U.S. Department of Health & Human Services

NIH National Institutes of Health
Turning Discovery Into Health

คู่มือการบริหารจัดการทุนวิจัยต่างประเทศ สถาบันNIH

จัดทำ กองการต่างประเทศ มหาวิทยาลัยขอนแก่น

พฤษภาคม ปี 2562

สารบัญ

คู่มือการบริหารจัดการทุนวิจัยต่างประเทศของสถาบัน NIH

1. About The National Institutes of Health (NIH)

NIH is the primary agency of the United States government responsible for biomedical and public health research. It was founded in the late 1870s and is now part of the United States Department of Health and Human Services. The majority of NIH facilities are located in Bethesda, Maryland.

Aerial photo of the NIH Mark O. Hatfield Clinical Research Center, Bethesda, Maryland

The NIH conducts its own scientific research through its Intramural Research Program (IRP) and provides major biomedical research funding to non-NIH research facilities through its Extramural Research Program.

As of 2013, the IRP had 1,200 principal investigators and more than 4,000 postdoctoral fellows in basic, translational, and clinical research, being the largest biomedical research institution in the world, while, as of 2003, the extramural arm provided 28% of biomedical research funding spent annually in the U.S., or about US$26.4 billion.

The NIH comprises 27 separate institutes and centers of different biomedical disciplines and is responsible for many scientific accomplishments, including the discovery of fluoride to prevent tooth decay, the use of lithium to manage bipolar disorder, and the creation of vaccines against hepatitis, *Haemophilus influenzae* (HIB), and human papillomavirus (HPV).

2. NIH Office of the Director (OD)

The Office of the Director is the central office at NIH for its 27 Institutes and Centers. The OD is responsible for setting policy for NIH and for planning, managing, and coordinating the programs and activities of all the NIH components. OD program offices include the Office of AIDS Research and the Office of Research on Women's Health, among others.

3. Types of Grant funding Programs

The following groupings represent the main types of grant funding NIH provides:

- Research Grants (R series)
- Career Development Awards (K series)
- Research Training and Fellowships (T & F series)
- Program Project/Center Grants (P series)
- Resource Grants (various series)
- Trans-NIH Programs
- Inactive Programs (Archive)

NIH uses activity Research grant codes (e.g. R01, R43, etc.) to differentiate the wide variety of research-related programs as following:

1) R03	NIH Small Grant Program (R03): Provides limited funding for a short period of time to support a variety of types of projects, including: pilot or feasibility studies, collection of preliminary data, secondary analysis of existing data, small, self-contained research projects, development of new research technology, etc. Limited to two years of funding Direct costs generally up to $50,000 per year Not renewable Utilized by more than half of the NIH ICs
2) R13	NIH Support for Conferences and Scientific Meetings (R13 and U13) Support for high quality conferences/scientific meetings that are relevant to NIH's scientific mission and to the public health Requires advance permission from the funding IC Foreign institutions are not eligible to apply Award amounts vary and limits are set by individual ICs Support for up to 5 years may be possible
3) R15	NIH Academic Research Enhancement Award (AREA) Support small research projects in the biomedical and behavioral sciences conducted by undergraduate and/or graduate students and faculty in institutions of higher education that have not been major recipients of NIH research grant funds Eligibility limited (see https://grants.nih.gov//grants/funding/area.htm) Direct cost limited to $300,000 over entire project period Project period limited to up to 3 years All NIH ICs utilize except FIC and NCATS
4) R21	NIH Exploratory/Developmental Research Grant Award (R21) Encourages new, exploratory and developmental research projects by providing support for the early stages of project development. Sometimes used for pilot and feasibility studies. Limited to up to two years of funding Combined budget for direct costs for the two year project period usually may not exceed $275,000. No preliminary data is generally required Most ICs utilize
5) R34	NIH Clinical Trial Planning Grant (R34) Program

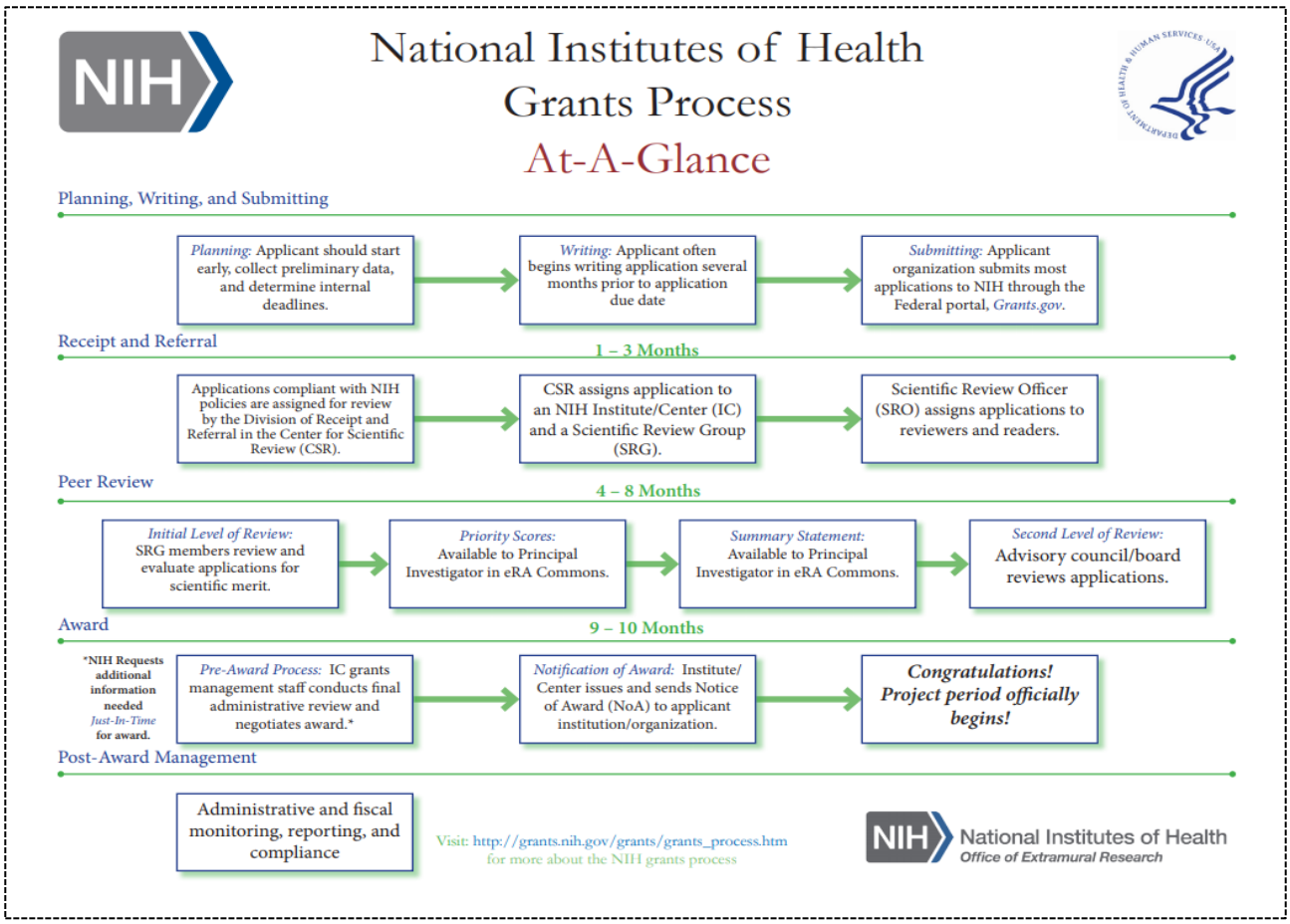
	Designed to permit early peer review of the rationale for the proposed clinical trial and support development of essential elements of a clinical trial Usually project period of one year, sometimes up to 3 Usually, allows for a budget of up to $100,000 direct costs, sometimes up to $450,000 Used only by select ICs; no parent FOA
6) R41/ R42	Small Business Technology Transfer (STTR) Intended to stimulate scientific and technological innovation through cooperative research/research and development (R/R&D) carried out between small business concerns (SBCs) and research institutions (RIs) Fosters technology transfer between SBCs and RIs Assists the small business and research communities in commercializing innovative technologies Three-phase structure: I - Feasibility study to establish scientific/technical merit of the proposed R/R&D efforts (generally, 1 year; $150,000) II - Full R/R&D efforts initiated in Phase I (generally 2 years; $1,000,000) III- Commercialization stage (cannot use STTR funds) Eligibility limited to U.S. small business concerns Project Director/Principal investigator (PD/PI) may be employed with the SBC *or* the participating non-profit research institution as long as he/she has a formal appointment with or commitment to the applicant SBC. Multiple PD/PIs allowed All ICs utilize except FIC
7) R43/ R44	Small Business Innovative Research (SBIR) Intended to stimulate technological innovation in the private sector by supporting research or research and development (R/R&D) for for-profit institutions for ideas that have potential for commercialization Assists the small business research community in commercializing innovative technologies Three-phase structure: I - Feasibility study to establish scientific/technical merit of the proposed R/R&D efforts (generally, 6 months; $150,000) II - Full research or R&D efforts initiated in Phase I (generally 2 years; $1,000,000) III- Commercialization stage (cannot use SBIR funds) Eligibility limited to U.S. small business concerns ○ The primary employment of the Project Director/Principal investigator (PD/PI) must be with the small business concern. ○ Multiple PD/PIs allowed. ○ All ICs utilize except FIC
8) R56	NIH High Priority, Short-Term Project Award (R56) • Will fund, for one or two years, high-priority new or competing renewal R01 applications with priority scores or percentiles that fall just outside the funding limits of participating NIH Institutes and Centers (IC). Investigators may not apply for R56 grants.
9) U01	Research Project Cooperative Agreement

	• Supports discrete, specified, circumscribed projects to be performed by investigator(s) in an area representing their specific interests and competencies • Used when substantial programmatic involvement is anticipated between the awarding Institute and Center • One of many types of cooperative agreements • No specific dollar limit unless specified in FOA

10) K99/R00	• NIH Pathway to Independence (PI) Award (K99/R00)
	Also see, New Investigators Program web page
	• Provides up to five years of support consisting of two phases
	  ○ I - will provide 1-2 years of mentored support for highly promising, postdoctoral research scientists
	  ○ II - up to 3 years of independent support contingent on securing an independent research position
	• Award recipients will be expected to compete successfully for independent R01 support from the NIH during the career transition award period
	• Eligible Principal Investigators include outstanding postdoctoral candidates who have terminal clinical or research doctorates who have no more than 4 years of postdoctoral research training
	• Foreign institutions are not eligible to apply
	• PI does not have to be a U.S. citizen

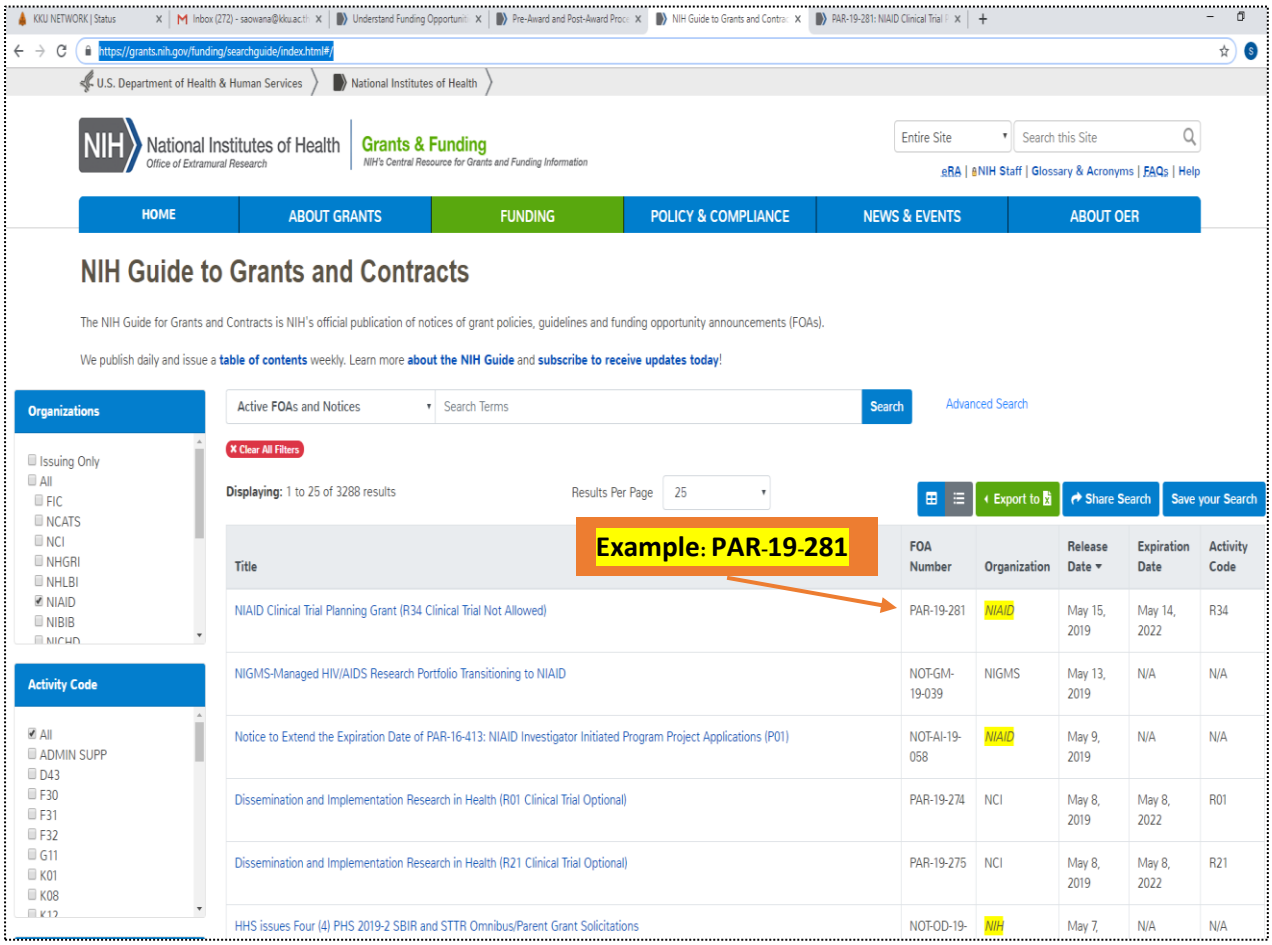
4. NIH Grants Process At-A-Glance

Learn about the steps required for an application to proceed from planning and submission through to award and closeout.



5. NIH Funding Opportunity Announcements (FOAs)

NIH advertises availability of grant support through funding opportunity announcements (FOAs). Search for an FOA specific to your area of interest, or apply to one of our generic **via** https://grants.nih.gov/funding/searchguide/index.html#/ as below image:



For Example: FOA Number PAR-19-281

After double clicking and then will find 2 Parts such as Over information & Full text of announcement. In the Part 2 contains 8 sections.

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)
National Institutes of Health (NIH)

Components of Participating Organizations
National Institute of Allergy and Infectious Diseases (NIAID)

Funding Opportunity Title
NIAID Clinical Trial Planning Grant (R34 Clinical Trial Not Allowed)

Activity Code
R34 Planning Grant

Grant type R34

Announcement Type
Reissue of PAR-16-272

Related Notices
None

Funding Opportunity Announcement (FOA) Number
PAR-19-281

FOA No.

Companion Funding Opportunity
PAR-18-633, U01 Research Project - Cooperative Agreements
PAR-18-632, U44 Small Business Innovation Research (SBIR) Cooperative Agreements - Phase II
PA-18-345, R01 Research Project Grants

Number of Applications
See Section III. 3. Additional Information on Eligibility.

Catalog of Federal Domestic Assistance (CFDA) Number(s)

93.855

Funding Opportunity Purpose

This Funding Opportunity Announcement (FOA) encourages applications that propose to complete planning, design, and preparation of the documentation necessary for implementation of investigator-initiated clinical trials. The trials should be hypothesis-driven, milestone-defined, related to the research mission of the NIAID and considered high-priority by the Institute. Investigators are encouraged to visit the NIAID website for additional information about the research mission and high-priority research areas of the NIAID (https://www.niaid.nih.gov/research/role).

Key Dates

Posted Date

May 15, 2019

Open Date (Earliest Submission Date)

August 13, 2019

Letter of Intent Due Date(s)

30 days prior to the application due date

Application Due Date(s)

September 13, 2019; January 13, 2020; May 12, 2020; September 14, 2020 January 12, 2021; May 14, 2021; September 13, 2021; January 14, 2022; May 13, 2022,

by 5:00 PM local time of applicant organization. All types of non-AIDS applications allowed for this funding opportunity announcement are due on these dates.

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.

AIDS Application Due Date(s)

September 13, 2019; January 13, 2020; May 12, 2020; September 14, 2020; January 12, 2021; May 14, 2021; September 13, 2021; January 14, 2022; May 13, 2022,

by 5:00 PM local time of applicant organization.

All types of AIDS and AIDS-related applications allowed for this funding opportunity announcement are due on these dates.

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.

Scientific Merit Review

Non-AIDS Applications: February 2020; June 2020; October 2020; February 2021; June 2021; October 2021; February 2022; June 2022; October 2022

AIDS Applications: December 2019; April 2020; August 2020; December 2020; April 2021; August 2021; December 2021; April 2022; August 2022

Advisory Council Review

Non AIDS Applications: May 2020; October, 2020; January 2021; May 2021; October 2021; January 2022; May 2022; October 2022; January 2023

AIDS Applications: January 2020; May 2020; October, 2020; January 2021; May 2021; October 2021; January 2022; May 2022; October 2022

Earliest Start Date

Non-AIDS Applications: July 2020; December 2020; March 2021; July 2021; December 2021; March 2022; July 2022; December 2022; March 2023

AIDS Applications: March 2020; July 2020; December 2020; March 2021; July 2021; December 2021; March 2022; July 2022; December 2022

Expiration Date

May 14, 2022

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,except where instructed to do otherwise (in this FOA or in a Notice from NIH Guide for Grants and Contracts).

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 to track your application. Check with your institutional officials regarding availability.

3. Use Grants.gov Workspace to prepare and submit your application and eRA Commons to track your application.

Table of Contents

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Research Purpose

This Funding Opportunity Announcement (FOA) encourages applications that propose planning, design, and preparation of documentation necessary for implementation of investigator-initiated clinical trials.

A clinical trial is defined by NIH 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." See more at https://grants.nih.gov/policy/clinical-trials/definition.htm.

In addition, any research study that will require a regulatory oversight (such as IND or IDE) will be in the scope of this FOA.

The NIAID Clinical Trial Planning Grant will support planning for clinical trials that address high-priority research questions related to the mission and goals of the NIAID. Sufficient pre-clinical data to support the planning of the clinical trial should be available prior to submission of the R34 grant application. The trials should be hypothesis-driven and milestone-defined.

The NIAID Clinical Trial Planning Grant is not a prerequisite for submission of an R01, U01 or U44 application for implementation of investigator-initiated clinical trials.

Background

Over the past three years, NIAID committed over $4 billion to clinical research, of which $2 billion was devoted to clinical trials. Clinical trials are one research strategy NIAID uses to improve the understanding of the clinical mechanisms of infectious, immunologic, and allergic diseases or to improve prevention, diagnosis, and treatment. For additional information about the mission, strategic plan, and research interests of the NIAID, applicants are encouraged to consult the NIAID web site https://www.niaid.nih.gov/research/role.

NIAID Supported Clinical Trials and Infrastructure

NIAID supports clinical trial infrastructure and networks thru a variety of funding mechanisms focused on high-priority disease research areas. Examples include the HIV/AIDS Clinical Trial Networks supported by the Division of AIDS (https://www.niaid.nih.gov/research/hivaids-clinical-trials-networks), the Division of Microbiology and Infectious Diseases Clinical Trials Programs and Networks (https://www.niaid.nih.gov/research/networks?keyword=&division=12) , and the Immune Tolerance Network supported by the Division of Allergy, Immunology and Transplantation (http://www.immunetolerance.org). NIAID's clinical research infrastructure includes coordinating centers, statistical units, data centers, central laboratories, clinical centers, and other specialized resources. For additional information on DMID-supported clinical trials refer to the DMID Good Clinical Practice and Human Subjects Protections (https://www.niaid.nih.gov/research/dmid-good-clinical-practices-human-subjects-protections). For additional information on DAIDS-supported clinical trials refer to the Division of AIDS Clinical Research Policies and Standard Procedures Documents: https://www.niaid.nih.gov/research/daids-clinical-research-policies-standard-procedures. For additional information on DAIT-supported clinical trials, refer to DAIT Clinical Research Policies and Standards: https://www.niaid.nih.gov/research/dait-clinical-research-policies-and-standards.

Investigator-Initiated Clinical Trials

The NIAID Clinical Trial Planning Grant is available to support planning activities associated with either high-risk or non-high-risk clinical trials. However, the NIAID Clinical Trial Planning Grant is not a prerequisite for any unsolicited NIAID clinical trial award. The planning grant is designed to: (1) permit early peer review of the rationale for the proposed clinical trial; (2) permit assessment of the design/protocol of the proposed trial in a preliminary form; (3) provide support for the development of a complete study protocol and associated documents, including a manual of operations and (4) support the development of other essential elements of a clinical trial. If a clinical trial is ready for implementation and readiness is adequately supported by documentation, submission of an R01, U01 or U44 application may occur. Note that funding of the Clinical Trial Planning Grant does not guarantee or imply funding of a subsequent NIAID Clinical Trial.

For additional information about NIAID's investigator-initiated clinical trial program, see https://www.niaid.nih.gov/grants-contracts/investigator-initiated-clinical-trial-resources .

Although the NIAID Clinical Terms of Award will not be applied to planning grant awards, applicants are encouraged to review the NIAID Clinical Terms of Award and associated guidance documents while preparing applications for submission under this FOA (see https://www.niaid.nih.gov/grants-contracts/niaid-clinical-terms-award).

Investigators are referred to the Division-specific research policies and standard procedures for protocol templates, guidance, and requirements for clinical trials. See Division of AIDS (DAIDS) Clinical Research Policies and Standard Procedure Documents;

Division of Microbiology and Infectious Diseases (DMID) Office of Clinical Research Affairs;

Division of Allergy, Immunology, and Transplantation (DAIT) Clinical Research Policies and Standards. Investigators are also referred to Rules and Policies for Clinical Research https://www.niaid.nih.gov/research/trans-niaid-clinical-research-toolkit.

Investigators are strongly encouraged to contact NIAID's program divisions (Agency Contacts) for more information regarding division-specific clinical research policies and procedures.

Scope

The NIAID Clinical Trial Planning Grant supports timely development of all materials required for implementation of the future clinical trial.

Awards made under this FOA will support all clinical trial planning activities, including, but not limited to:

- establishment of the research team
- identification of collaborators and enrollment sites
- finalization of the design of the study
- development of the complete clinical protocol
- development of the statistical analysis plan
- development of the data management plan
- development of the informed consent(s) and assent form(s), if applicable
- development of the investigator's brochure or equivalent
- development of a manual of operations
- development of a data sharing plan
- development of milestones
- development of case report forms
- development of a plan for the acquisition and administration of study agent(s)
- obtaining required Office of Human Research Protections (OHRP) assurances, if not already in place
- determination of whether the trial will be conducted under an IND/IDE and who will hold the IND/IDE (NIAID reserves the right to decide whether the applicant should apply for an IND/IDE, as well as the right to hold the IND/IDE)

- development of a complete set of suitable documents for submission to the appropriate regulatory authorities, including the development of a regulatory strategy
- development of a data and safety monitoring plan
- development of a detailed budget for conduct and completion of the clinical trial, including funding for preparation of a final study report and appropriate budgeting plans for coordinating centers, central laboratories, data centers, and clinical safety and monitoring capabilities
- development of training materials and training plans for study staff

The planning grant will not support planning for more than one clinical trial or collection of preliminary (clinical or pre-clinical) or prospective data to support the rationale for a clinical trial. Applications that propose planning for more than one trial, collection of preliminary or prospective data, or implementation of a trial are not appropriate for this FOA.

For more information, please see the Investigator-Initiated Clinical Trial Questions and Answers at: https://www.niaid.nih.gov/grants-contracts/investigator-initiated-clinical-trials-faqs

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

Section II. Award Information

Funding Instrument

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

Application Types Allowed

New
Resubmission
Revision

The OER Glossary and the SF424 (R&R) Application Guide provide details on these application types.

Clinical Trial?

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

Need help determining whether you are doing a clinical trial?

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.

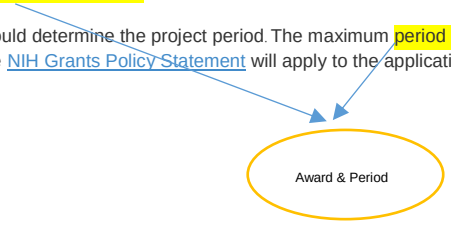
Award Budget

Application budgets are limited to $150,000 direct costs.

Award Project Period

The scope of the proposed project should determine the project period. The maximum period is one year.

NIH grants policies as described in the NIH Grants Policy Statement 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) 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)
- 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*, **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 states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- Dun and Bradstreet Universal Numbering System (DUNS) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- System for Award Management (SAM) – 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 – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- eRA Commons - Applicants must have an active DUNS number to register in eRA Commons. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration , but 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 – Applicants must have an active DUNS number and 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 underrepresented racial and ethnic groups as well as individuals with disabilities 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.

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. 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 NOT-OD-11-101)

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 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:

Priti Mehrotra, M.Sc., Ph.D.
National Institute of Allergy and Infectious Diseases (NIAID)
Telephone: 240-669-5066
Email: pm158b@nih.gov

Page Limitations

All page limitations described in the SF424 Application Guide and the Table of Page Limits 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.

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:

Specific Aims: The goals of the trial and the expected outcome(s) should be concisely stated in the Specific Aims section. The specific objectives of the trial must be clearly and concisely presented, including a specification of the primary and major secondary endpoints to be measured. There should be a clear explanation of the importance of various endpoints.

Research Strategy: The following three sections comprise the Research Strategy: Significance, Innovation, and Approach. The Research Strategy must include:

- A discussion of the significance of the problem being studied, the need for the trial, and the potential impact of the results of the trial, as well as how the trial will test the hypothesis(es) proposed;
- A concise description of the overall strategy, methodology and analyses to be used to accomplish the goals and specific aims of the trial;
- Sufficient details of the clinical trial (e.g. study design, primary objective, inclusion and exclusion criteria, proposed study population, proposed study agent(s), preliminary sample size, clinical end points, duration of recruitment and follow-up, etc.) to allow assessment of the likelihood that a feasible clinical trial will be developed;
- A description of the potential problems, alternative strategies, and benchmarks for success of the planning period and future trial;
- A description of how the planning period will be used and descriptions of the activities to be carried out during the planning period, including participants in the planning process and their roles;
- Information about how the clinical trial documents will be developed; and
- A description of how the trial will be organized and managed, including the plans to identify and select additional collaborators, if applicable.

Letters of Support: Provide all appropriate letters of support, including any letters necessary to demonstrate the support of consortium/site participants, cores, laboratories, pharmacies and other collaborators, including cost-sharing by NIH resources, in the case of intramural collaborators. If co-funding or in-kind support is planned from any source (non-NIH sources or NIH sources), letter(s) outlining details of the commitment (e.g. type, amount and source of support), signed by a business official on organization letterhead, must be included.

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.

The following modifications also apply:

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.

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 NIH-defined human subjects research, clinical research, and/or 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 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, 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 , the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (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, 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.

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 .

Pre-award costs are allowable only as described in the NIH Grants Policy Statement.

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. 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 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 Component of the SF424(R&R) Application Package. 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 DUNS number it provides on the application is the same number 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 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.

Prior Consultation with NIAID

Consultation with NIAID staff at least 10 weeks prior to the application due date is strongly encouraged for submission of the NIAID Clinical Trial Planning Grant application, including new and resubmission applications. If requested, NIAID staff will consider whether the proposed clinical trial meets the goals and mission of the Institute, whether it addresses one or more high-priority research areas, and whether it is appropriate to conduct as an investigator-initiated clinical trial. NIAID staff will not evaluate the technical and scientific merit of the proposed trial; technical and scientific merit will be determined during peer review using the review criteria indicated in this FOA. NIAID staff members are also available to work with potential applicants to determine the risk level of the proposed trial and delineate all documentation that will be needed to support submission of an R21, R01, U01 or U44 application for clinical trial implementation. During the consultation phase, if the proposed trial does not meet NIAID's programmatic needs or is not appropriate as an investigator-initiated clinical trial, applicants will be strongly encouraged to consider other funding opportunities.

A letter that summarizes the discussion during prior consultation may be obtained from the appropriate NIAID Division Director and attached as a Cover Letter on the SF424(R&R) Cover form.

For further information on prior consultation with NIAID program staff, refer to the NIAID Standard Operating Procedure for Investigator Initiated Clinical Trial Planning and Implementation Awards (https://www.niaid.nih.gov/research/investigator-initiated-clinical-trial-planning-implementation-awards).

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in the policy. 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 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?

If mechanistic studies are proposed, are they appropriate and will they provide important scientific information? Are the study objectives(s) and hypothesis(es) adequately defined?

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?

Do the investigator and the clinical trial team demonstrate adequate expertise and ability to develop, organize, manage, and execute the proposed trial?

Innovation

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

Approach

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

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

Environment

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

Additional Review Criteria

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

Protections for Human Subjects

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

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

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.

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.

Biohazards

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

Resubmissions

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

Renewals

Not Applicable

Revisions

For Revisions, the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

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; (2) Sharing Model Organisms; and (3) Genomic Data Sharing Plan (GDS).

Authentication of Key Biological and/or Chemical Resources:

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

Budget and Period of Support

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

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by the National Institute of Allergy and Infectious Diseases, in accordance with NIH peer review policy and procedures, 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:

- 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.
- Will receive a written critique.

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 National Advisory Allergy and Infectious Disease 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. 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 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.

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 grantee's business official.

Awardees 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 website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the NIH Grants Policy Statement 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 and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities. More information is provided at Award Conditions and Information for NIH Grants.

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. 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.

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 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships.

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. HHS provides general guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/index.html. The HHS Office for Civil Rights also provides guidance on complying with civil rights laws enforced by HHS. Please see https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.htmlhttps://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/index.html. Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see https://www.hhs.gov/civil-rights/for-individuals/disability/index.html. Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at https://www.hhs.gov/ocr/about-us/contact-us/index.html or call 1-800-368-1019 or TDD 1-800-537-7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53.

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Reporting

When multiple years are involved, awardees will be required to submit the Research Performance Progress Report (RPPR) annually and financial statements as required in the NIH Grants Policy Statement.

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.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over $25,000. See the NIH Grants Policy Statement 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/ (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 (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

Scientific/Research Contact(s)

Greg Deye, M.D.
Division of Microbiology and Infectious Diseases (DMID)
National Institute of Allergy and Infgregory.deye@nih.govectious Diseases (NIAID)
Telephone: 240-627-3371
Email: gregory.deye@nih.gov

Ellen Goldmuntz, M.D.
Division of Allergy, Immunology and Transplantation (DAIT)
National Institute of Allergy and Infectious Diseases (NIAID)
Telephone: 240-627-3502
Email: egoldmuntz@niaid.nih.gov

Martin Gutierrez
Division of Acquired Immunodeficiency Syndrome (DAIDS)
National Institute of Allergy and Infectious Diseases (NIAID)
Telephone: 240-292-4844
Email: mgutierrez@niaid.nih.gov

Peer Review Contact(s)

Priti Mehrotra, Ph.D.
National Institute of Allergy and Infectious Diseases (NIAID)
Telephone: 240-669-5066
Email: pm158b@nih.gov

Financial/Grants Management Contact(s)

Laura Pone
National Institute of Allergy and Infectious Diseases (NIAID)
Telephone: 240-669-2951
Email: laura.pone@nih.gov

Section VIII. Other Information

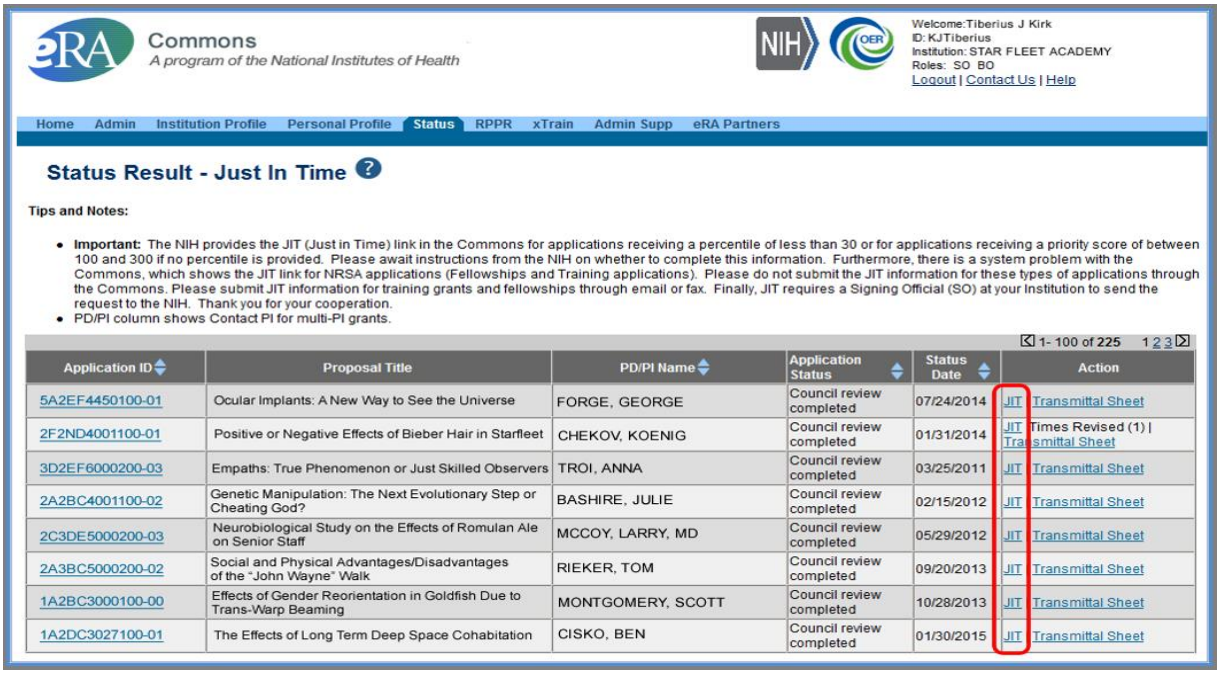
Recently issued trans-NIH policy notices may affect your application submission. A full list of policy notices published by NIH is provided in the NIH Guide for Grants and Contracts. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement.

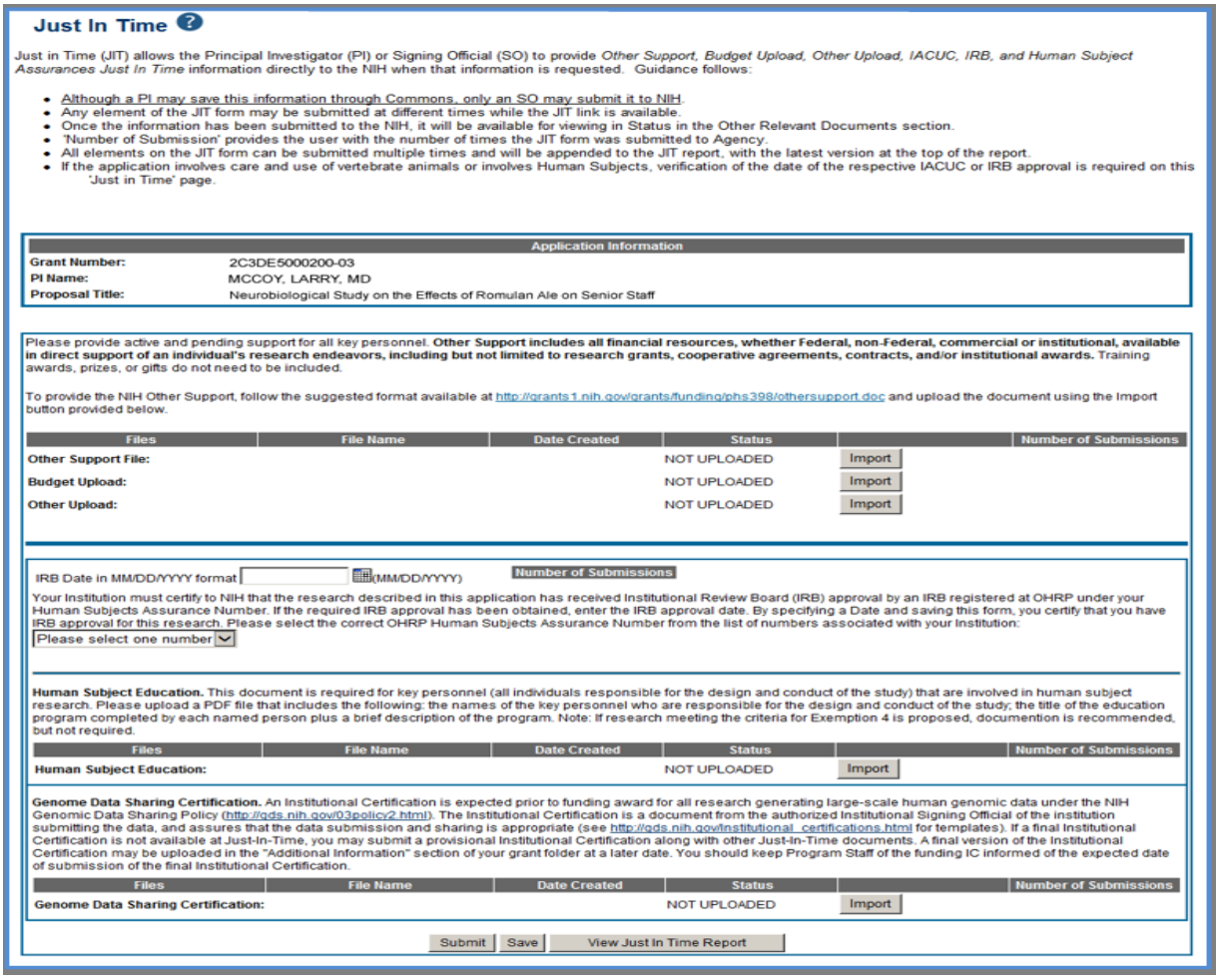
Authority and Regulations

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.

6. Just-in-time (JIT) Information

If the application is under consideration for funding, NIH will request "just-in-time" (JIT) information from the applicant. The JIT feature of the eRA Commons allows the electronic submittal of additional grant application information after the completion of the peer review, and prior to funding. The PD/PI and the SO work together to complete and submit. Other Support, Budget, IACUC, IRB, and/or Human Subject Assurances information directly to the NIH when that information is requested.





The Application Information section can be used to verify that information for the correct application is being submitted:

- Human Subjects Research Verification
- Requited education in the protection of human research participants
- FIC assistance questionnaire for financial & administrative management systems
- Genome Data Sharing Certification
- Others

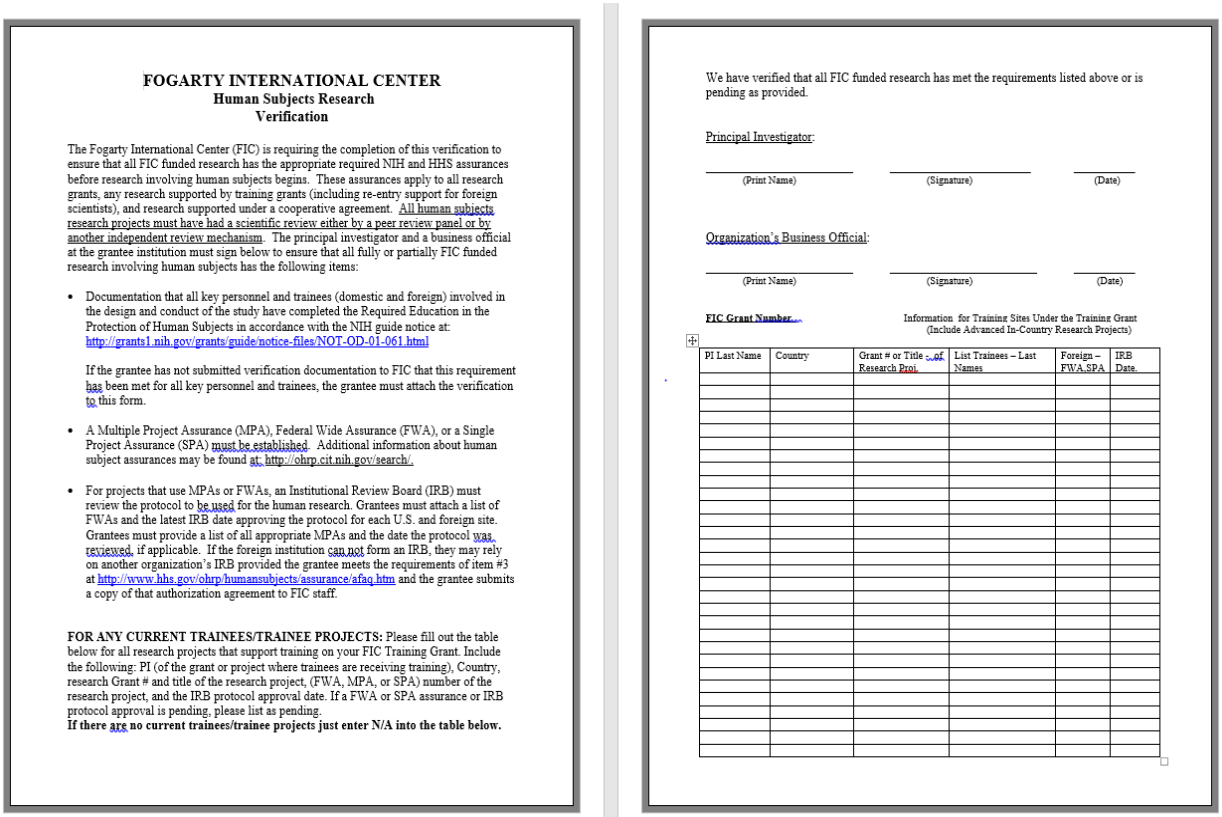
NOTE: 1) If you have the PI role, you may upload and save JIT information; however, you must be an SO to submit it to NIH.

The JIT feature is available for applications meeting established business criteria. In general this feature becomes available for applications that fall within a certain percentile or priority score range; *however, applicants should not submit any JIT information until specifically requested by the agency.* These requests can be eRA-system generated e-mails or contacts directly from the specific awarding agency via email and/or phone.

2) All JIT attachments should be submitted in PDF format with a maximum size of 6MB.

Example of document:

1. Human Subjects Research Verification



FOGARTY INTERNATIONAL CENTER
Human Subjects Research
Verification

The Fogarty International Center (FIC) is requiring the completion of this verification to ensure that all FIC funded research has the appropriate required NIH and HHS assurances before research involving human subjects begins. These assurances apply to all research grants, any research supported by training grants (including re-entry support for foreign scientists), and research supported under a cooperative agreement. All human subjects research projects must have had a scientific review either by a peer review panel or by another independent review mechanism. The principal investigator and a business official at the grantee institution must sign below to ensure that all fully or partially FIC funded research involving human subjects has the following items:

- Documentation that all key personnel and trainees (domestic and foreign) involved in the design and conduct of the study have completed the Required Education in the Protection of Human Subjects in accordance with the NIH guide notice at: http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-01-061.html

  If the grantee has not submitted verification documentation to FIC that this requirement has been met for all key personnel and trainees, the grantee must attach the verification to this form.

- A Multiple Project Assurance (MPA), Federal Wide Assurance (FWA), or a Single Project Assurance (SPA) must be established. Additional information about human subject assurances may be found at: http://ohrp.cit.nih.gov/search/.

- For projects that use MPAs or FWAs, an Institutional Review Board (IRB) must review the protocol to be used for the human research. Grantees must attach a list of FWAs and the latest IRB date approving the protocol for each U.S. and foreign site. Grantees must provide a list of all appropriate MPAs and the date the protocol was reviewed, if applicable. If the foreign institution can not form an IRB, they may rely on another organization's IRB provided the grantee meets the requirements of item #3 at http://www.hhs.gov/ohrp/humansubjects/assurance/afaq.htm and the grantee submits a copy of that authorization agreement to FIC staff.

FOR ANY CURRENT TRAINEES/TRAINEE PROJECTS: Please fill out the table below for all research projects that support training on your FIC Training Grant. Include the following: PI (of the grant or project where trainees are receiving training), Country, research Grant # and title of the research project, (FWA, MPA, or SPA) number of the research project, and the IRB protocol approval date. If a FWA or SPA assurance or IRB protocol approval is pending, please list as pending.
If there are no current trainees/trainee projects just enter N/A into the table below.

We have verified that all FIC funded research has met the requirements listed above or is pending as provided.

Principal Investigator:

(Print Name) (Signature) (Date)

Organization's Business Official:

(Print Name) (Signature) (Date)

FIC Grant Number

Information for Training Sites Under the Training Grant
(Include Advanced In-Country Research Projects)

PI Last Name	Country	Grant # or Title of Research Proj.	List Trainees – Last Names	Foreign – FWA,SPA	IRB Date.

2. Requited education in the protection of human research participants

DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
Fogarty International Center
Grants Office, Bldg. 31, Rm. B2C29
Bethesda, Maryland 20892-2220

REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

Beginning on October 1, 2000, the NIH began requiring education in the protection of human research participants for all investigators submitting NIH applications for grants, or receiving new or non-competing awards for research involving human subjects. The education requirement also applies to key personnel listed in the grant application, and key personnel at consortium institutions or performance sites if they are participating in research that involves human subjects. The original NIH Guide notice can be found at:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html

An example of a recommended website for the Education in the Protection of Human Subjects can be found at:

http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp

Key personnel are defined as individuals who contribute in a substantive measurable way to the scientific development or execution of the project, whether or not a salary is requested.

Please provide us with the names of all key personnel. Also provide the title of the education program completed by each named personnel and a one-sentence description of the program. A blank page should be used if more space is needed. Do not send copies of certifications.

A business official must sign this form and send it back to the Grants Management Specialist via email or the eRA Commons Just-in-Time submission module. No award will be issued until this form is received.

(Business Official Printed Name)_____

Signature:

3. FIC assistance questionnaire for financial & administrative management systems

FIC ASSISTANCE QUESTIONNAIRE
FOR FINANCIAL & ADMINISTRATIVE MANAGEMENT SYSTEMS

Updated 1/10/03

If the answer to any of the following questions (except E.2.) is "no", please explain.	*Answer in space provided below, or on a separate page, as necessary. If the answer is no, please state the reason.*
A. RECEIPT OF NIH FUNDS AND THE MONITORING OF EXPENDITURES	
1. Does the organization have a procedure in place to ensure that grant funds sent to your institution are deposited into a specific account for grant related expenses?	
2. Does the organization have a procedure in place to ensure that grant funds are expended only on allowable costs? (See Allowable Costs section in the Grants Information Resource Package) – Grantee organizations are only eligible to charge overhead costs, to administer the grant, up to the amount awarded for F&A costs.	
3. Does the organization have a procedure in place to ensure that the principal investigator approves all costs expended or charged to a grant and that the principal investigator is given periodic financial reports about expenditures?	
4a. Does the organization have a procedure in place to ensure that all Terms and Conditions on the Notice of Grant Award (NGA), the official notification from NIH awarding the grant, have been reviewed? **4b.** Does the organization have a procedure in place to ensure that any restrictions on the Notice of Grant Award are identified and resolved?	Please provide a mailing address for a check, that would provide grant funds, if the grant is selected for funding.
B. ACCOUNTING SYSTEM	
1a. Is there an accounting system and procedures in place to ensure that all income and expenses are allocated to the correct grant account?	
2. Is there a Chart of Accounts (list of accounts that shows categories of items that could be expensed) that provides for consistent treatment of direct costs and facilities & administrative (indirect) costs?	
3. Are timekeeping procedures in place to ensure that personnel charges are allocated appropriately to individual sources of support?	

1

C. FINANCIAL REPORTING	
1. Does the organization prepare financial statements, at least annually? (If the organization has expended U.S. Government federal funds of $300,000 or more per year in either of the last 2 years, please provide a copy of the most recent financial statement.)	
2. Has your organization expended $500,000 or more in any previous year from the U. S. Department of Health and Human Services, (includes NIH, FDA, CDC, HCFA, IHS and AHRQ)? If yes, Code of Federal Regulations (Title 45 Part 74) requires that either a Circular A-133 audit or a financial related audit, in accordance with Government Auditing Standards ("Yellow Book Audit"), be performed annually. Please provide a copy of the most recent audit.	
D. INTERNAL CONTROLS	
1. Is there a separation of responsibilities in the approval of charges to the grant and the disbursement of grant funds?	
2. Does the organization have separation of responsibilities in the preparation and payment of employee salaries (i.e. payroll), and are written procedures in place?	
E. GENERAL	
1. Is there an equipment policy at the organization that ensures that equipment purchased under a NIH grant will be used for grant related purposes until the grant has ended?	
2. Foreign grantees must submit annual Financial Status Reports (FSRs) on Standard Form SF-269. Do you have a procedure in place to ensure that the SF-269 will be submitted to NIH each year?	
3. Have you reviewed the FIC Grants Information Resource Package? FIC staff plan to perform a limited number of site visits to grantees to assist grantees in complying with NIH policy.	

Signature of Principal Investigator: _____ Date: _____

Signature of Organization's Business Official _____ Date: _____

2

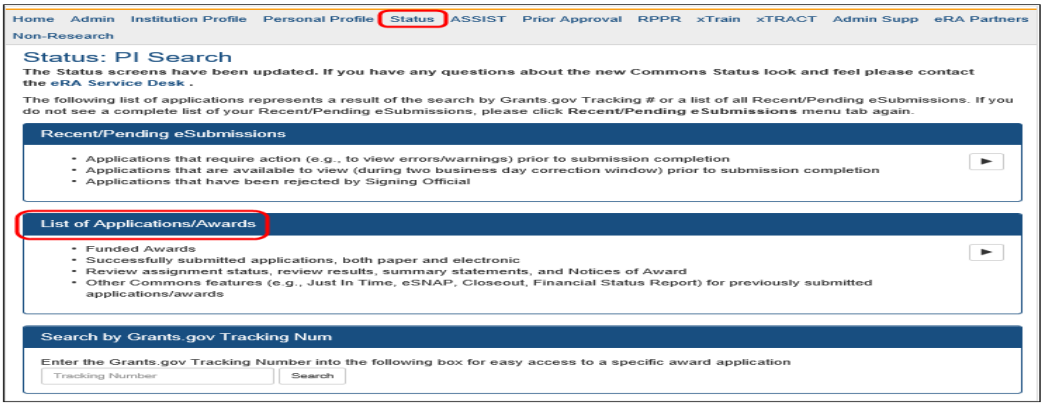
7. A Notice of Award (NoA)

The Notice of Award (NoA) is the official grant award document notifying the grantee and others that an award has been made. The NoA contains all terms and conditions of the grant award and provides the support documentation for recording the obligation of federal funds in the agency's accounting system.

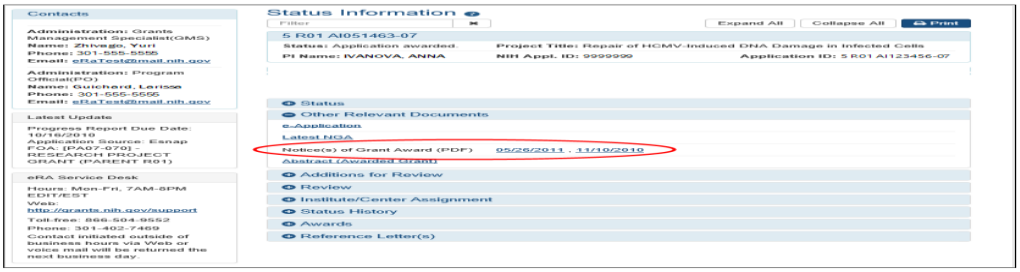
NoAs are sent to the specified email address entered in the NoA email field by the grantee organization when completing the eRA Commons registration process. The signing official can update this email address through the Institutional Profile section in eRA Commons. The NoA can also be viewed from the Status Information page in eRA Commons; look in the Other Relevant Documents section.

To view NoA in eRA Common:

1. Log into Commons.
2. Select Status from the Commons menu and select the List of Applications/Awards section.



3. Select the application ID link for the specific application.
4. The *Status Information* screen displays. The screen includes a section called Other Relevant Documents. This section houses links to various application-related documents, including the NOA. The NOA link is displayed as a date next to the field titled Notice(s) of Grant Award (PDF).
5. Select the NOA date link. It will open in a separate window.



Example of NoA

NoA: 1 D71 TW011198-01 PI: Pitiphat, Waranuch Inbox × Personal Info ×

era-notify@mail.nih.gov Sun, Sep 16, 2018, 7:13 PM
to ora

Grant Number: 1 D71 TW011198-01
Principal Investigator: Pitiphat, Waranuch
Project Title: Developing clinical and public health research training in oral health for Southeast Asia
Institution: KHON KAEN UNIVERSITY
CFDA: 93.989
OC: 414A
PCC: NCDDPLNG
Award Issue Date: 09/16/2018
Grants Management Officer: BUTRUM, BRUCE
Program Official: Michels, Kathleen
Grants Specialist: RAYCHOWDHURY, SATABDI

*** This is an automated notification - Please do not reply to this message. ***

Notice of Award

International Research Training Planning Grant **Federal Award Date:** 09/16/2018
Department of Health and Human Services
National Institutes of Health

FOGARTY INTERNATIONAL CENTER

Name of Institute who funds the grants

Grant Number: 1D71TW011198-01
FAIN: D71TW011198

FAIN = Federal Award Identification Number, identifies new grants and cooperative agreements & must be used in consortiums agreement.

Principal Investigator(s):
Waranuch Pitiphat, DDS

Project Title: Developing clinical and public health research training in oral health for Southeast Asia

Dr. Pitiphat, Waranuch
Assoc. Professor & Dean, Faculty of Dentistry
123 Mittraphap Highway
Muang District, 40002
THA

Business Office Information

Award e-mailed to: ora@kku.ac.th

Period Of Performance:
Budget Period: 04/01/2019 – 03/31/2020
Project Period: 04/01/2019 – 03/31/2020

Award amount

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of $49,680 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to KHON KAEN UNIVERSITY in support of the above referenced project. This award is pursuant to the authority of 42 USC 287b 42 CFR 63a and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Fogarty International Center of the National Institutes of Health under Award Number D71TW011198. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Page-1

NIH NGA T | Version: 3 from 6/21/2017 6:39:00 PM | Generated on: 9/16/2018 8:13:50 AM

SECTION I – AWARD DATA – 1D71TW011198-01

Award Calculation (U.S. Dollars)

Salaries and Wages	$3,800
Personnel Costs (Subtotal)	$3,800
Consultant Services	$5,330
Materials & Supplies	$1,170
Travel	$420
Other	$1,590
Participant Subsistence	$15,050
Participant Travel	$15,640
Participant Other	$3,000
Federal Direct Costs	$46,000
Federal F&A Costs	$3,680
Approved Budget	$49,680
Total Amount of Federal Funds Obligated (Federal Share)	$49,680
TOTAL FEDERAL AWARD AMOUNT	$49,680
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$49,680

Always check this page to ensure the received anticipated amount

Amount we can use

SUMMARY TOTALS FOR ALL YEARS		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$49,680	$49,680

Fiscal Information:

CFDA Name:	International Research and Research Training
CFDA Number:	93.989
EIN:	1900217267A1
Document Number:	DTW011198A
PMS Account Type:	B (Subaccount)
Fiscal Year:	2018

Amount awarded

IC	CAN	2018
TW	8476374	$49,680

NIH Administrative Data:
PCC: NCDDPLNG / **OC:** 414A / **Released:** BUTRUMBR 09/14/2018
Award Processed:9/16/2018 8:13:50 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1D71TW011198-01

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm.

SECTION III – TERMS AND CONDITIONS – 1D71TW011198-01

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.

Transparency Act

c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is excluded from Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) D71TW011198. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.
This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the eRA Commons (Commons) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final expenditure FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) quarterly cash transaction data. It is important to note that for financial closeout, if a grantee fails to submit a required final

expenditure FFR, NIH will close the grant using the last recorded cash drawdown level. If the grantee submits a final expenditure FFR but does not reconcile any discrepancies between expenditures reported on the final expenditure FFR and the last cash report to PMS, NIH will close the award at the lower amount. This could be considered a debt or result in disallowed costs.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience.*

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and should be submitted electronically as noted above.

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 with cumulative total value greater than $10,000,000 must report and maintain information 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 the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income: Program Income
Additional Costs

SECTION IV – TW Special Terms and Conditions – 1D71TW011198-01

FUNDING LEVEL
Per the NIH Guide Notice NOT-OD-18-180, Fogarty will issue competing grants in accordance with FIC's Funding Strategy:
https://www.fic.nih.gov/About/FundingStrategy/Pages/fiscal-year-2018-funding-strategy.aspx
Your institution may re-budget funds in accordance with the NIH Grants Policy Statement.

PAYMENTS TO FOREIGN GRANT RECIPIENTS
The NIH has made several changes to the policies and procedures for awards to Foreign Institutions. Awards made on or after October 1, 2012 will now be paid through the Payment Management System (PMS). Please refer to NIH Guide Notice NOT-OD-12-139 for guidance (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-139.html).
1. To receive payment Grantees must complete the SF-1199A Direct Deposit Form, the DPM PMS System Access Form for NIH Foreign Grantees, and provide an International Bank Letter on your bank letterhead with authorized signatures for all new PMS accounts and new PMS users.
2. Detailed instructions and forms have been sent to all grantees. Contact your Grants Management Specialist if you did not receive this information.
3. Forms must be completed for each NIH Grant Award and Access Forms must be completed for each individual who needs access to an existing or new PMS account.Send the forms to the Division of Payment Management (DPM) as instructed on the forms.

4. Please contact Thuy Tran with any questions about your PMS account by phone at (301) 492-4985 or by email at thuy.tran@psc.hhs.gov.

CHANGES TO F&A FOR FOREIGN INSTITUTIONS
Per Notice Number NOT-OD-15-046, the Department of Health and Human Services published an interim rule adapting OMB's final Uniform Grant Guidance in 2 CFR part 200 with certain amendments, based on existing HHS regulations, to supplement the guidance as needed for the Department effective December 26, 2014. Per NOT-OD-18-005 a revised NIH Grants Policy Statement was published; the revision is applicable to all NIH grants and cooperative agreements with budget periods beginning on or after October 1, 2017. Links to the revised Grants Policy Statement and a document summarizing the significant changes that were implemented are provided in the Notice.
Highlighted below are some select items of costs of particular note to FIC grant recipients:

- **F&A for Foreign and International Organizations:** NIH and FIC continue to provide F&A costs under grants to foreign and international organizations will be funded at a rate of 8 percent of modified total direct costs, exclusive of equipment, tuition and related fees, and subawards in excess of $25,000. These funds are paid to support the costs of compliance with federal requirements. This applies to direct foreign awards and foreign subawards.
- **F&A for Career/Fellowship/Training Awards:** NIH and FIC continue to provide F&A costs under research training, some education grants, and Career (K) awards will be funded at a rate of 8 percent of modified total direct costs, exclusive of tuition and fees, health insurance (when awarded as part of tuition and fees), equipment, and consortiums in excess of $25,000, consistent with existing policy.
- **Value Added Tax:** Foreign taxes charged for the purchase of goods or services that a non-Federal entity is legally required to pay in country is an allowable expense under Federal awards. However, for many countries an exemption of this tax for research exists. Consequently, requesting this cost should be unallowable for research grants involving such countries as a performance site.
- **Visa Costs:** Allowable as a direct cost as part of recruiting costs on an NIH grant. Allowable as a trainee cost and not allowable for other non-trainee project personnel, consistent with existing FIC policy.

FIRST TIME GRANTEES
First-time NIH grantee organizations can find information about funding, policy, and administrative issues by visiting our "Welcome Wagon letter":
http://grants.nih.gov/grants/funding/welcomewagon.htm

DISCONTINUATION OF ESCALATION
In accordance with the NIH fiscal policies described in NIH Guide Notice NOT-OD-12-036, inflationary increases for future year commitments will be discontinued for all competing and non-competing grant awards issued in FY2012 and beyond: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-036.html. Adjustments for special needs (such as equipment and added personnel) will continue to be accommodated. Built-in escalation must be re-budgeted.

FUNDING ANNOUNCEMENT
This award is subject to the conditions set forth PAR17-097 . The PAR can be found at:
https://grants.nih.gov/grants/guide/pa-files/PAR-17-097.html

KEY PERSONNEL
For purposes of this award the following person(s) are considered key personnel in addition to the PI(s) already named on this Notice of Award. All policies that apply to the PI(s) (e.g. the requirement to obtain NIH prior approval for personnel changes and to supply information about other support with each progress report) are hereby applied to the following person(s):

Dr. Matana Kettratad, Thammasat University. Thailand

In addition to the PI, any absence, replacement, or substantial reduction in effort of the individual(s), requires the written prior approval of the National Institutes of Health awarding component.

CHANGES IN SCOPE
Prior approval must be obtained from the NIH awarding component for any changes in the direction, type of research or training, the use of human or animal subjects, or other areas that constitute a significant change from the aims, objectives, purpose, or scope of the approved project.

F&A COSTS
Limited F&A of 8% for administrative costs is provided to support the administrative needs of managing this project. F&A charges are limited to eight percent for both domestic and foreign research training partners. Consortia institutions also may only charge eight percent of applicable direct costs for F&A.

- **F&A for Foreign and International Organizations:** NIH and FIC continue to provide F&A costs under grants to foreign and international organizations will be funded at a rate of 8 percent of modified total direct costs, exclusive of equipment, tuition and related fees, and subawards in excess of $25,000. These funds are paid to support the costs of compliance with federal requirements. This applies to direct foreign awards and foreign subawards.

RESTRICTION AGAINST MEAL COSTS
In accordance with the NIH Grants Policy Statement, when certain meals are an integral and necessary part of a meeting or conference (i.e., a working meal where business is transacted), grant funds may be used for such meals. Unless part of a working meal, grant funds may not be used. Recurring business meetings, such as staff meetings, should not be broadly considered as working meetings in order to justify charging meals or refreshment costs to grants.

RESTRICTION AGAINST VISA COSTS
Visa costs are allowable only as a trainee/student expense or as described in the NIH Grants Policy Statement. Visa costs requested that are not for trainees are unallowable and must be re-budgeted.

RESTRICTION AGAINST HONORARIA
In accordance with the NIH Grants Policy Statement, honoraria are not allowed when the primary intent is to confer distinction on, or to symbolize respect, esteem, or admiration for, the recipient of the honorarium. A payment for services rendered, such as a speaker's fee is allowable.

FOREIGN TRAVEL
U.S. Flag carriers must be used for departure from or entry into the U.S. and for other portions of the trip where available.

SALARY CAP
None of the funds in this award shall be used to pay the salary of an individual at a rate per year in excess of the amounts reflected in the following NIH Guide Notice NOT-OD-18-137:
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-137.html
Therefore, this award and/or future years may be adjusted through re-budgeting.

CONSORTIUM/CONTRACTUAL COSTS

TRAINING GRANT RESTRICTION
FIC funded research must have the appropriate required NIH and HHS assurances before any research or research training involving human subjects begins. These assurances apply to all research grants, any research supported by training grants (including re-entry support for foreign scientists), and research supported under a cooperative agreement. All human subjects research projects must have had a scientific review either by a peer review panel or by another independent review mechanism. Activity in which human subjects are involved may be undertaken if the institution has an active FWA assurance and if the project has been reviewed and approved by the appropriate Institutional Review Board (IRB).

Grant recipients must provide human subjects and IRB approval information in Section G.1 "Special NOA terms and FOA reporting requirements" of the RPPR for each trainee/scholar supported by the grant award during the reporting period. Additional information on this requirement can be found in the FIC Progress Report Supplemental Guidance on the FIC webpage: http://www.fic.nih.gov/Grants/Pages/progress-reports.aspx.

HUMAN SUBJECTS FWA/IRB APPROVAL
The applicant organization is responsible for ensuring that any activities involving human subjects at the parent or any consortium/subcontract organization has an appropriate IRB and FWA approval.
Any changes in the use of human subjects requires prior approval from the NIH awarding component.
Refer to Chapter 4.1.15 of the NIH Grants Policy Statement (NIH GPS) for additional information: http://grants.nih.gov/grants/policy/nihgps/index.htm.

REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS
Investigators must ensure that the description of the education completed in the protection of human subjects for each individual, identified as "key personnel", in the proposed research has been documented and provided to the FIC awarding office. Key personnel include all individuals responsible for the design and conduct of the study. The Notice for this policy can be found at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

ACKNOWLEDGEMENT OF FUNDING
Each publication, press release, or other document about research supported by an NIH award must include acknowledgment of FIC and NIH award support with the following or comparable footnote and disclaimer:
Research reported in this publication was supported by the Fogarty International Center of the National Institutes of Health under Award Number D71 TW11198. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.
Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.
This publication requirement applies not only to the primary grantee, but also to any subcontractors and /or trainees involved with the project.
For additional information, please visit http://www.nih.gov/about/publicaccess/.

RESPONSIBLE CONDUCT OF RESEARCH
NIH policy requires instruction in responsible conduct of research by individuals supported by any NIH research training or career awards. It is expected that course attendance is monitored and that a certificate or documentation of participation is available upon course completion. NIH does not require certification of compliance or submission of documentation, but expects institutions to maintain records sufficient to demonstrate that NIH-supported trainees, fellows, and scholars have received the required instruction.

Each annual progress report must include the following information about activities that took place during the past budget period:
* a description of the instruction in responsible conduct of research (RCR)
* a description of who received RCR instruction
* a description of any enhancements and/or modifications to the five instructional components described in the competing application or the previous year's progress report
* a list of names of faculty who contributed to formal instruction in RCR and the specific training they provided
More information is available in the NIH Guide Notice NOT-OD-10-019
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html

ASSURANCES
For foreign awards, assurances for Research Misconduct, Lobbying, Drug-Free Workplace, Delinquent Federal Debt, Financial Conflict of Interest and Debarment are required. The signature of an authorized organizational official on the grant application certifies that the organization will comply with all applicable assurances and certifications referenced in the application. Further information regarding public policy requirements and objectives applicable to NIH awards may be found in Chapter 16.4 of the NIH Grants Policy Statement:
http://grants.nih.gov/grants/policy/nihgps/index.htm.

INTEREST EARNED ON ADVANCES OF GRANT FUNDS
NIH grantees subject to the requirements of 2 CFR part 200 that receives advance payments must maintain those advances in an interest-bearing account (2 CFR 200.305.8). The timing and amount of cash advances shall be as close as is administratively feasible to the actual disbursements by the recipient organization for direct program or project costs. However, any interest on Federal advances of grant funds that exceeds US$500 per year in the aggregate must be remitted annually to the Department of Health and Human Services, Payment Management System, PO Box 6021, Rockville, MD 20852 (as the government-wide agent for collection). Interest amounts up to US$500 per year may be retained by the recipient for administrative expenses (2 CFR 200.305.9).

RESEARCH MISCONDUCT
The regulations governing research misconduct require the grantee to submit an annual report (Form 6349) to the Office of Research Integrity (ORI) detailing aggregate information on allegations, inquiries, and investigations handled by the grantee in the previous year. ORI automatically sends this form to NIH grantees at the end of the calendar year. Any questions regarding misconduct issues may be addressed to the office below:
Robin Parker
Assurance Program Manager
Office of Research Integrity
Rockville, MD 20852
Phone # 240-453-8402
Fax # 301-594-0042
Robin.parker@hhs.gov
http://ori.dhhs.gov/assurance/fis.shtml

Audit Term

AUDIT REQUIREMENT
A foreign organization is required to have a non-Federal audit if:
*It has expended a total of $750,000 or more under one or more HHS award (as a direct grantee and/or under a consortium participant and at least one of those awards is an HHS grant).
If an audit is required, there are two options regarding the type of audit that will satisfy the audit requirements. The grantee may have EITHER:
(1) a financial-related audit (as defined in, and in accordance with, the Government Auditing Standards (commonly known as the <Yellow Book>), GPO stock 020-000- 00-265-4, of all the HHS awards
(2) an audit that meets the requirements of OMB Circular A-133.

The requirements for non-Federal audits of foreign organizations are specified in 2 CFR 200 which incorporates the thresholds and deadlines of OMB Circular A-133.

The Government Auditing Standards are available electronically at http://www.gao.gov/govaud/ybk01.htm. Audits must be completed and submitted to the following office within 30 days after receipt of the auditors report(s), or 9 months after the end of the audit period, i.e., the end of the organizations fiscal year, whichever is earlier. The address is:
National External Audit Review Center
HHS Office of Audit Services
323 West 8th Street
Lucas Place, Room 514
Kansas City, MO 64105
For up-to-date information, you may access the NIH Home Page at http://www.nih.gov/ and the FIC Home Page at http://www.fic.nih.gov/.

NEW GRANT CLOSEOUT REQUIREMENTS
Effective October 1, 2014, NIH closeout policy has changed (see NOT-OD-14-084 and NOT-OD-15-065). If the grants closeout process is not completed **WITHIN 180 days of the project period end date**(the expiration date of a grant, which will be AFTER any approved no-cost extension periods), new HHS policy stipulates that the NIH must initiate unilateral closeout (i.e. Closeout without the receipt of acceptable final reports).
Unilateral closeout may include unilateral financial closeout using the last recorded cash drawdown level in the Payment Management System. If the grantee submits a final expenditure FFR but has not reconciled any discrepancies between expenditures reported on the final expenditure FFR and the last cash report to PMS, NIH is required to close the award at the lower amount. (This could be considered a debt or result in disallowed costs.) ***This means your institution may lose and have to repay to the Federal Government, any funds associated with the un-reconciled costs. ***
In order to avoid unilateral closeout, final reports must be submitted in a timely manner. In addition to unilateral closeout, failure to submit accurate final reports could result in enforcement actions such as corrective actions, removal of authorities on active grants, and/or delay or withholding of future awards.

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Satabdi Raychowdhury
Email: satabdi.raychowdhury@nih.gov **Phone**: 301-496-9750

Program Official: Kathleen M Michels
Email: kathleen_michels@nih.gov **Phone**: 301-435-6031 **Fax**: 301-402-0779

SPREADSHEET SUMMARY
GRANT NUMBER: 1D71TW011198-01

INSTITUTION: KHON KAEN UNIVERSITY

Budget	Year 1

Salaries and Wages	$3,800
Personnel Costs (Subtotal)	$3,800
Consultant Services	$5,330
Materials & Supplies	$1,170
Travel	$420
Other	$1,590
Participant Subsistence	$15,050
Participant Travel	$15,640
Participant Other	$3,000
TOTAL FEDERAL DC	$46,000
TOTAL FEDERAL F&A	$3,680
TOTAL COST	$49,680

Facilities and Administrative Costs	Year 1
F&A Cost Rate 1	8%
F&A Cost Base 1	$46,000
F&A Costs 1	$3,680

8. Eligible Organizations

In general, foreign institutions and international organizations, including public or private non-profit or for-profit organizations, are eligible to apply for research project grants. Foreign institutions and international organizations are not eligible to apply for Kirschstein-NRSA institutional research training grants, program project grants, center grants, resource grants, SBIR/STTR grants, or construction grants. However, some activity codes, such as program project grants (P01), may support projects awarded to a domestic institution with a foreign component. For purposes of this policy, a "foreign component" is defined as performance of any significant element or segment of the project outside the United States (U.S.) either by the grantee or by a researcher employed by a foreign institution, whether or not grant funds are expended. Proposed research should provide special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions in other countries that are not readily available in the U.S. or that augment existing U.S. resources.

Foreign applicants are strongly encouraged to review the Eligibility section of the Funding Opportunity Announcement (FOA) to determine whether their non-domestic (non-U.S.) entity (foreign organization) is eligible to respond to that particular FOA. Additional information on grants to foreign institutions, international organizations and domestic grants with foreign components is found in the NIH Grants Policy Statement.

Registrations Needed to Submit Applications to NIH

In order to apply for any NIH grant, each institution must complete a series of registrations. These registrations are used for verification of eligibility; validation for legal representation (any organization that accepts a federal grant enters into a binding and lawful contract); tracking and accounting of federal moneys; and reporting purposes.

All of these registrations must be completed and active before the time of submission.

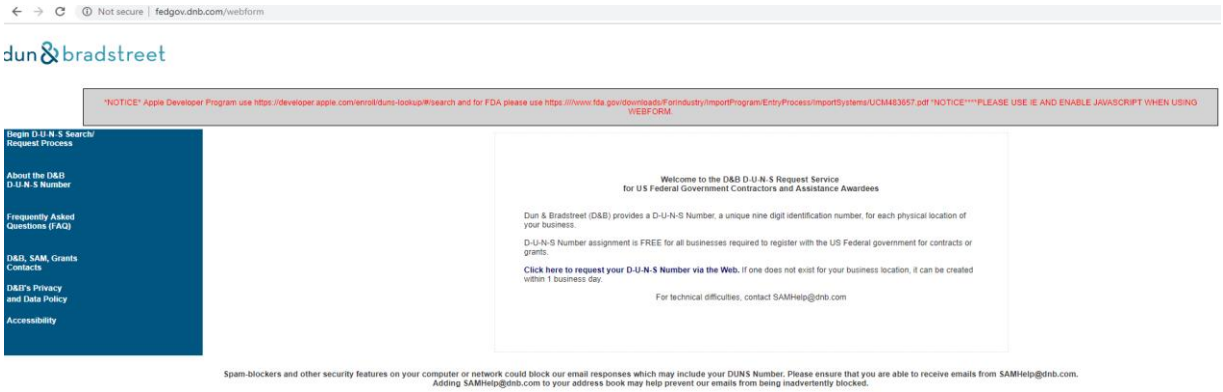
- Register early! Registration is a multi-step process that can take 6-8 weeks to complete.

- All organizations must register with **Dun and Bradstreet**, **SAM**, and **Commons**. **NCAGE** is required for nondomestic organizations.
- The registration process is not sequential. As soon as an organization has obtained its DUNS number, it can
  begin registering with SAM and then Grants.gov and eRA Commons.

1) <u>Dun & Bradstreet Universal Numbering System (D-U-N-S)</u>

Dun & Bradstreet (D&B) provides a unique nine digit identification number for your business / institution

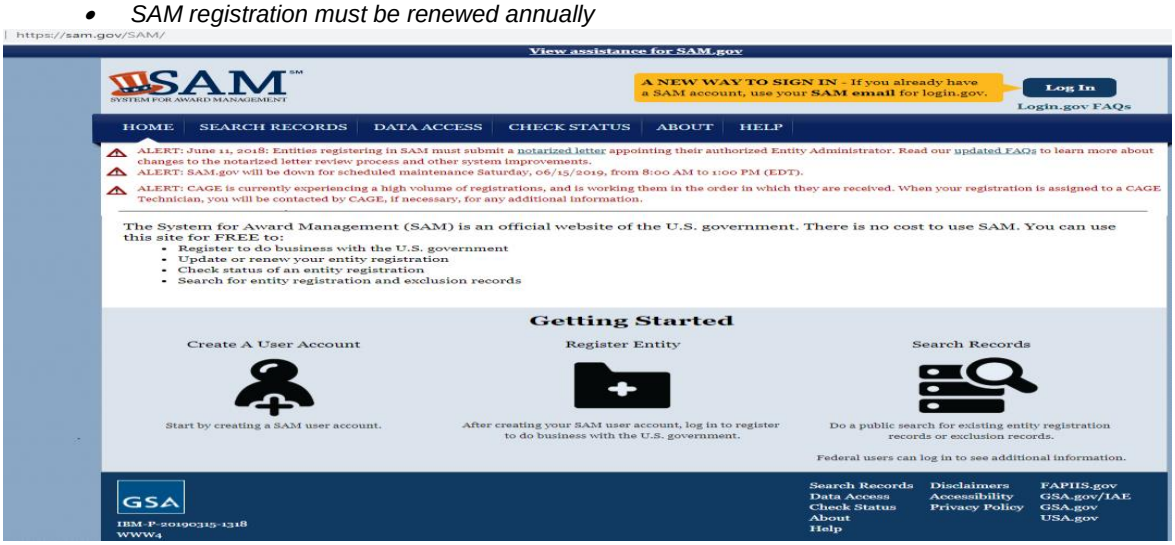
- Dun & Bradstreet does not charge a fee for assigning a number for doing business with the government
- A D-U-N-S Number is required by NIH for all application submissions.
- Begin the process at: http://fedgov.dnb.com/webform



2) System for Award Management (SAM)

The GSA's System for Award Management

- GSA assigns a CAGE Code during the SAM registration process if one is not already assigned
- SAM confirms supplied information with the IRS, a step that may take a few days
- *SAM registration must be renewed annually*



<u>Steps for Registering Your Entity (Organization) in SAM</u>:

1) Go to www.sam.gov
2) Create a Personal Account and Login
3) Click "Register New Entity" under "Manage Entity"
4) Select type of Entity
5) If you plan to compete for contract awards, select "Yes" to "Do you wish to bid on contracts?
a) Additional data may be requested if you select 'Yes'
6) Select "Yes" to "Do you want to be eligible for grants and other federal assistance?"

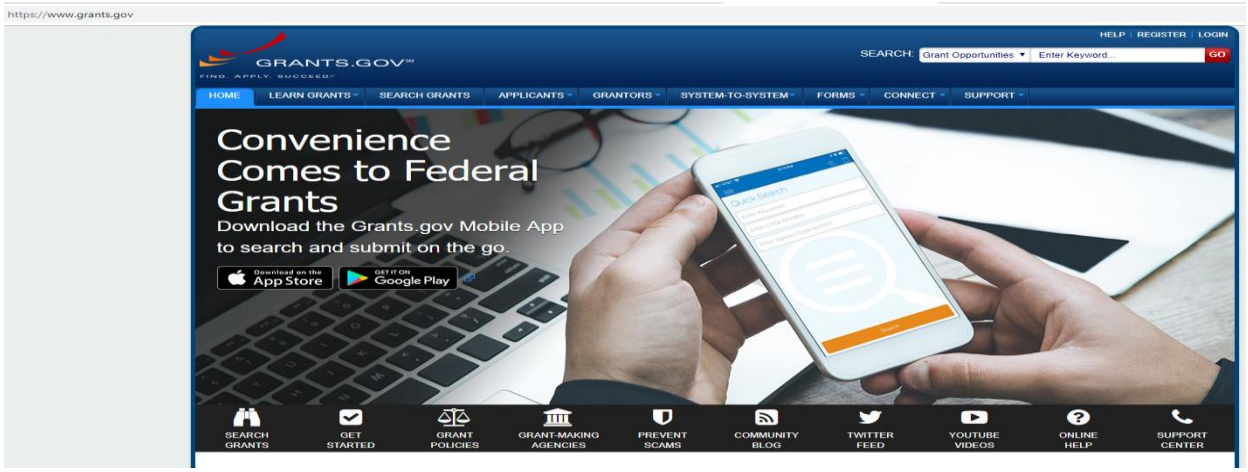
7) Complete "Core Data"
8) Complete "Points of Contact"
9) Wait for registration validation

Be aware of potential issues:

- You should log in to SAM, Grants.gov and Commons prior to the deadline to verify that you can access the required systems
- If you need to renew your record, or modify any of the registration record data, do so well ahead of the deadline
- When you modify your SAM record, SAM reports to Grants.gov that the record is "in process," resulting in
- Grants.gov rejecting an application. Grants.gov rejects any submitted applications until the data is
- synchronized again
- It takes at least one day for SAM registration or modification to become available in Grants.gov
- If a problem with access arises, it may take more than a day to resolve
- NATO Commercial & Government Entity Code (NCAGE)
- Non-domestic (foreign) organizations must obtain a NATO Commercial & Government Entity Codes
- It is a 5 character code used to identify the organization, and its specific location
- This code is required for System for Award Management (SAM) registration

3) Grants.gov

Steps for Registering Your Organization in Grants.gov

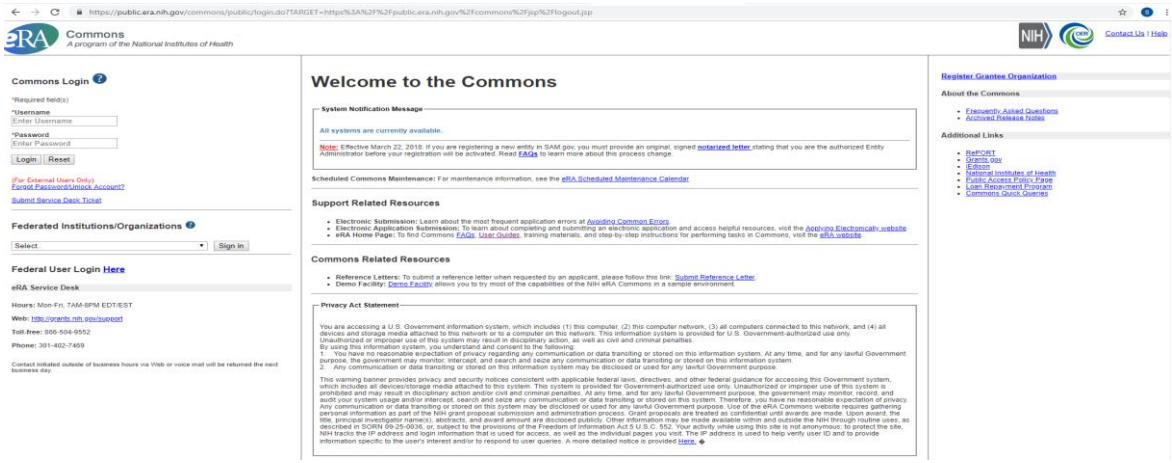


1) Obtain a D-U-N-S Number
2) Obtain an NCAGE Code (foreign applicants only)
3) Register with SAM
- Designate an E-business Point of Contact (E-Biz POC) who is responsible for approving requests for application submission authority, and
is assigned an MPIN which is required to login and establish an AOR
4) Establish your Grants.gov Username and Password
Anyone who will submit or track applications for your organization must complete an Authorized Organization Representative (AOR) profile
on Grants.gov and create a username and password
5) AOR Authorization
- The E-Biz POC will receive an email regarding the AOR request and must login to Grants.gov to approve the request by providing the "Authorized Applicant" role to the user.
- You can and should have more than one AOR in your organization to provide backup coverage in case the primary person is not available
to submit your application. All AORs can also track the status of submitted applications.
6) Verify your AOR Status. At any time, you can track your AOR status by logging in with your username and password

4) eRA Commons

Steps for Registering Your Organization in eRA Commons

1) Complete the online Institution Registration Form at https://public.era.nih.gov/commons/public/registration/registrationInstructions.jsp



2) Signing Official must verify email address

a. Once the registration is submitted electronically, email verification is sent and the SO must click the link to verify email

b. The SO will receive an "Approval" email from NIH

c. The "Approval" email contains a link to information that you must verify as correct before the confirmation process is completed

3) Signing Official (SO) and Account Administrator (AA) receives username and temporary password

a. After the completion of the confirmation, the SO and AA will receive two emails that contain the user names and temporary password for the SO and AA accounts created during the registration process

b. The Signing Official must log into eRA Commons before the AA can log in. The SO will log in with the username and temporary password and then be prompted to change password.

c. Once the password has been successfully changed, the SO will see a screen that has the "Accept" button at the bottom of the screen. The SO must accept in order for the AA to be able to navigate in Commons.

4) Log into Commons

a. The SO and AA log into Commons and administer additional accounts as needed.

5) Affiliate your PIs

a. Your Principal Investigators must work with your organization to be registered in eRA Commons if they do not have an existing account. If they have an account, you must affiliate it with your organization. Verify that you have selected the correct PI account! More information: https://era.nih.gov/commons/faq_commons.cfm#II

5) The Payment Management System (PMS)

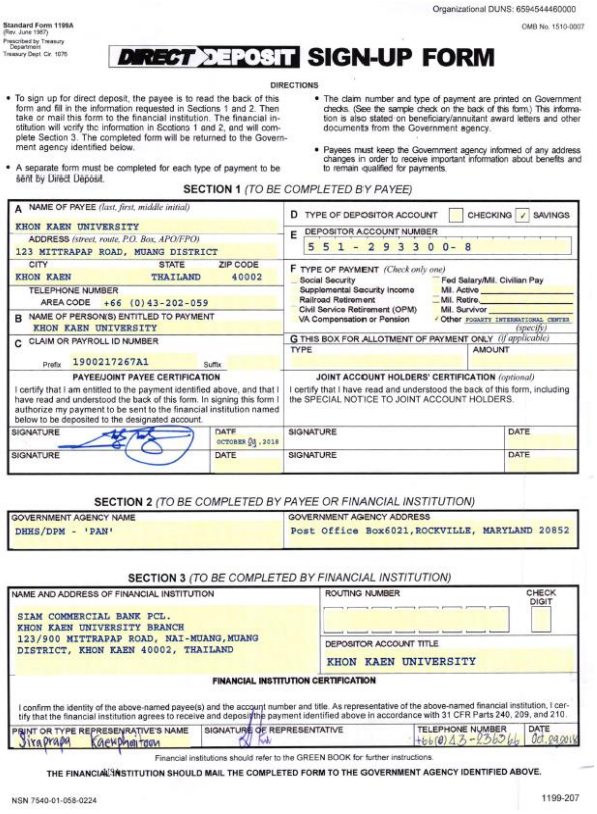
The Payment Management System (PMS) is a tool to help grant recipients draw down funds and file the Federal Financial Report (FFR). Primary responsibilities include executing awards; maintaining minimum federal cash on hand by requesting funds from the Payment Management System only for immediate disbursement (3 business days) and reimbursement unless otherwise specified in your Notice of Award; Reporting cash disbursements to the Payment Management System and Maintaining your accounting records.

Add/Update Banking Information

Use this option to establish or change a bank accounts direct deposit information for a payee account or a payee subaccount. The payee account, subaccount, and the financial institution must be established before bank account information can be associated to an account. Additionally, you must have been granted access to the payee accounts and have been granted banking privileges. You will have the ability to modify both domestic and international banking information (if applicable). All banking requests are required to have supporting documentation attached to the request.

Document Requirements

All banking requests must include a copy of the SF-1199A Direct Deposit Sign-Up form. International bank account requests must also contain an International Bank Letter.



Standard Form 1199A (Rev. June 1987) Prescribed by Treasury Department Treasury Dept. Cir. 1075

Organizational DUNS: 6594544460000

OMB No. 1510-0007

DIRECT DEPOSIT SIGN-UP FORM

DIRECTIONS

- To sign up for direct deposit, the payee is to read the back of this form and fill in the information requested in Sections 1 and 2. Then take or mail this form to the financial institution. The financial institution will verify the information in Sections 1 and 2, and will complete Section 3. The completed form will be returned to the Government agency identified below.
- A separate form must be completed for each type of payment to be sent by Direct Deposit.
- The claim number and type of payment are printed on Government checks. (See the sample check on the back of this form.) This information is also stated on beneficiary/annuitant award letters and other documents from the Government agency.
- Payees must keep the Government agency informed of any address changes in order to receive important information about benefits and to remain qualified for payments.

SECTION 1 *(TO BE COMPLETED BY PAYEE)*

A NAME OF PAYEE *(last, first, middle initial)*: KHON KAEN UNIVERSITY

ADDRESS *(street, route, P.O. Box, APO/FPO)*: 123 MITTRAPAP ROAD, MUANG DISTRICT

CITY: KHON KAEN | STATE: THAILAND | ZIP CODE: 40002

TELEPHONE NUMBER: AREA CODE +66 (0)43-202-059

B NAME OF PERSON(S) ENTITLED TO PAYMENT: KHON KAEN UNIVERSITY

C CLAIM OR PAYROLL ID NUMBER: Prefix 1900217267A1 Suffix

D TYPE OF DEPOSITOR ACCOUNT: ☐ CHECKING ☑ SAVINGS

E DEPOSITOR ACCOUNT NUMBER: 551-293300-8

F TYPE OF PAYMENT *(Check only one)*: ☐ Social Security ☐ Fed Salary/Mil. Civilian Pay ☐ Supplemental Security Income ☐ Mil. Active ☐ Railroad Retirement ☐ Mil. Retire ☐ Civil Service Retirement (OPM) ☐ Mil. Survivor ☐ VA Compensation or Pension ☑ Other POGARTY INTERNATIONAL CENTER *(specify)*

G THIS BOX FOR ALLOTMENT OF PAYMENT ONLY *(If applicable)*: TYPE | AMOUNT

PAYEE/JOINT PAYEE CERTIFICATION

I certify that I am entitled to the payment identified above, and that I have read and understood the back of this form. In signing this form I authorize my payment to be sent to the financial institution named below to be deposited to the designated account.

SIGNATURE | DATE OCTOBER 29, 2018 | SIGNATURE | DATE

JOINT ACCOUNT HOLDERS' CERTIFICATION *(optional)*

I certify that I have read and understood the back of this form, including the SPECIAL NOTICE TO JOINT ACCOUNT HOLDERS.

SIGNATURE | DATE | SIGNATURE | DATE

SECTION 2 *(TO BE COMPLETED BY PAYEE OR FINANCIAL INSTITUTION)*

GOVERNMENT AGENCY NAME: DHHS/DPM - 'PAN'

GOVERNMENT AGENCY ADDRESS: Post Office Box6021,ROCKVILLE, MARYLAND 20852

SECTION 3 *(TO BE COMPLETED BY FINANCIAL INSTITUTION)*

NAME AND ADDRESS OF FINANCIAL INSTITUTION: SIAM COMMERCIAL BANK PCL. KHON KAEN UNIVERSITY BRANCH 123/900 MITTRAPAP ROAD, NAI-MUANG,MUANG DISTRICT, KHON KAEN 40002, THAILAND

ROUTING NUMBER | CHECK DIGIT

DEPOSITOR ACCOUNT TITLE: KHON KAEN UNIVERSITY

FINANCIAL INSTITUTION CERTIFICATION

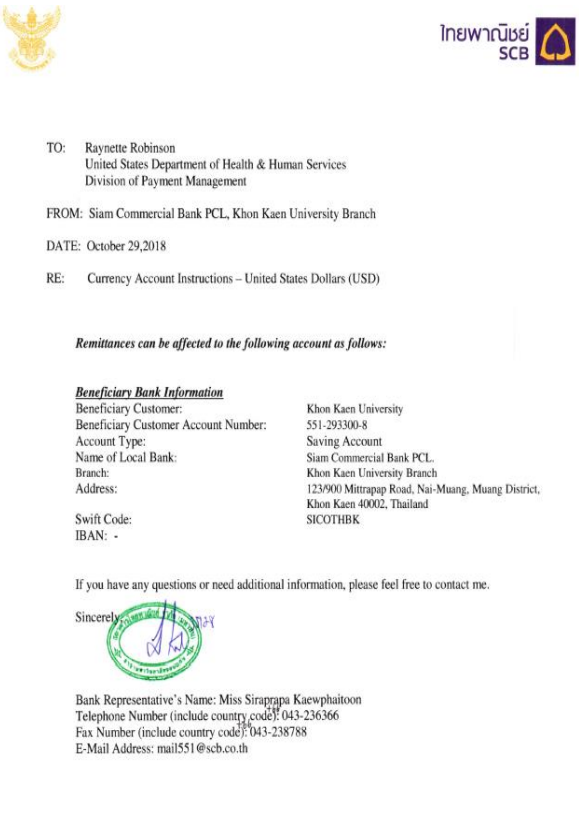
I confirm the identity of the above-named payee(s) and the account number and title. As representative of the above-named financial institution, I certify that the financial institution agrees to receive and deposit the payment identified above in accordance with 31 CFR Parts 240, 209, and 210.

PRINT OR TYPE REPRESENTATIVE'S NAME: Siraprapa Kaewphaitoon | SIGNATURE OF REPRESENTATIVE | TELEPHONE NUMBER: +66(0)43-236366 | DATE: Oct.29,2018

Financial institutions should refer to the GREEN BOOK for further instructions.

THE FINANCIAL INSTITUTION SHOULD MAIL THE COMPLETED FORM TO THE GOVERNMENT AGENCY IDENTIFIED ABOVE.

NSN 7540-01-058-0224 1199-207



ไทยพาณิชย์ SCB

TO: Raynette Robinson
United States Department of Health & Human Services
Division of Payment Management

FROM: Siam Commercial Bank PCL, Khon Kaen University Branch

DATE: October 29,2018

RE: Currency Account Instructions – United States Dollars (USD)

Remittances can be affected to the following account as follows:

Beneficiary Bank Information

Beneficiary Customer:	Khon Kaen University
Beneficiary Customer Account Number:	551-293300-8
Account Type:	Saving Account
Name of Local Bank:	Siam Commercial Bank PCL.
Branch:	Khon Kaen University Branch
Address:	123/900 Mittrapap Road, Nai-Muang, Muang District, Khon Kaen 40002, Thailand
Swift Code:	SICOTHBK
IBAN: -	

If you have any questions or need additional information, please feel free to contact me.

Sincerely,

Bank Representative's Name: Miss Siraprapa Kaewphaitoon
Telephone Number (include country code): 043-236366
Fax Number (include country code): 043-238788
E-Mail Address: mail551@scb.co.th

All information is to be typed or printed on the SF-1199A and then uploaded to your banking request prior to submission. Alterations such as erasures, correction fluid, and strike-outs are unacceptable and will invalidate the form.

Best Practices
Insider Tips for Making the PMS Process Work Smoothly For You:

1. In accordance with OMB Circulars A-102/2 CFR Part 215 and A-110, award funds are to be requested for immediate disbursement (3 business days) unless otherwise stated in the Notice of Award. Requests for reimbursement may be made at any time. Grantees should not be holding excess cash. Funds may be requested as needed.
2. Promptly return any funds you will not spend within three business days.
3. Be sure to submit your Federal Cash Transaction Report (FCTR) on time. If PSC does not receive your report by the due date, funds may not be released until the report is completed.
4. Promptly respond to PSC requests for information. PSC cannot release funding until it receives the information.
5. Be accurate; this goes without saying. Review your FCTR each quarter and reconcile any differences with your records.
6. Contact your awarding office (not PSC) for issues regarding your award or the Federal Financial Report. PMSvcs does not issue or adjust awards.
7. Contact the ONE DHHS Help Desk for issues regarding your draw-down requests, password resets, and the FFR. Always have your PMS PIN, payment account number (PAN), or EIN handy.

9. ขั้นตอนการสมัครหรือลงทะเบียนเพิ่มชื่อในระบบ eRA Commons

โครงการของนักวิจัยที่สมัครขอรับทุนสนับสนุนจาก NIH จะเป็นในรูปแบบ Prime Awards หรือเป็นแบบ Sub-Awards ที่ได้ร่วมทำวิจัยกับมหาวิทยาลัยหรือสถาบันในประเทศสหรัฐอเมริกา อย่างไรก็ตามสถาบันของนักวิจัยที่สังกัดจักต้องมีข้อมูลระดับสถาบันของระบบ SAM, DUN, NATO (NCAGE). Grants.govและจะต้องไม่หมดอายุและยังมีสถานะเป็นปัจจุบัน นั้น

9.1 ขั้นตอนสมัคร PI สำหรับกรณี Sub-Contract

1. **การกรอกข้อมูลออนไลน์ผ่าน eRA Commons** ซึ่งกองการต่างประเทศผู้ดูระบบ eRA Commons ของม.ขอนแก่น

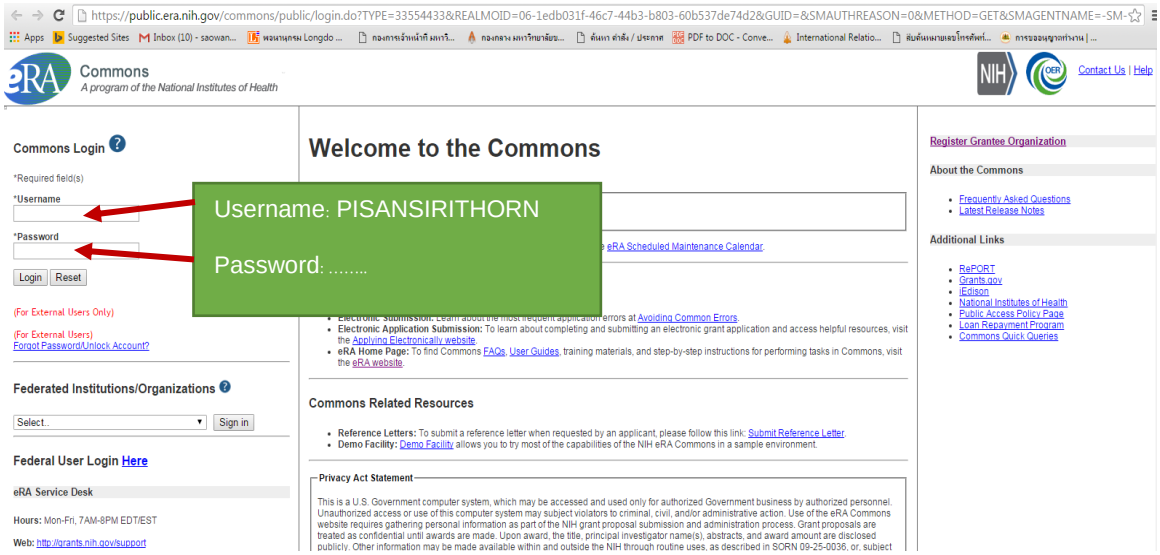
   eRA Commons ของ ม.ขอนแก่น :

   Username: PISANSIRITHORN

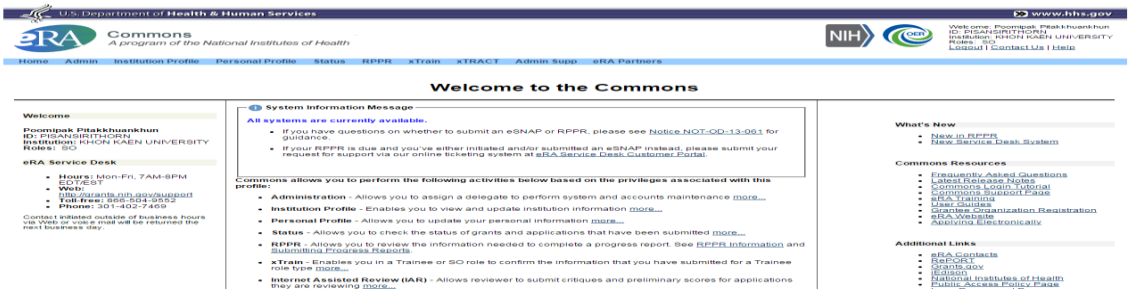
   Password: *KhonKaen***** (หมายเหตุ รหัสผ่านจะต้องเปลี่ยนทุกๆ 3 เดือน)

ค้นหา eRA Commons จาก google หรือตามลิงค์ https://public.era.nih.gov/commons/public/login.do?TYPE=33554433&REALMOID=06-1edb031f-46c7-44b3-b803-60b537de74d2&GUID=&SMAUTHREASON=0&METHOD=GET&SMAGENTNAME=-SM-938PYmoLVb4VrDeXo04LZUDVDvc%2b3899ByInEAjuSUvWNIGfB2zRpWiCivYGCogG&TARGET=-SM-http%3a%2f%2fpublic%2eera%2enih%2egov%2fcommons

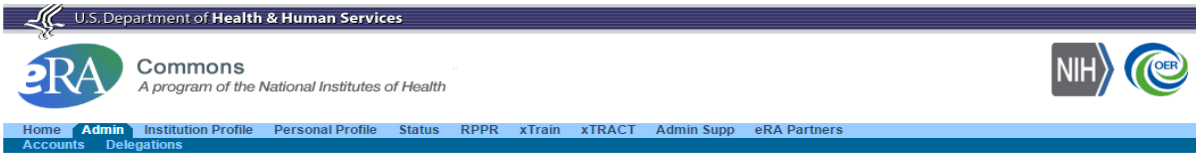
ดังรายละเอียดในหน้าต่าง



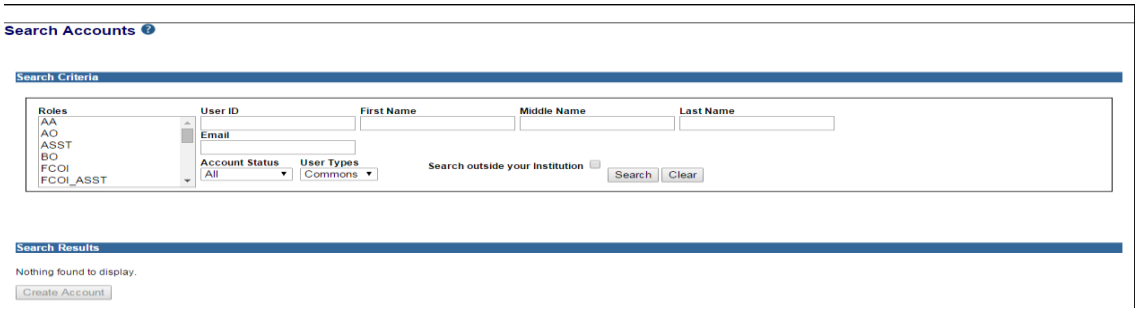
2) หลังจาก **Login eRA Commons** ด้วย Username: PISANSIRITHORN และ Password: *KhonKaen******



3) ไปที่ **Admin** แล้วเลือก **Accounts**



4) ไปที่ **Accounts** แล้วเลือก **Manage Accounts**



กรณีSub-Contract ให้กรอกดังนี้:

- * Roles: เลือก PI
- User ID: Capital Letter (First Name) เพราะต้องนำไปใช้ต่อในขั้นตอนการกรอก **Assigned PI**
- First Name: ....
- Last Name: ...
- E-Mail: ...
- Account Status: All
- User Types: Commons
- * มี Roles อาทิ AA (Account Administrator), AO (Administrative Official), ASST (Assistant), BO (Business Official), FCOI (Financial Conflict of Interest), FCOI_ASST (Financial Conflict of Interest Assistant Role), FSR (Financial Status Reporter), PI (Principal Investigators) เป็นต้น
- จากนั้น Create Account

5) หลังจากนั้นดำเนินการ **Assigned PI** ต่อ

- User Types: Commons
- User ID: Capital Letter (First Name)
- Organization: Khon Kaen University ....
- Last Name: ...
- E-Mail: ...
- ...
- จากนั้น กด Add แล้ว Save =➔ หากสมบูรณ์จะโชว์ ****"Account was successfully created!"****

10. สรุปรหัสสำคัญระดับสถาบันที่ต้องทราบในการขอทุนสนับสนุนจาก NIH

No	Code	Details	Remarks
1	eRA Commons (Electronic Research Administration Commons)	eRA Commons for Institution https://public.era.nih.gov/commons/public/login.do?TARGET=https%3A%2F%2Fpublic.era.nih.gov%2Fcommons%2Fjsp%2Flogout.jsp	Password must be renewed every 3 months
2	DUNS (Dun & Bradstreet Universal Numbering System)	A unique 9 digit identification no http://fedgov.dnb.com/webform (without fee for assigning a no for doing business with the government)	must be renewed every 6 months
3	SAM (System for Award Management)	www.sam.gov	must be renewed annually
4	NATO Commercial & Government Entity Code (NCAGE)	5 character code http://www.dlis.dla.mil/Forms/Form_AC135.asp.	must be renewed annually
5	Grants.Gov	https://www.grants.gov/	must be renewed every 2 months
6	PMS The Payment Management System (PMS)	https://pms.psc.gov/	
7	Federal wide assurance (FWA)	KKU agrees to follow Human Research Protections https://ohrp.cit.nih.gov/	must be renewed every 5 years
8	Misconduct	Annual Report on Possible Research Misconduct https://ori.hhs.gov/FR_Doc_05-9643	Via ORI website beginning January 1, and no later than April 30 of every year