-ตรวจสอบ+ARC-

งานบริหารงานวิจัยและนวัตกรรม
เลขที่รับ 820
วันที่ 21/11/65
เวลา

รหัสแฟ้ม.....
เก็บเอกสารถึงปี พ.ศ.....
MUSIS

คณะเภสัชศาสตร์
เลขที่รับ 6460
วันที่ 14 พ.ย. 2565
เวลา 10.27 น.

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

ที่ อว 78.016/ว 6109
วันที่ 14 พฤศจิกายน 2565
เรื่อง ประชาสัมพันธ์การเปิดรับข้อเสนอโครงการจากแหล่งทุน National Institutes of Health (NIH) ประเภท Research Project – Cooperative Agreements หัวข้อ "Immunity in Older Adults (U01 Clinical Trial Not Allowed)" หมายเลขประกาศทุน RFA-AI-22-060

สิ่งที่ส่งมาด้วย 1. รายละเอียดประกาศทุน RFA-AI-22-060
2. ขั้นตอนการสมัครขอรับทุน

เรียน คณบดี / ผู้อำนวยการ

ด้วยแหล่งทุน National Institutes of Health (NIH) ประเภท Research Project – Cooperative Agreements หัวข้อ "Immunity in Older Adults (U01 Clinical Trial Not Allowed)" หมายเลขประกาศทุน RFA-AI-22-060 โดย**เปิดรับข้อเสนอโครงการตั้งแต่วันที่ 14 มกราคม 2566 จนถึงวันที่ 14 กุมภาพันธ์ 2566 เวลา 17.00 น. ตามเวลาประเทศไทย** ทั้งนี้ โครงการที่เสนอขอทุนให้ปฏิบัติตามประกาศมหาวิทยาลัยมหิดล เรื่องหลักเกณฑ์และอัตราเงินค่าธรรมเนียมพัฒนาการวิจัยของมหาวิทยาลัยและส่วนงานที่จัดเก็บจากโครงการวิจัยที่ได้รับเงินอุดหนุนจากแหล่งทุนภายนอกมหาวิทยาลัย พ.ศ. 2560 และขอให้ดำเนินการตามที่ระบุในหนังสือชักชวน แนวปฏิบัติ เรื่องมาตรฐานการวิจัยของโครงการวิจัย รายละเอียดดังเอกสารแนบมาด้วยนี้ ทั้งนี้ อาจารย์/นักวิจัยที่สนใจสามารถศึกษารายละเอียดเพิ่มเติมได้ตามเอกสารที่แนบมาด้วยนี้ หรือเว็บไซต์ของแหล่งทุนที่ https://grants.nih.gov/grants/guide/rfa-files/rfa-ai-22-060.html

ในการนี้ กองบริหารงานวิจัย มหาวิทยาลัยมหิดล จึงขอแจ้งข่าวประกาศทุนมายังท่าน เพื่อโปรดประชาสัมพันธ์ทุนวิจัยดังกล่าวให้บุคลากรในหน่วยงานของท่านทราบโดยทั่วกัน และขอให้อาจารย์/นักวิจัย **<u>โปรดแจ้งความประสงค์การจัดส่งข้อเสนอ ภายในวันที่ 14 มกราคม 2566 และจัดส่งข้อเสนอโครงการวิจัยผ่านส่วนงานต้นสังกัดมายังกองบริหารงานวิจัยเพื่อตรวจสอบรายละเอียดข้อเสนอโครงการฉบับสมบูรณ์ภายในวันที่ 7 กุมภาพันธ์ 2566</u> ทั้งนี้ หากส่วนงานแจ้งความประสงค์การจัดส่งข้อเสนอโครงการวิจัยหลังจากวันที่ 7 กุมภาพันธ์ 2566 มหาวิทยาลัยขอสงวนสิทธิ์ในการยื่นข้อเสนอโครงการวิจัยเพื่อขอรับทุนดังกล่าว**

จึงเรียนมาเพื่อโปรดทราบและประชาสัมพันธ์ข่าวทุนวิจัยดังกล่าวต่อไปด้วย จักขอบคุณยิ่ง

งานบริหารงานวิจัยและนวัตกรรม
14 พ.ย. 65

ทราบ
15/พ.ย./65

(ศาสตราจารย์ ดร. นายแพทย์ ภัทรชัย กีรติสิน)
รองอธิการบดีฝ่ายวิจัย

เรียน คณบดี (ผ่านรองฯวิจัย)
- เพื่อโปรดทราบ มหาวิทยาลัยประชาสัมพันธ์ข้อเสนอขอทุน NIH ประเภท Research Project – Cooperative Agreement หมายเลขประกาศทุน RFA-AI-22-060 ซึ่งเปิดรับข้อเสนอตั้งแต่ 14 ม.ค. – 14 ก.พ. 2566 เวลา 17.00 น. (ตามเวลาประเทศไทย) ผู้สนใจที่จะเสนอขอทุนโปรดแจ้งความประสงค์การเสนอขอทุนต่อวิทยาลัยฯ ภายในวันที่ 13 ม.ค. 2566 เพื่อจัดทำ proposal ส่งให้มหาวิทยาลัยตรวจสอบภายใน 6 ก.พ. 2566
- ประชาสัมพันธ์ทุกภาควิชา

ผู้ประสานงาน : นางสาวจิตติพร นวลละออง
โทร 02-849-6252 อีเมล chittiporn.nua@mahidol.edu

รับเรื่องคืนจากเลขานุการคณะฯ
21 พ.ย. 2565
วันที่

- ตาม เชิญวิทยากรบรรยายวิจัย
14 พ.ย. 65

ประชาสัมพันธ์ทุกภาควิชา
14/11/65

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

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

Components of Participating Organizations

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

National Institute on Aging (NIA (https://www.nia.nih.gov/))

National Institute of Dental and Craniofacial Research (NIDCR (https://www.nidcr.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/))

Funding Opportunity Title

Immunity in Older Adults (U01 Clinical Trial Not Allowed)

Activity Code

U01 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=u01&Search.x=0&Search.y=0&Search_Type=Activity) Research Project – Cooperative Agreements

Announcement Type

New

Related Notices

None

Funding Opportunity Announcement (FOA) Number

RFA-AI-22-060

Companion Funding Opportunity

None

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)

93.855, 93.121, 93.866, 93.313

Funding Opportunity Purpose

The purpose of this Funding Opportunity Announcement (FOA) is to support studies that provide mechanistic insights into innate and adaptive immune changes that occur during the aging process. The main objective of the program is to define the contribution of age-related alterations in different components of the immune system and the functional consequences in relation to infections, vaccine responses, and chronic inflammatory conditions.

Key Dates

Posted Date

October 04, 2022

Open Date (Earliest Submission Date)

January 14, 2023

Letter of Intent Due Date(s)

30 days prior to the application due date

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS	Scientific Merit Review	Advisory Council Review	Earliest Start Date
February 14, 2023	Not Applicable	Not Applicable	July 2023	October 2023	December 2023

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

February 15, 2023

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 SF424 (R&R) Application Guide (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400), except where instructed to do otherwise (in this FOA or in a Notice from NIH Guide for Grants and Contracts (//grants.nih.gov/grants/guide/url_redirect.htm?id=11164)).

Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in 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 (http://public.era.nih.gov/commons/) to track your application. Check with your institutional officials regarding availability.

3. Use Grants.gov (https://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=RFA-AI-22-060) Workspace to prepare and submit your application and eRA Commons (http://public.era.nih.gov/commons/) to track your application.

Table of Contents

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Purpose

This Funding Opportunity Announcement (FOA) invites applicants to participate in the Immunity in Older Adults (65 years and older) cooperative agreement research program, which will focus on developing mechanistic insights into innate and adaptive immune function changes that occur during the aging process. The major goal of the program is to define the contribution of age-related alterations in different components of the immune system and the functional consequences in relation to infections, vaccine responses, and chronic inflammatory conditions.

Additionally, the program aims to foster collaborative science and establish innovative approaches that accelerate the discovery of cellular changes and the underlying molecular events occurring in the aging immune system that may potentially be exploited to improve the health of older adults.

Background

Studies in the biology of aging have demonstrated alterations in the immune response and increased susceptibility to infectious, chronic, and autoimmune diseases. While the impact of aging on both innate and adaptive immunity has been well documented, the mechanisms regulating these processes are not well understood. Systemic low-grade inflammation in the absence of pathogens, referred to as inflammaging, is characterized by the production of pro-inflammatory mediators such as interleukin-6 and tumor necrosis factor-alpha. The age-related mechanisms responsible for this chronic inflammation include cellular senescence, impact of prior immunity, mitochondrial dysfunction, autophagy defects, and microbiome composition changes, which contribute to age-related diseases and accompanying morbidity and mortality in older adults. Not all cells in an aging individual may have a senescent phenotype, but accumulation of senescent cells can impact the function of normal cells. Mechanisms to control senescent cell levels appear to be present in younger individuals but decline with increasing age.

Senescent cell accumulation in tissues increases the risk of many age-related diseases, such as osteoarthritis, neurodegeneration, and atherosclerosis, and diminishes responses to infections and vaccines. Impaired clearance of senescent cells with increasing age results in their accumulation and secretion of factors that characterize a condition termed the senescent associated secretory phenotype (SASP). Deciphering the senescent cell types that drive aging most intensely continues to be a crucial question. Although studies using interventions to retard senescence (e.g., senolytics, mTORC1 inhibitors) are being examined, the precise role that senescence and SASP play in age-related changes in innate and adaptive immunity remains to be determined. Immunosenescence, the progressive deterioration of the immune system typically, but not always, observed with aging, stifles the generation of protective innate and T and B cell-mediated adaptive immunity in response to various pathogens, resulting in increased susceptibility to and severity of disease in older adults.

Advances in single-cell techniques in recent years have significantly expanded the current paradigm of immune aging. For example, these techniques have made it possible to better understand the heterogeneity of human CD8 T effector memory cells and distinguish between granzyme K+ and granzyme B+ populations, indicating the granzyme K+ cells as the crucial age associated CD8+ effector memory T cell subset in humans. Additional developments in T cell and B cell receptor repertoire sequencing and other next-generation profiling techniques will permit further assessment of additional questions in the immune aging field. Some of these areas include defining the mechanisms by which aging alters the structure and function of lymph node stroma and the functional consequences for protective immunity; and delineating the molecular processes by which metabolic disease and obesity impair immune function in advanced age. Important work is being done to identify biomarkers associated with immunological aging in the hope of developing prognostic tools to assess an individual's risk of developing specific age-related diseases.

Recent studies have described a novel framework for age-associated and age-independent immunosenescence in which identifiable changes in healthy compared to dysfunctional or dysregulated states are integrated to create clinically useful immune health grades. In these studies, lymphocyte-based and gene-based metrics were used to define an immunologic fitness landscape shaped by an individual's antigenic exposure. Using this approach, the relative burden of progressive COVID-19 was shown to be dependent on the prevalence of individuals who maintained their immune resilience before and during the course of disease. Immune health grades tracked levels of immune competence and levels of inflammation independent of age. In another study using cellular immune phenotypes, cytokine responses and gene expression demonstrated an immunological age metric (IMM-AGE) that predicted overall survival independent of age, gender, and cardiovascular disease. Increased immune age also was associated with autoimmunity and autoinflammatory disease. Thus, metrics of immune age may have the potential to serve as broadly relevant biomarkers of immune function in health and disease.

Despite their crucial role in health and disease, our knowledge of immune cells within human tissues remains limited. Many studies involve an analysis of immune cell populations obtained from peripheral blood, likely due to ease of access. Many of the more mechanistic studies that have been published focused on healthy individuals. It is unclear if such findings can be generalized to less healthy individuals. Thus, mechanistic studies of T cell homeostasis in populations including frail older adults are necessary. While animal studies provide information on immunosenescence, differences between mouse and human immune aging have been observed and a need for caution exists when extrapolating data from one model to the next. Therefore, this initiative will place an emphasis on novel approaches and techniques to probe the aging immune system in human and relevant animal studies.

Research Objectives and Scope

The main objective of the Immunity in Older Adults program is to improve our mechanistic understanding of the immunologic processes during aging in humans. Additionally, this initiative seeks to expand research addressing basic immune mechanisms associated with oral, dental, and craniofacial health and pathologies in older individuals. As many of the changes evident in older adults (>65 years) and pathogenesis of age-related diseases may begin at younger ages (<50-60 years), comparisons between this latter, younger age group and older adults, or projects studying immune changes emerging in older adults are necessary. Applicants are encouraged to leverage existing longitudinal cohorts or obtain biospecimens from independently funded clinical trials. Study samples also may be included from repositories such as the Baltimore Longitudinal Study on Aging (BLSA (https://www.blsa.nih.gov/)) or other existing repositories. Interested applicants are expected to establish collaborations with investigators responsible for these repositories prior to submitting an application to this FOA.

Research projects proposed in response to this FOA should test hypotheses related to this objective and must adhere to the following parameters:

- All studies must be performed using human subjects and/or materials.
- Relevant and appropriately aged animal models may be included to extend human studies and/or investigate mechanisms using approaches that may not be feasible in human subjects.
- Studies must include sex/gender and racial/ethnic considerations.

Research Areas of Interest for NIAID and NIA include, but are not limited to the following:

- Defining mechanisms of dysfunction in the aged innate and mucosal immune systems;
- Determining molecular processes of age-independent immune dysfunction;
- Defining mechanisms by which chronic infection or unresolved inflammation influences the development of accelerated immune aging;
- Defining the impact of persistent or latent infections on immunosenescence;
- Determining correlates of protection, markers of disease progression and severity of disease in response to infection or vaccination;
- Examining the impact of prior immunity on host responses to vaccination and subsequent infection;
- Elucidating mechanisms by which DNA damage activates the immune response or drives chronic inflammation during the aging process;
- Defining how aging alters the structure and function of lymph node stroma and the functional consequences for protective immunity;
- Delineating the mechanisms involved in how advanced age, metabolic disease and obesity impair immune function;
- Determining how tissue resident immune cells regulate tissue function and homeostasis in aged tissues and organs;
- Defining age-related changes in the host microbiota and their effect on local immune regulation and hematopoiesis;
- Examining the process and mechanisms by which aging alters communication between other cell types (e.g., platelets, adipocytes, stromal cells), tissues and organs (e.g., lung, CNS, lymphatics);
- Elucidating age-related immune changes that alter vaccine efficacy against infectious diseases;
- Determining mechanisms that promote durable immune memory formation;
- Elucidating the role and mechanisms of the microbiome on conferring effective vaccine responses and inflammatory processes during aging;
- Identifying unique markers of B cell immunosenescence, the developmental pathways by which these populations arise, and mechanisms that restore antibody production and quality;
- Analyzing vaccines with or without adjuvants for their effects on T cell repertoires in aging individuals;
- Defining the impact of aging on innate and adaptive immunity in the female genital tract
- Immunologic profiling across different racial/ethnic backgrounds for the development of immunological interventions and vaccines that are effective for diverse older populations;
- Studies to understand the heterogeneity of immune cells during aging such as age-and environmentally-associated changes of immune cell diversity;
- Studies on the composition, phenotype, and antigen specificity of immune cells such as B and T cells in the CNS during the aging process;
- Studies on interactions between innate and adaptive immunity in the CNS during aging.

Research areas of interest to NIDCR include, but are not limited to:

- Understanding tissue-specific mechanisms of age-related immunologic processes that drive aging in dental, oral, and craniofacial tissues;
- Defining mechanisms of inflammaging in resolution or decreased resilience in later life;
- Utilization of aged animal models for studying immune mechanisms in tissues in oral health and disease;
- Investigating how biological variables (e.g., sex/gender, age) alter disease recovery due to immunosenescence.

NIH Office of Research on Women's Health (ORWH)

The Office of Research on Women's Health (ORWH) is part of the NIH Office of the Director, and works in partnership with the 28 NIH Institutes, Centers, and Offices (ICOs) to ensure that women's health research is part of the NIH scientific framework and supported throughout the biomedical enterprise.ORWH uses a multidimensional framework to represent the intersection of factors that underlie patterns of disease and determinants of health outcomes in populations.

ORWH isinterested in supportingbiomedical research that considers sex and/or gender influences andincludes adequate plans for collecting and reporting sex-specific data. There is a crucial need to address sex and/or gender influences in basic, translational, interdisciplinary, behavioral, clinical, and/or health services research relevant to women's health, and, where appropriate, include both sexes to better understand the influence of sex asa biological variable (SABV (https://orwh.od.nih.gov/sites/orwh/files/docs/NOT-OD-15-102_Guidance.pdf)) on health and disease. Integrating the purposeful accounting for SABV in biomedical research,from the most basic to the clinical and applied efforts, will fill gaps in our knowledge, and will inform more effective and personalized approaches for women and men. For additional guidance,please reviewthe 2019-2023 Trans-NIH Strategic Plan for the Health of Women (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)).

All applicants are encouraged to incorporate and test novel approaches or combinations of approaches that may hold promise to reduce cost and clinical burden on longitudinal cohort studies. These approaches include, but are not limited to:

- Analytic approaches that will enable extraction from small biospecimens pertinent to understanding the immunologic events that drive clinical outcomes in older adults;
- Determination of the relative advantages of using peripheral blood and other biospecimens for obtaining immunologically valuable data.

Applications proposing any of the following will be deemed non-responsive and will not be reviewed:

- Clinical trials; however, clinical research using specimens obtained from human subjects in clinical trials funded through other mechanisms is allowed
- Projects focused on cancer
- Projects focused on HIV/SIV/AIDS
- Genome-wide association studies
- Projects that do not use human samples
- Projects focused exclusively on animal studies and/or samples
- Projects that do not focus on aging
- Projects focused on behavioral studies
- Epidemiological studies

Steering Committee:

Immunity in Older Adults will be coordinated by a Steering Committee composed of the PD(s)/PI(s) of each award. A NIAID, NIDCR, or NIA Program Officer will be responsible for the scientific and programmatic stewardship of an award and will be named in the award notice. NIAID staff assistance will be provided by Project Scientists from NIAID's Division of Allergy, Immunology and Transplantation (DAIT) along with other NIH staff. The Steering Committee will conduct regular meetings by teleconference as well as an annual plenary meeting where all investigators will have an opportunity to formally discuss progress and possibilities for collaboration with the group and staff from NIAID, NIA, and NIDCR.

See Section VIII. Other Information for award authorities and regulations.

Section II. Award Information

Funding Instrument

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

Application Types Allowed

New

The OER Glossary (//grants.nih.gov/grants/guide/url_redirect.htm?id=11116) and the SF424 (R&R) Application Guide provide details on these application types. Only those application types listed here are allowed for this FOA.

Clinical Trial?

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

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

Funds Available and Anticipated Number of Awards

NIAID and partner components intend to commit an estimated total of $4.42M to fund 5-7 awards.

Award Budget

Application budgets are not expected to exceed $400,000 in direct costs per year and should reflect the actual needs of the proposed project.

Award Project Period

The project period must be five years.

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

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

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 Government

- 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 Institutions)

Foreign Institutions

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

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

Foreign components, as defined in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11118), **are** allowed.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The NIH Policy on Late Submission of Grant Applications (//grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html) states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

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

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

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

Eligible Individuals (Program Director/Principal Investigator)

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

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

2. Cost Sharing

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

3. Additional Information on Eligibility

Number of Applications

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

The NIH will not accept duplicate or highly overlapping applications under review at the same time, per 2.3.7.4 Submission of Resubmission Application (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.3.7_policies_affecting_applications.htm#Submissi). 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 2.3.9.4 Similar, Essentially Identical, or Identical Applications (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.3.9_application_receipt_information_and_deadlines.htm#Similar.))

Section IV. Application and Submission Information

1. Requesting an Application Package

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

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the Research (R) Instructions in the SF424 (R&R) Application Guide (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Letter of Intent

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

By the date listed in 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:

Vanitha Raman, Ph.D.
Telephone: 240-457-2783
Email: vanitha.raman@nih.gov (mailto:vanitha.raman@nih.gov)

Page Limitations

All page limitations described in the SF424 Application Guide and the Table of Page Limits (//grants.nih.gov/grants/guide/url_redirect.htm?id=11133) must be followed.

Instructions for Application Submission

The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this FOA.

SF424(R&R) Cover

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

SF424(R&R) Project/Performance Site Locations

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

SF424(R&R) Other Project Information

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

SF424(R&R) Senior/Key Person Profile

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

R&R or Modular Budget

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

Include travel costs for the PD/PI and relevant key personnel to attend annual meetings which will be held for one-and-a-half days in the Bethesda/Rockville, MD area.

R&R Subaward Budget

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

PHS 398 Cover Page Supplement

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

PHS 398 Research Plan

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

Research Strategy: In the description and explanation of the research strategy, address specifically the following points:

- Describe how the proposed studies will elucidate mechanisms driving the immune dysfunction during aging in older adults.
- Provide the rationale for the choice of subject populations.
- Since pathogenesis of age-related diseases involves gradually accumulating damage to organ systems, and age-independent immunosenescence also may occur, describe the approach for cohort comparison of findings for older adults (i.e., inclusion of a younger cohort).

- Describe approaches and measures to be taken to reduce noise and bias in the data collected from all cohorts.
- Describe how the proposed studies and any innovative approaches used will reduce or remove barriers to studying immune mechanisms in younger and older adults.
- Provide the rationale for the selection of biospecimens for the study.
- Describe potential confounders and statistical considerations inherent in the use of preexisting specimens or cohorts, or in analysis of merged cohorts.
- Provide details regarding the innovative approaches for biospecimen procurement or analysis.
- If the proposed study includes an animal model(s), describe and justify the unique features of the animal model, including for example, the relative age of the animal model corresponding to the equivalent age in humans, as it pertains to the experimental hypothesis.

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

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.
- All investigators funded under this FOA are expected to share their data publicly through ImmPort (http://www.immport.org (http://www.immport.org)) or other public portals approved by NIAID. Therefore, the Data Sharing Plan should include a summary of how the applicant will manage data submission and interactions with ImmPort or other NIAID-approved public portal.

Appendix:

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

PHS Human Subjects and Clinical Trials Information

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

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

Study Record: PHS Human Subjects and Clinical Trials Information

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

Delayed Onset Study

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

PHS Assignment Request Form

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

Foreign Institutions

Foreign (non-U.S.) institutions must follow policies described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11137), and procedures for foreign institutions described throughout the SF424 (R&R) Application Guide.

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

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

4. Submission Dates and Times

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

Organizations must submit applications to Grants.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=11128) (the online portal to find and apply for grants across all Federal agencies). 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.htm?id=11123), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission.

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

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

5. Intergovernmental Review (E.O. 12372)

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

6. Funding Restrictions

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

Pre-award costs are allowable only as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11143).

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

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/how-to-apply-application-guide.html). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Dealing with System Issues (https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm) guidance. For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:

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

The applicant organization must ensure that the unique entity identifier provided on the application is the same identifier used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the SF424 (R&R) Application Guide.

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

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

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in the policy (//grants.nih.gov/grants/guide/url_redirect.htm?id=82299). 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 (//grants.nih.gov/grants/guide/url_redirect.htm?id=11149) are evaluated for scientific and technical merit through the NIH peer review system.

Overall Impact

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

Scored Review Criteria

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

Significance

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

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?

Specific to this FOA

Does the applicant propose innovative approaches to the study of immune mechanisms in older adults with respect to biospecimen procurement or analysis?

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 tne investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

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

Specific to this FOA

Are the proposed approaches likely to facilitate further elucidation of immune mechanisms in older adults? Is there a younger cohort or samples from a younger cohort included for comparison? Are the cohorts appropriately designed to reduce bias and noise in the data? Are the cohorts used, whether new or existing, sufficiently justified for the goal of the project and adequately sized to provide sufficient statistical power for the proposed studies? If cohorts are to be merged, are potential confounders adequately addressed? If the proposed study includes an animal model(s), If the proposed study includes an animal model(s), are there unique features of the animal model, including for example, the relative age of the animal model that correspond to the equivalent age in humans, as it pertains to the experimental hypothesis?

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/url_redirect.htm?id=11175).

Inclusion of Women, Minorities, and Individuals Across the Lifespan

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of individuals of all ages (including children and older adults) to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research (//grants.nih.gov/grants/guide/url_redirect.htm?id=11174).

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section (//grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

Biohazards

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

Resubmissions

Not Applicable

Renewals

Not Applicable

Revisions

Not Applicable

Additional Review Considerations

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 following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: (1) Data Sharing Plan (//grants.nih.gov/grants/guide/url_redirect.htm?id=11151); (2) Sharing Model Organisms (https://sharing.nih.gov/other-sharing-policies/model-organism-sharing-policy#policy-overview); and (3) Genomic Data Sharing Plan (GDS) (https://sharing.nih.gov/genomic-data-sharing-policy).

Authentication of Key Biological and/or Chemical Resources:

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

Budget and Period of Support

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

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by the National Institute of Allergy and Infectious Diseases (NIAID), in accordance with NIH peer review policy and procedures (//grants.nih.gov/grants/guide/url_redirect.htm?id=11154), using the stated review criteria (file:///C:/Users/mckenziene/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/13V4QPZR/Research%20Draft.doc#_1._Criteria). Assignment to a Scientific Review Group will be shown in the eRA Commons.

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

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

Appeals (https://grants.nih.gov/grants/policy/nihgps/html5/section_2/2.4.2_appeals_of_initial_scientific_review.htm)of initial peer review will not be accepted for applications submitted in response to this FOA.

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

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

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 (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

Information regarding the disposition of applications is available in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the NIH Grants Policy Statement (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.5.1_just-in-time_procedures.htm).

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

Recipients must comply with any funding restrictions described in Section IV.5. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

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

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

2. Administrative and National Policy Requirements

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

- Federalwide Research Terms and Conditions (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_3/3.1_federalwide_standard_terms_and_conditions_for_research_grants.htm)
- Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-041.html)
- Acknowledgment of Federal Funding (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.2.1_acknowledgement_of_federal_funding.htm)

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

Should the applicant organization successfully compete for an award, recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identify, sexual orientation, and pregnancy). This includes ensuring programs are accessible to persons with limited English proficiency and persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please see https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html (https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html) and https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html (https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html)

HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols

that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research. For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this FOA.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html (https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html) and https://www.lep.gov (https://www.lep.gov/).
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including reasonable accommodations and making services accessible to them, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html (http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html).
- HHS funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html (https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html). For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm (https://grants.nih.gov/grants/policy/harassment.htm).
- For guidance on administering programs in compliance with applicable federal conscience protection and associated anti-discrimination laws see https://www.hhs.gov/conscience/conscience-protections/index.html (https://www.hhs.gov/conscience/conscience-protections/index.html) and https://www.hhs.gov/conscience/religious-freedom/index.html (https://www.hhs.gov/conscience/religious-freedom/index.html).

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

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 and 2 CFR Part 200.206 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships.

Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Part 75 and 2 CFR Part 200, and other HHS, PHS, and NIH grant administration policies.

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

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

- Advancing and coordinating the activities of their project(s) scientifically and administratively;
- Implementing policies approved by the Steering Committee or placed by NIAID;
- Sharing all data publicly through ImmPort or other public portals designated by NIAID, as appropriate and consistent with achieving the goals of the program;
- Ensuring that one PD/PI (or their designee) from each grant will attend meetings and serve as a voting member of the Steering Committee.
- Recipients will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and NIH policies.

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

A NIAID, NIDCR, or NIA Program Officer will be responsible for the scientific and programmatic stewardship of the award and will be named in the award notice. NIAID staff assistance will be provided by Project Scientists from NIAID's Division of Allergy, Immunology and Transplantation (DAIT) along with other NIH staff. They will have substantial programmatic involvement during the conduct of this activity through technical assistance, advice, and coordination, including:

- Participating in monitoring with respect to compliance with Federal regulations, quality control, accuracy of data recording, sample accrual, and any other key activities;
- Facilitating collaborations with and access to other NIAID/NIA/NIDCR-supported research resources and services;
- Serving as liaison and facilitator among recipients and with the data portal ImmPort and its staff;
- Providing oversight for human subjects protections and providing monitoring for any studies that involve more than minimal risk for participants who are considered vulnerable populations;
- Providing assistance to the Steering Committee in the development of procedures for evaluating the performance of research studies;
- Participating on the Steering Committee, coordinating Steering Committee activities, and implementing its recommendations, decisions, and policies;
- Sharing information regarding promising new approaches, strategies, and developments when appropriate;
- Identifying scientific gaps and organizing meetings to facilitate the exchange of scientific and regulatory information;
- Participating in the presentation of research results, including publications, and attending annual meetings of the program.

Areas of joint responsibility include:

Steering Committee

A Steering Committee will serve as the coordinating body for the Immunity in Older Adults research program. It will be formed by a single PI/PD from each grant, a representative from NIAID, NIA, NIDCR, and other members as needed to effectively achieve the goals of the program. Each member of the Steering Committee will have one vote. The NIAID/NIA/NIDCR representative will neither vote nor serve as Chair of the Steering Committee. All participants in the Immunity in Older Adults program are bound by the decisions, policies, and procedures developed by the Steering Committee.

The Steering Committee responsibilities include:

- Coordinating the research activities of the Immunity in Older Adults group;
- Developing policies and procedures as needed to facilitate achievement of the goals of the Immunity in Older Adults program;
- Conducting a plenary meeting of Immunity in Older Adults investigators and other invited participants as deemed necessary by the Committee, no less than annually to assess progress;
- Identifying persistent technical and intellectual gaps in the field and recommending actions to remedy those gaps.

Dispute resolution:

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

3. Reporting

When multiple years are involved, recipients will be required to submit the Research Performance Progress Report (RPPR) (//grants.nih.gov/grants/rppr/index.htm) annually and financial statements as required in the NIH Grants Policy Statement. (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.4.1_reporting.htm)

A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the NIH Grants Policy Statement (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.6_closeout.htm). NIH FOAs outline intended research goals and objectives. Post award, NIH will review and measure performance based on the details and outcomes that are shared within the RPPR, as described at 45 CFR Part 75.301 and 2 CFR Part 200.301.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=11170) on all subawards over $25,000. See the NIH Grants Policy Statement (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1.8_federal_funding_accountability_and_transparency_act__ffata_.htm) for additional information on this reporting requirement.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than $10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 – Award Term and Conditions for Recipient Integrity and Performance Matters.

Section VII. Agency Contacts

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

Application Submission Contacts

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

Finding Help Online: http://grants.nih.gov/support/ (//grants.nih.gov/support/) (preferred method of contact)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

General Grants Information (Questions regarding application instructions, application processes, and NIH grant resources)
Email: GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov) (preferred method of contact)
Telephone: 301-945-7573

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)

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Financial/Grants Management Contact(s)

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Section VIII. Other Information

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

Authority and Regulations

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

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?10-07-22)
NIH Funding Opportunities and Notices (/grants/guide/index.html)

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

ขั้นตอนการสมัครขอรับทุน National Institute of Health (NIH)

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

   Name: Surname:

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

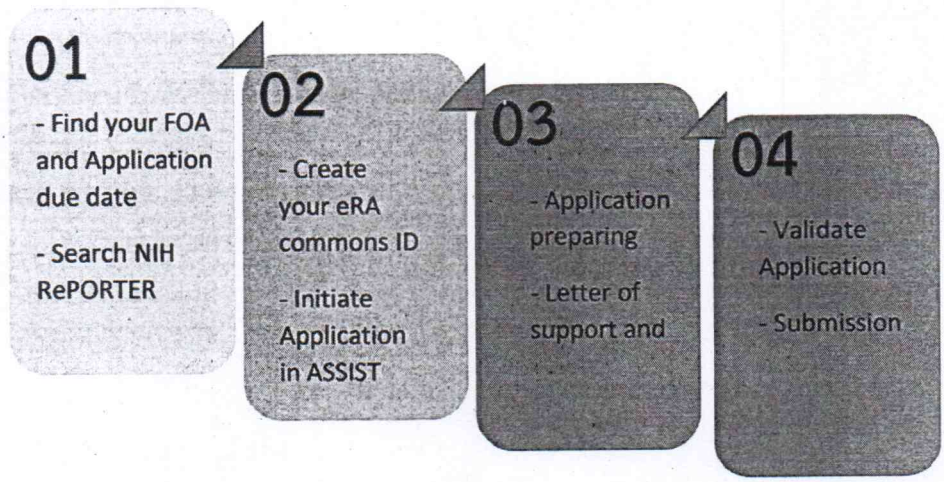
   Funding Opportunity Announcement (FOA) Number:

   Application title:

   Application due date:

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

   (**หากผู้สมัครขอรับทุนนำส่งข้อเสนอโครงการให้กองบริหารงานวิจัยตรวจสอบล่าช้ากว่ากำหนดของมหาวิทยาลัย มหาวิทยาลัยขอสงวนสิทธิ์ในการรับข้อเสนอโครงการเพื่อนำส่งแหล่งทุนในรอบนั้นๆ)



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