contact(s)**

Sunshine Wilson

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

Telephone: 301-827-4670

Email: [Sunshine.Wilson@nih.gov](mailto:Sunshine.Wilson@nih.gov) (<mailto:Sunshine.Wilson@nih.gov>)

Ann Devine

National Institute of Allergy and Infectious Diseases (NIAID)

Telephone: 240-669-2988

Email: [adevine@niaid.nih.gov](mailto:adevine@niaid.nih.gov) (<mailto:adevine@niaid.nih.gov>)

## **Section VIII. Other Information**

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

### **Authority and Regulations**

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





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



[\(http://www.hhs.gov/\)](http://www.hhs.gov/) Department of Health  
and Human Services (HHS)



[\(http://www.usa.gov/\)](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](mailto:chittiporn.nua@mahidol.edu) เพื่อขอเปิดบัญชี eRA commons และขอสร้างข้อเสนอโครงการในระบบออนไลน์ ASSIST ของแหล่งทุน NIH โดยแจ้งข้อมูลดังนี้

Name: Surname:

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

Funding Opportunity Announcement (FOA) Number:

Application title: .

Application due date:

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

(\*\*หากผู้สมัครขอรับทุนนำส่งข้อเสนอโครงการให้กองบริหารงานวิจัยตรวจสอบล่าช้ากว่ากำหนดของมหาวิทยาลัย มหาวิทยาลัยขอสงวนสิทธิ์ในการรับข้อเสนอโครงการเพื่อนำส่งแหล่งทุนในรอบนั้นๆ)

01

- Find your FOA and Application due date
- Search NIH RePORTER

02

- Create your eRA commons ID
- Initiate Application in ASSIST

03

- Application preparing
- Letter of support

04

- Validate Application
- Submission

สอบถามข้อมูลเพิ่มเติม คุณจิตติพร 02-8496252 [chittiporn.nua@mahidol.edu](mailto:chittiporn.nua@mahidol.edu)

หน่วยสนับสนุนการขอทุนวิจัยจากแหล่งทุนต่างประเทศ

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