



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

ที่ 朝 78.016/154  
วันที่ 14 มกราคม 2569  
เรื่อง ประชาสัมพันธ์การเปิดรับข้อเสนอโครงการจากแหล่งทุน National Institutes of Health (NIH)  
รอบ Cycle I/2026 หมายเลขประกาศทุน PA-25-305

สิ่งที่ส่งมาด้วย 1. รายละเอียดประกาศทุน Parent Announcements  
2. ขั้นตอนการสมัครขอรับทุน

เรียน คณบดี / ผู้อำนวยการ

ด้วยแหล่งทุน National Institutes of Health (NIH) ประเทศ Parent Announcements (For Unsolicited or Investigator-Initiated Applications) รอบ Cycle I/2026 หัวข้อ “NIH Research Project Grant (Parent R01 Clinical Trial Required)” หมายเลขประกาศทุน PA-25-305 โดยเปิดรับข้อเสนอโครงการตั้งแต่วันนี้ จนถึง วันที่ 5 กุมภาพันธ์ 2569 เวลา 17.00 น. ตามเวลาประเทศไทย ทั้งนี้ โครงการที่เสนอขอทุนให้ปฏิบัติตาม ประกาศมหาวิทยาลัยมหิดล เรื่องหลักเกณฑ์และอัตราเงินค่าธรรมเนียมพัฒนาการวิจัยของมหาวิทยาลัยและส่วนงานที่ จัดเก็บจากโครงการวิจัยที่ได้รับเงินอุดหนุนจากแหล่งทุนภายนอกมหาวิทยาลัย พ.ศ. 2560 ทั้งนี้ อาจารย์/นักวิจัยที่ สนใจสามารถศึกษารายละเอียดเพิ่มเติมได้ตามเอกสารที่แนบมาด้วยนี้ หรือเว็บไซต์ของแหล่งทุนที่ <https://grants.nih.gov/grants/guide/pa-files/PA-25-305.html>

ในการนี้ กองบริหารงานวิจัย มหาวิทยาลัยมหิดล จึงขอแจ้งข่าวประกาศทุนมา�ังท่าน เพื่อโปรด ประชาสัมพันธ์ทุนวิจัยดังกล่าวให้บุคลากรในหน่วยงานของท่านทราบโดยทั่วไป และขอให้อาจารย์/นักวิจัย โปรดแจ้ง ความประสงค์การจัดส่งข้อเสนอ ภายในวันที่ 16 มกราคม 2569 และจัดส่งข้อเสนอโครงการวิจัยผ่านส่วนงานด้วย สังกัดมายังกองบริหารงานวิจัยเพื่อตรวจสอบรายละเอียดข้อเสนอโครงการฉบับสมบูรณ์ภายในวันที่ 29 มกราคม 2569

จึงเรียนมาเพื่อโปรดทราบและประชาสัมพันธ์ข่าวทุนวิจัยดังกล่าวต่อไปด้วย จักขอบคุณยิ่ง

(ศาสตราจารย์ นายแพทย์ หมื่นหลวงชาครรัตน์ กิติยากร)  
รองอธิการบดีฝ่ายวิจัย

## March 31, 2025

This funding opportunity was updated to align with agency priorities. Carefully reread the full funding opportunity and make any needed adjustments to your application prior to submission.

# Department of Health and Human Services

## Part 1. Overview Information

Participating Organization(s)	National Institutes of Health ( <a href="http://www.nih.gov">NIH</a> )
Components of Participating Organizations	<p>NATIONAL INSTITUTES OF HEALTH (<a href="https://www.nih.gov">NIH</a>)</p> <p>National Eye Institute (<a href="https://www.nei.nih.gov">NEI</a>)</p> <p>National Heart, Lung, and Blood Institute (<a href="https://www.nhlbi.nih.gov">NHLBI</a>)</p> <p>National Human Genome Research Institute (<a href="https://www.genome.gov">NHGRI</a>)</p> <p>National Institute on Aging (<a href="https://www.nia.nih.gov">NIA</a>)</p> <p>National Institute on Alcohol Abuse and Alcoholism (<a href="https://www.niaaa.nih.gov">NIAAA</a>)</p> <p>National Institute of Allergy and Infectious Diseases (<a href="https://www.niaid.nih.gov">NIAID</a>)</p> <p>National Institute of Arthritis and Musculoskeletal and Skin Diseases (<a href="https://www.niams.nih.gov">NIAMS</a>)</p> <p>National Institute of Biomedical Imaging and Bioengineering (<a href="https://www.nibib.nih.gov">NIBIB</a>)</p> <p>Eunice Kennedy Shriver National Institute of Child Health and Human Development (<a href="https://www.nichd.nih.gov">NICHD</a>)</p> <p>National Institute on Deafness and Other Communication Disorders (<a href="https://www.nidcd.nih.gov">NIDCD</a>)</p> <p>National Institute of Diabetes and Digestive and Kidney Diseases (<a href="https://www.niddk.nih.gov">NIDDK</a>)</p> <p>National Institute on Drug Abuse (<a href="https://www.drugabuse.gov">NIDA</a>)</p> <p>National Institute of Environmental Health Sciences (<a href="https://www.niehs.nih.gov">NIEHS</a>)</p> <p>National Institute of General Medical Sciences (<a href="https://www.nigms.nih.gov">NIGMS</a>)</p> <p>National Institute of Mental Health (<a href="https://www.nimh.nih.gov/index.shtml">NIMH</a>)</p> <p>National Institute of Neurological Disorders and Stroke (<a href="https://www.ninds.nih.gov">NINDS</a>)</p> <p>National Institute of Nursing Research (<a href="https://www.ninr.nih.gov">NINR</a>)</p> <p>National Institute on Minority Health and Health Disparities (<a href="https://www.nimhd.nih.gov">NIMHD</a>)</p> <p>National Library of Medicine (<a href="https://www.nlm.nih.gov">NLM</a>)</p> <p>National Center for Complementary and Integrative Health (<a href="https://nccih.nih.gov">NCCIH</a>)</p>

Note: Not all NIH Institutes and Centers (ICs) participate in Parent Announcements. Applicants should carefully note which ICs participate in this announcement and view their respective areas of research interest at the [R01 Clinical Trial Required IC-Specific Scientific Interests and Contact website](https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-305.html). Applicants should also carefully note which ICs accept only mechanistic trials. ICs that do not participate in this announcement will not consider applications for funding.

Funding Opportunity Title	NIH Research Project Grant (Parent R01 Clinical Trial Required)
Activity Code	<a href="https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r01&amp;Search.x=0&amp;Search.y=0&amp;Search_Type=Activity">R01</a> Research Project Grant
Announcement Type	Reissue of <a href="https://grants.nih.gov/grants/guide/pa-files/PA-20-183.html">PA-20-183</a>
Related Notices	<p>See <a href="https://grants.nih.gov/grants/guide/NOSIs_targeting_list.cfm?GuideDocID=42179">Notices of Special Interest</a> associated with this funding opportunity</p> <ul style="list-style-type: none"><li><b>March 31, 2025</b> - This funding opportunity was updated to align with agency priorities. Carefully reread the full funding opportunity and make any needed adjustments to your application prior to submission.</li><li><b>April 4, 2024</b> - Overview of Grant Application and Review Changes for Due Dates on or after January 25, 2025. See Notice <a href="https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-084.html">NOT-OD-24-084</a>.</li><li><b>September 14, 2023</b> - Consolidated Notice on NIMH Clinical Trials Policies. See Notice <a href="https://grants.nih.gov/grants/guide/notice-files/NOT-MH-23-375.html">NOT-MH-23-375</a>.</li><li><b>December 21, 2018</b> - NIMH Acceptance of Clinical Trial Applications under the Parent R01 and R21 Clinical Trial Required, or Basic Experimental Studies Involving Humans (BESH) Announcements is Limited to Mechanistic Clinical Trials. See Notice <a href="https://grants.nih.gov/grants/guide/notice-files/NOT-MH-19-006.html">NOT-MH-19-006</a>.</li><li><b>August 31, 2022</b> - Implementation Changes for Genomic Data Sharing Plans Included with Applications Due on or after January 25, 2023. See Notice <a href="https://grants.nih.gov/grants/guide/notice-files/not-od-22-198.html">NOT-OD-22-198</a>.</li><li><b>August 5, 2022</b> - Implementation Details for the NIH Data Management and Sharing Policy. See Notice <a href="https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-189.html">NOT-OD-22-189</a>.</li></ul>

## Funding Opportunity Number (FON)

Companion Funding Opportunity	PA-25-301 ( <a href="https://grants.nih.gov/grants/guide/pa-files/PA-25-301.html">https://grants.nih.gov/grants/guide/pa-files/PA-25-301.html</a> ), R01 ( <a href="https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=R01&amp;&amp;Search.x=0&amp;&amp;Search.y=0&amp;&amp;Search.Type=Activity">https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=R01&amp;&amp;Search.x=0&amp;&amp;Search.y=0&amp;&amp;Search.Type=Activity</a> ), Research Project PA-25-303 ( <a href="https://grants.nih.gov/grants/guide/pa-files/PA-25-303.html">https://grants.nih.gov/grants/guide/pa-files/PA-25-303.html</a> ), R01 ( <a href="https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=R01&amp;&amp;Search.x=0&amp;&amp;Search.y=0&amp;&amp;Search.Type=Activity">https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=R01&amp;&amp;Search.x=0&amp;&amp;Search.y=0&amp;&amp;Search.Type=Activity</a> ), Research Project
Number of Applications	See Part 2, Section III. 3. Additional Information on Eligibility.
Assistance Listing Number(s)	93.242, 93.867, 93.847, 93.855, 93.286, 93.879, 93.173, 93.865, 93.837, 93.853, 93.233, 93.838, 93.839, 93.840, 93.273, 93.846, 93.279, 93.859, 93.172, 93.307, 93.866, 93.361, 93.113, 93.143, 93.213
Funding Opportunity Purpose	<p>The NIH Research Project Grant supports a discrete, specified, circumscribed project in areas representing the specific interests and competencies of the investigator(s). This Parent Notice of Funding Opportunity requires that at least 1 clinical trial be proposed. The proposed project must be related to the programmatic interests of one or more of the participating NIH Institutes and Centers (ICs) based on their scientific missions.</p> <p>Applicants should note that some ICs only accept applications proposing mechanistic studies that meet NIH's definition of a clinical trial through this funding opportunity announcement.</p>
Funding Opportunity Goal(s)	<p>The goals are:</p> <ul style="list-style-type: none"> <li>to foster fundamental creative discoveries, innovative research strategies, and their applications as a basis for ultimately protecting and improving health;</li> <li>to develop, maintain, and renew scientific human and physical resources that will ensure the Nation's capability to prevent disease;</li> <li>to expand the knowledge base in medical and associated sciences in order to enhance the Nation's economic well-being and ensure a continued high return on the public investment in research; and</li> <li>to exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science.</li> </ul> <p>In realizing these goals, the NIH provides leadership and direction to programs designed to improve the health of the Nation by conducting and supporting research:</p> <ul style="list-style-type: none"> <li>in the causes, diagnosis, prevention, and cure of human diseases;</li> <li>in the processes of human growth and development;</li> <li>in the biological effects of environmental contaminants;</li> <li>in the understanding of mental, addictive and physical disorders; and</li> <li>in directing programs for the collection, dissemination, and exchange of information in medicine and health, including the development and support of medical libraries and the training of medical librarians and other health information specialists.</li> </ul>

## Key Dates

Posted Date	December 18, 2024				
Open Date (Earliest Submission Date)	January 05, 2025				
The following table includes NIH <a href="https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm">standard due dates</a> ( <a href="https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm">https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm</a> ) marked with an asterisk.					
Application Due Dates	Review and Award Cycles				
New	Renewal / Resubmission / Revision (as allowed)	AIDS - New/Renewal/Resubmission/Revision, as allowed	Scientific Merit Review	Advisory Council Review	Earliest Start Date
February 05, 2025 *	March 05, 2025 *	May 07, 2025 *	July 2025	October 2025	December 2025
June 05, 2025 *	July 05, 2025 *	September 07, 2025 *	November 2025	January 2026	April 2026
October 05, 2025 *	November 05, 2025 *	January 07, 2026 *	March 2026	May 2026	July 2026
February 05, 2026 *	March 05, 2026 *	May 07, 2026 *	July 2026	October 2026	December 2026
June 05, 2026 *	July 05, 2026 *	September 07, 2026 *	November 2026	January 2027	April 2027
October 05, 2026 *	November 05, 2026 *	January 07, 2027 *	March 2027	May 2027	July 2027
February 05, 2027 *	March 05, 2027 *	May 07, 2027 *	July 2027	October 2027	December 2027
June 05, 2027 *	July 05, 2027 *	September 07, 2027 *	November 2027	January 2028	April 2028
October 05, 2027 *	November 05, 2027 *	January 07, 2028 *	March 2028	May 2028	July 2028

All applications are due by 5:00 PM local time of applicant organization.

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

Expiration Date	January 08, 2028
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## 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](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](https://grants.nih.gov/grants/guide/url_redirect.php?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/) (<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=closedarchived|posted|forecasted&fon=PA-25-305) (<https://grants.gov/search-grants?oppStatuses=closedarchived|posted|forecasted&fon=PA-25-305>) 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

The NIH Research Project Grant supports a discrete, specified, circumscribed project in scientific areas that represent the investigators' specific interests and competencies and that fall within the mission of the participating NIH Institutes and Centers (ICs). The R01 is the original, and historically the oldest, grant mechanism used by the NIH to support health-related research and development.

All applications submitted to this Parent Notice of Funding Opportunity must propose [clinical trial\(s\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82370) ([https://grants.nih.gov/grants/guide/url\\_redirect.php?id=82370](https://grants.nih.gov/grants/guide/url_redirect.php?id=82370)).

Research grant applications are assigned to participating ICs based on receipt and referral guidelines and many applications are assigned to multiple participating ICs with related research interests. Applicants are encouraged to identify a participating IC that supports their area of research via the [R01 Clinical Trial Required IC-Specific Scientific Interests and Contact website](https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-305.html) (<https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-305.html>) and contact Scientific/Research staff from relevant ICs to inquire about their interest in supporting the proposed research project.

For specific information about the mission of each NIH IC, visit the [List of NIH Institutes, Centers, and Offices](http://www.nih.gov/institutes-nih/list-nih-institutes-centers-offices) (<http://www.nih.gov/institutes-nih/list-nih-institutes-centers-offices>) website.

NIH defines a clinical trial as "A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes." ([NOT-OD-15-015](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html>))

NIH not only supports trials of safety and efficacy, it also supports mechanistic exploratory studies that meet the definition of a clinical trial and are designed to explore or understand a biological or behavioral process, the pathophysiology of a disease, or the mechanism of action of an intervention. These studies may focus on basic and/or translational discovery research in healthy human subjects and in human subjects who are affected by the pathophysiology of diseases and disorders. By addressing basic questions and concepts in biology, behavior, and pathophysiology, these studies may provide insight into understanding human diseases and disorders along with potential treatments or preventive strategies. NIH also supports biomarker studies that meet the definition of a clinical trial and that may provide information about physiological function, target engagement of novel therapeutics, and/or the impact of therapeutics on treatment response. NIH thus supports studies that meet the definition of clinical trials (as noted above) but do not seek to establish safety, clinical efficacy, effectiveness, clinical management, and/or implementation of preventive, therapeutic, and services interventions.

Applicants should note that some ICs (see the Related Notices section above) only accept applications proposing mechanistic studies that meet NIH's definition of a clinical trial through this funding opportunity announcement. A mechanistic study is designed to understand a biological or behavioral process, the pathophysiology of a disease, or the mechanism of action of an intervention. If the proposed research project includes clinical trial other than a mechanistic study that would be assigned to one of these ICs, applicants are advised to contact relevant [Scientific/Research staff](https://grants.nih.gov/grants/guide/contacts/Clinical-Trial-Parent-R01.html) (<https://grants.nih.gov/grants/guide/contacts/Clinical-Trial-Parent-R01.html>) to discuss alternative mechanisms of support of these studies.

Investigators proposing NIH-defined clinical trials may refer to the [Research Methods Resources](https://researchmethodsresources.nih.gov) (<https://researchmethodsresources.nih.gov>) website for information about developing statistical methods and study designs.

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

### Section II. Award Information

#### Funding Instrument

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

#### Application Types Allowed

The [QER Glossary](#) and the How to Apply Application Guide provide details on these application types. Only those application types listed here are allowed for this NOFO.

**Clinical Trial?**

Required: Only accepting applications that propose clinical trial(s).

[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))

**Funds Available and Anticipated Number of Awards**

The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.

**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](#) 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

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](#), are allowed.

### Required Registrations

Applicant Organizations

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

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

## 2. Cost Sharing

This NOFO does not require cost sharing as defined in the [NIH Grants Policy Statement Section 1.2 Definition of Terms \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=11126\)](https://grants.nih.gov/grants/guide/url_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 \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=82415\)](https://grants.nih.gov/grants/guide/url_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 \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=82423\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82423)).

# Section IV. Application and Submission Information

## 1. Requesting an Application Package

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

## 2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the Research (R) Instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) except where instructed in this notice of funding opportunity to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

### Page Limitations

All page limitations described in the [How to Apply- Application Guide \(https://grants.nih.gov/grants/how-to-apply-application-guide.html\)](https://grants.nih.gov/grants/how-to-apply-application-guide.html), and the [Table of Page Limits \(https://grants.nih.gov/grants/guide/url\\_redirect.php?id=61134\)](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 \(https://grants.nih.gov/grants/how-to-apply-application-guide.html\)](https://grants.nih.gov/grants/how-to-apply-application-guide.html) and should be used for preparing an application to this NOFO.

#### SF424(R&R) Cover

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

**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):

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 \(https://grants.nih.gov/grants/guide/url\\_redirect.php?id=82400\)](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](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](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) (<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](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](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) ([//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 described throughout 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)).

### **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](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) ([//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) ([//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) ([//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.

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

This initiative is not subject to [intergovernmental review](https://grants.nih.gov/grants/policy/nihgps/html5/section_10/10.1_executive_orders.htm) ([https://grants.nih.gov/grants/policy/nihgps/html5/section\\_10/10.1\\_executive\\_orders.htm](https://grants.nih.gov/grants/policy/nihgps/html5/section_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](https://grants.nih.gov/grants/guide/url_redirect.php?id=11120) ([//grants.nih.gov/grants/guide/url\\_redirect.php?id=11120](https://grants.nih.gov/grants/guide/url_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](https://grants.nih.gov/grants/guide/url_redirect.php?id=11143). ([//grants.nih.gov/grants/guide/url\\_redirect.php?id=11143](https://grants.nih.gov/grants/guide/url_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. Paper applications will not be accepted.

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

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

#### **Important reminders:**

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

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

See [more tips](https://grants.nih.gov/grants/guide/url_redirect.php?id=11146) ([//grants.nih.gov/grants/guide/url\\_redirect.php?id=11146](https://grants.nih.gov/grants/guide/url_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, NIH. Applications that are incomplete or non-compliant will not be reviewed.

### **Requests of \$500,000 or more for direct costs in any year**

Applicants requesting \$500,000 or more in direct costs in any year (excluding consortium F&A) must contact a Scientific/ Research Contact at least 6 weeks before submitting the application and follow the Policy on the Acceptance for Review of Unsolicited Applications that Request \$500,000 or More in Direct Costs 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)).

### **Mandatory Disclosure**

Recipients or subrecipients must submit any information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. See Mandatory Disclosures, [2 CFR 200.113](https://www.ecfr.gov/current/title-2/subtitle-A/chapter-I/part-200/subpart-B/section-200.113) (<https://www.ecfr.gov/current/title-2/subtitle-A/chapter-I/part-200/subpart-B/section-200.113>) and [NIH Grants Policy Statement Section 4.1.35](https://grants.nih.gov/grants/policy/nihgps/html5/section_4/4.1.35_mandatory_disclosures.htm) ([//grants.nih.gov/grants/policy/nihgps/html5/section\\_4/4.1.35\\_mandatory\\_disclosures.htm](https://grants.nih.gov/grants/policy/nihgps/html5/section_4/4.1.35_mandatory_disclosures.htm)).

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

### **Post Submission Materials**

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

Any instructions provided here are in addition to the instructions in the policy.

## **Section V. Application Review Information**

### **1. Criteria**

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

## Overall Impact

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

## Scored Review Criteria

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

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

#### Significance

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

#### Innovation

- Evaluate the extent to which innovation influences the importance of undertaking the proposed research. Note that while technical or conceptual innovation can influence the importance of the proposed research, a project that is not applying novel concepts or approaches may be of critical importance for the field.
- Evaluate whether the proposed work applies novel concepts, methods or technologies or uses existing concepts, methods, technologies in novel ways, to enhance the overall impact of the project.

### Factor 2. Rigor and Feasibility (Approach)

#### Approach

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

#### Rigor:

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

#### Feasibility:

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

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

#### Investigator(s)

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

#### Environment

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

## Additional Review Criteria

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

#### Protections for Human Subjects

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

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

#### Vertebrate Animals

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

#### Biohazards

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

#### Resubmissions

As applicable, evaluate the full application as now presented.

#### **Renewals**

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

#### **Revisions**

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

#### **Additional Review Considerations**

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

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

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

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

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

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

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) in accordance with NIH peer review policies and practices, 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.

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.

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the [NIH Grants Policy Statement Section 2.5.1. Just-in-Time Procedures](#) ([/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.

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

### **3. Anticipated Announcement and Award Dates**

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the [eRA Commons](#) ([/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**

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

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

Recipients must comply with any funding restrictions described in [Section IV.6. Funding Restrictions](#). Any pre-award costs incurred before receipt of the NoA are at the applicant's own risk. For more information on the Notice of Award, please refer to the [NIH Grants Policy Statement Section 5. The Notice of Award](#) ([https://grants.nih.gov/grants/policy/nihgps/HTML5/section\\_5/5\\_the\\_notice\\_of\\_award.htm](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_5/5_the_notice_of_award.htm)) and NIH Grants & Funding website, see [Award Process](#). (<https://grants.nih.gov/grants/pre-award-process.htm#award>)

Individual awards are based on the application submitted to, and as approved by, the NIH and are subject to the IC-specific terms and conditions identified in the NoA.

ClinicalTrials.gov: If an award provides for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register and submit results information for certain "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration and Results System Information Website (<https://register.clinicaltrials.gov>). NIH expects registration and results reporting of all trials whether required under the law or not. For more information, see <https://grants.nih.gov/policy/clinical-trials/reporting/index.htm> (<https://grants.nih.gov/policy/clinical-trials/reporting/index.htm>).

Institutional Review Board or Independent Ethics Committee Approval: Recipient institutions must ensure that all 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.

Data and Safety Monitoring Requirements: The NIH policy for data and safety monitoring requires oversight and monitoring of all NIH-conducted or -supported human biomedical and behavioral intervention studies (clinical trials) to ensure the safety of participants and the validity and integrity of the data. Further information concerning these requirements is found at [http://grants.nih.gov/grants/policy/hs/data\\_safety.htm](http://grants.nih.gov/grants/policy/hs/data_safety.htm) ([https://grants.nih.gov/grants/policy/hs/data\\_safety.htm](https://grants.nih.gov/grants/policy/hs/data_safety.htm)) and in the application instructions (SF424 (R&R) and PHS 398).

Investigational New Drug or Investigational Device Exemption Requirements: Consistent with federal regulations, clinical research projects involving the use of investigational therapeutics, vaccines, or other medical interventions (including licensed products and devices for a purpose other than that for which they were licensed) in humans under a research protocol must be performed under a Food and Drug Administration (FDA) investigational new drug (IND) or investigational device exemption (IDE).

### **2. Administrative and National Policy Requirements**

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

- The rules listed at [2 CFR Part 200](#) (<https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200>), Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.
- 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 terms and conditions in the Notice of Award (NoA). The NoA includes the requirements of this NOFO. For these terms of award, see the [NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General](#) ([/grants.nih.gov/grants/guide/url\\_redirect.php?id=11120](https://grants.nih.gov/grants/guide/url_redirect.php?id=11120)) 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)).
- 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 [Law 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>).

- o 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.

All federal statutes and regulations relevant to federal financial assistance, including those highlighted in [NIH Grants Policy Statement Section 4 Public Policy Requirements, Objectives and Other Appropriation Mandates.](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4_public_policy_requirements_objectives_and_other_appropriation_mandates.htm) ([https://grants.nih.gov/grants/policy/nihgps/HTML5/section\\_4/4\\_public\\_policy\\_requirements\\_objectives\\_and\\_other\\_appropriation\\_mandates.htm](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4_public_policy_requirements_objectives_and_other_appropriation_mandates.htm))

Recipients are responsible for ensuring that their activities comply with all applicable federal regulations. NIH may terminate awards under certain circumstances. See [2 CFR Part 200.340 Termination](https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-D/subject-group-ECFR86b76dde0e1e9dc/section-200.340) (<https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-D/subject-group-ECFR86b76dde0e1e9dc/section-200.340>), and [NIH Grants Policy Statement Section 8.5.2 Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support](https://grants.nih.gov/grants/policy/nihgps/html5/section_8/8.5.2_remedies_for_noncompliance_or_enforcement_actions- suspension_termination_and_withholding_of_support.htm) ([https://grants.nih.gov/grants/policy/nihgps/html5/section\\_8/8.5.2\\_remedies\\_for\\_noncompliance\\_or\\_enforcement\\_actions- suspension\\_termination\\_and\\_withholding\\_of\\_support.htm](https://grants.nih.gov/grants/policy/nihgps/html5/section_8/8.5.2_remedies_for_noncompliance_or_enforcement_actions- suspension_termination_and_withholding_of_support.htm)).

Successful recipients under this NOFO agree that:

Where the award funding involves implementing, acquiring, or upgrading health IT for activities by any funded entity, recipients and subrecipient(s) are required to: Use health IT that meets standards and implementation specifications adopted in 45 CFR part 170, Subpart B, if such standards and implementation specifications can support the activity. Visit <https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-B> (<https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-B>) to learn more.

Where the award funding involves implementing, acquiring, or upgrading health IT for activities by eligible clinicians in ambulatory settings, or hospitals, eligible under Sections 4101, 4102, and 4201 of the HITECH Act, use health IT certified under the ONC Health IT Certification Program if certified technology can support the activity. Visit <https://www.healthit.gov/topic/certification-ehrs/certification-health-it> (<https://www.healthit.gov/topic/certification-ehrs/certification-health-it>) to learn more.

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

Successful recipients under this NOFO agree that:

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

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

Recipients shall develop plans and procedures, modeled after the [NIST Cybersecurity framework](https://www.nist.gov/cyberframework) (<https://www.nist.gov/cyberframework>), to protect HHS systems and data. Please refer to [NIH Post-Award Monitoring and Reporting](https://grants.nih.gov/grants/post-award-monitoring-and-reporting.htm) (<https://grants.nih.gov/grants/post-award-monitoring-and-reporting.htm>) for additional information.

### 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](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) ([//grants.nih.gov/grants/rppr/index.htm](https://grants.nih.gov/grants/rppr/index.htm)) annually and financial statements as required in the [NIH Grants Policy Statement Section 8.4.1 Reporting](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.4.1_reporting.htm) ([https://grants.nih.gov/grants/policy/nihgps/HTML5/section\\_8/8.4.1\\_reporting.htm](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.4.1_reporting.htm)). To learn more about post-award monitoring and reporting, see the NIH Grants & Funding website, see [Post-Award Monitoring and Reporting](https://grants.nih.gov/grants/guide/redirect.php?id=82428) (<https://grants.nih.gov/grants/guide/redirect.php?id=82428>).

A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the [NIH Grants Policy Statement Section 8.6 Closeout](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.6_Closeout.htm) ([//grants.nih.gov/grants/guide/redirect.php?id=82420](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 2 CFR Part 200.301.

## 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: 301-480-7075

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)

Participating NIH Institutes and Centers are listed in "Components of Participating Organizations" in Part 1. Overview. Scientific/Research Contact information is listed on [R01 Clinical Trial Required IC-Specific Scientific Interests and Contact website](https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-305.html) (<https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-305.html>).

### Peer Review Contact(s)

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

### Financial/Grants Management Contact(s)

Participating NIH Institutes and Centers are listed in "Components of Participating Organizations" in Part 1. Overview. Financial/Grants Management Contact information is listed on the [R01 Clinical Trial Required IC-Specific Scientific Interests and Contact website](https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-305.html) (<https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-305.html>).

## Section VIII. Other Information

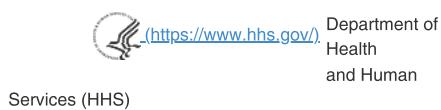
Recently issued trans-NIH [policy notices](https://grants.nih.gov/grants/guide/redirect.php?id=11163) ([//grants.nih.gov/grants/guide/redirect.php?id=11163](https://grants.nih.gov/grants/guide/redirect.php?id=11163)) may affect your application submission. A full list of policy notices published by NIH is provided in the [NIH Guide for Grants and Contracts](https://grants.nih.gov/grants/guide/redirect.php?id=11164) ([//grants.nih.gov/grants/guide/redirect.php?id=11164](https://grants.nih.gov/grants/guide/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/redirect.php?id=11120) ([//grants.nih.gov/grants/guide/redirect.php?id=11120](https://grants.nih.gov/grants/guide/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.

[Weekly TOC for this Announcement \(/grants/guide/WeeklyIndex.cfm?12-20-24\)](#)

[NIH Funding Opportunities and Notices \(/grants/guide/index.html\)](#)



NIH... Turning Discovery Into Health®

## ขั้นตอนการสมัครขอรับทุน National Institute of Health (NIH)

- 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:

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

(\*\*หากผู้สมัครขอรับทุนนำส่งข้อเสนอโครงการให้กับกองบริหารงานวิจัยตรวจสอบล่าช้ากว่ากำหนดของมหาวิทยาลัย มหาวิทยาลัยขอสงวนสิทธิ์ในการรับข้อเสนอโครงการเพื่อนำส่งแหล่งทุนในรอบนั้นๆ)

01

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

02

- Create your eRA commons ID
- Initiate Application in ASSIST

03

- Application preparing
- Letter of support and

04

- Validate Application
- Submission

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

หน่วยสนับสนุนการขอทุนวิจัยจากแหล่งทุนต่างประเทศ

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



# International Fund CLINIC

กลุ่มเป้าหมาย

ทุกวันศุกร์ เวลา 8.00 – 9.00 น.  
ผ่านระบบ Cisco Webex Meetings

✓ อาจารย์/นักวิจัย ผู้สนใจขอรับทุนจากแหล่งทุนต่างประเทศ  
เช่น **NIH Wellcome Trust ERC** เป็นต้น

## กิจกรรมให้คำปรึกษา

- ✓ แนะนำการเขียนข้อเสนอโครงการให้ตรงตามหลักเกณฑ์ของแหล่งทุน
- ✓ แนะนำการจัดเตรียมงบประมาณโครงการให้เหมาะสม
- ✓ แนะนำการเลือกแหล่งทุน เพิ่มโอกาสการได้รับทุนวิจัย  
ตามความเชี่ยวชาญของกิมวิจัย

โดยวิทยากรผู้มีความเชี่ยวชาญและได้รับทุนต่างประเทศอย่างต่อเนื่อง

ฟรี!!  
ไม่มีค่าใช้จ่าย

จองนัดหมาย



ศ.วิจัย ดร.เจตสุวน ประจำศรี

รองคณบดีฝ่ายวิจัย คณะเวชศาสตร์เขตร้อน



รศ.ดร.โรมัส กวาดาเมช

คณะเวชศาสตร์เขตร้อน

ผู้สนใจสามารถจองนัดหมายผ่าน QR code หรือที่ <https://forms.gle/nAZiRbCQXu6pbcr5>

สอบถามรายละเอียดเพิ่มเติมได้ที่ 02-849-6252 [chittiporn.nua@mahidol.ac.th](mailto:chittiporn.nua@mahidol.ac.th)