# Department of Health and Human Services Part 1. Overview Information

Participating Organization(s)	National institutes of Health ( <u>INTH (Inttp://www.filin.gov))</u>
Components of Participating Organizations	National Institute of Allergy and Infectious Diseases (NIAID (http://www.niaid.nih.gov))
Funding Opportunity Title	Global Infectious Disease Research Administration Development
	Award for Low-and Middle-Income Country Institutions (G11
	Clinical Trial Not Allowed)
Activity Code	
	text curr=g11&Search.x=11&Search.y=5&Search Type=Activity) Extramural Associate Research  Development Award (EARDA)
Announcement Type	Reissue of PAR-15-131 (https://grants.nih.gov/grants/guide/pa-files/PAR-15-131.html)
Related Notices	October 20, 2020 - This PA has been reissued as PAR-21-037     (https://grants.nih.gov/grants/guide/pa-files/PAR-21-037.html).
	<ul> <li>March 10, 2020 - Reminder: FORMS-F Grant Application Forms &amp; Instructions Must be Used for Due Dates On or After May 25, 2020- New Grant Application Instructions Now Available.</li> </ul>
	See Notice NOT-OD-20-077 (/grants/guide/notice-files/NOT-OD-20-077.html).
	<ul> <li>August 23, 2019 - Clarifying Competing Application Instructions and Notice of Publication of Frequently Asked Questions (FAQs) Regarding Proposed Human Fetal Tissue Research. See</li> </ul>
	Notice NOT-OD-19-137 (/grants/guide/notice-files/NOT-OD-19-137.html).
	<ul> <li>July 26, 2019 - Changes to NIH Requirements Regarding Proposed Human Fetal Tissue     Research. See Notice NOT-OD-19-128 (/grants/guide/notice-files/NOT-OD-19-128.html).</li> </ul>
	<ul> <li>November 26, 2018 - NIH &amp; AHRQ Announce Upcoming Updates to Application Instructions and Review Criteria for Research Grant Applications. See Notice NOT-OD-18-228</li> </ul>
	(/grants/guide/notice-files/NOT-OD-18-228.html)
	<ul> <li>June 19, 2018 (//grants.nih.gov/grants/guide/notice-files/NOT-AI-18-041.html) - Notice of Change to Eligible Organizations in NIAID PAR-18-335 Global Infectious Disease Research</li> </ul>
	Administration Development Award for Low-and Middle-Income Country Institutions (G11
	Clinical Trial Not Allowed). See Notice NOT-Al-18-041 (//grants.nih.gov/grants/guide/notice-files/NOT-Al-18-041.html).
Funding Opportunity Announcement (FOA) Number	PAR-18-335
Companion Funding Opportunity	none
Number of Applications	See Section III. 3. Additional Information on Eligibility.
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.855
Funding Opportunity Purpose	The purpose of this Funding Opportunity Announcement (FOA) is to invite applications from research
	institutions in low- to middle-income countries (LMIC) to provide senior administrators from these institutions with advanced training in the management of NIH grants. The ultimate goal is to improve
	oversight of NIAID grant awards and compliance with NIH funding policies and Federal research
	funding requirements for NIAID-supported foreign institutions in low to middle-income countries.
Key Dates	
Posted Date	October 31, 2017
Open Date (Earliest Submission Date)	June 30, 2018
Letter of Intent Due Date(s)	30 days prior to the application due date
Application Due Date(s)	July 31, 2018; July 31, 2019; July 31, 2020, 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)	July 31, 2018; July 31, 2019; July 31, 2020, by 5:00 PM local time of applicant organization. All <u>types</u> of AIDS and AIDS-related <u>applications</u> 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	November 2018; November 2019; November 2020
Advisory Council Review	
Earliest Start Date	May 2019; May 2020; May 2021
Expiration Date	August 1, 2020
Due Dates for E.O. 12372	Not Applicable

### **Required Application Instructions**

It is critical that applicants follow the Research (R) Instructions in the SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url\_redirect.htm? id=12000), except where instructed to do otherwise (in this FOA or in a Notice from the NIH Guide for Grants and Contracts (//grants.nih.gov/grants/guide/)). 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.

https://grants.nih.gov/grants/guide/pa-files/PAR-18-335.html

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Part 2. Full Text of the Announcement

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### Part 2. Full Text of Announcement

### Section I. Funding Opportunity Description

#### **Background**

Since 1997, the NIH has dramatically increased its funding of research and training in developing countries. To help NIAID foreign research partners successfully manage grants and cooperative agreements, regional post-award grants policies and management training workshops are held twice a year. NIAID hosts the three-day regional post-award grants management training workshops in countries where there are institutions that receive NIAID research funding. The objective is to help business officials, scientists, and grants managers better understand NIAID/NIH funding policies and DHHS regulations.

While these regional training events have helped many attendees, they are usually too short and the cost of travel is often not affordable to institutions. This Funding Opportunity Announcement (FOA) will enable senior administrators from low- to middle-income countries (LMICs) to receive training in NIH grants policy and financial management of grants, including compliance with NIH scientific reporting requirements. For this FOA a senior administrator is considered to be institutional staff with responsibility for grants administration including business officials, grants managers and scientists with administrative responsibilities.

#### **Purpose and Scope**

The purpose of this FOA is to encourage submission of applications from research institutions in LMICs, as defined by <a href="The World Bank">The World Bank</a> (<a href="https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups">https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups</a>), to provide their senior administrators with advanced training in the management of NIH grants. The overall intent of the initiative is to support the training of senior administrators and empower them to serve as institutional grants management leaders; provide them with access to good business practices for managing awards; assist the administrative staff in developing and implementing standard operating procedures for tracking grant expenditures, complying with NIH funding policies; and assist or train other administrators in the local area.

This FOA will provide support for travel of senior administrator(s) from the LMIC institution to a partner US host institution where they will receive hands-on training in grants administration. These senior administrator(s) are expected to train others at their home institutions and, as needed, implement grants management changes, as well as serve as a resource for training other local or regional institutions receiving NIAID funds.

Up to two senior administrators from the LMIC institution will receive training at a US host institution for up to 1 month during the award period (2 weeks in the first year and 2 weeks in the second year), as well as attend either a NIH regional workshop on program funding and grants administration, or a NIAID post- award grants policy and management training event. The FOA will also support up to two senior administrators from the LMIC institution for five days of in-house training with the Grants Management Program (GMP) at NIAID in Rockville, MD. This training will allow GMP staff to provide customized information about managing NIAID awards, as well as tailored hands-on training based on the needs of the institutions.

An additional goal of the FOA is to support "sustainability initiatives" for NIH research grants administration. Sustainability initiatives include activities that facilitate research grants administration activities that would be initiated during the grant funding period with the potential to continue after the funding has ended. Examples include, but are not limited to, development of standard operating procedures (SOPs) that include specific steps for effectively managing sponsored research funds within the local institution and the development of a new in-house grants management career track for business management trainees or college students. The purpose of this element is to enable the PD(s)/Pl(s) to collect data to demonstrate the importance of developing or strengthening grants management activities that can help to maintain institutional competitiveness and/or the efficiency and productivity of research administration operations.

For additional information see NIAID questions and answers webpage for PAR-18-335 <a href="https://www.niaid.nih.gov/grants-contracts/opportunity-specific-questions-and-answers">https://www.niaid.nih.gov/grants-contracts/opportunity-specific-questions-and-answers</a>)

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 The OER Glossary (//grants.nih.gov/grants/guide/url_redirect.htm?id=11116) and the SF424 (R&R) Application Guide provide details on these application types.
Clinical Trial?	Not Allowed: Only accepting applications that do not propose clinical trials  Need help determining whether you are doing a clinical trial?  (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82370)
Funds Available and Anticipated Number of Awards	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 \$100,000 per 18 months in direct costs. Indirect costs for foreign grantees are limited to 8%.
Award Project Period	The total project period may not exceed 18 months.

NIH grants policies as described in the <u>NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url\_redirect.htm?id=11120)</u> will apply to the applications submitted and awards made in response to this FOA.

### Section III. Eligibility Information

### 1. Eligible Applicants

### Eligible Organizations

Non-domestic (non-U.S.) Entities (Foreign Institutions)

Eligible organizations must be in a LMIC, as defined by <u>The World Bank (https://datahelpdesk.worldbank.org/knowledgebase/articles/906519)</u>, and include research institutions in LMICs. Eligible applicant foreign institutions in LMICs are limited to those receiving NIAID grant and/or cooperative agreement funding at the time of application submission. Eligible organizations must have received less than \$2.2 million in total NIH grant and/or cooperative agreement support (direct awards) in the last 5 years at the time of application submission. In order to assure that the US host institutions have appropriate expertise in the management and administration of NIH grants, the applicants' US host institutions are limited to US institutions that, at the time of submission, have received at least \$5 million per year in total NIH research grant and/or cooperative agreement support over the last 10 years.

### Foreign Institutions

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

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

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

### Required Registrations

### Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants

https://grants.nih.gov/grants/guide/pa-files/PAR-18-335.html

should begin the registration process as soon as possible. The <u>NIH Policy on Late Submission of Grant Applications (//grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html)</u> states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- <u>Dun and Bradstreet Universal Numbering System (DUNS) (http://fedgov.dnb.com/webform)</u> 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) (https://www.sam.gov/portal/public/SAM/) (formerly CCR) Applicants must complete and maintain an active registration, which requires renewal at least annually. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
  - NATO Commercial and Government Entity (NCAGE) Code (//grants.nih.gov/grants/guide/url\_redirect.htm?id=11176) Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- <u>eRA Commons (//grants.nih.gov/grants/guide/url\_redirect.htm?id=11123)</u> Applicants must have an active DUNS number and SAM registration in order to complete the eRA Commons registration. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration. 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.
- <u>Grants.gov (//grants.nih.gov/grants/guide/url\_redirect.htm?id=82300)</u> 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/Pls, 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.

The PD/PI should be a senior institutional staff member with responsibility for grants administration (e.g. grants administrator, business official, or scientist with institutional grants management responsibilities). A doctorate degree is not required to be the PD/PI.

### 2. Cost Sharing

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

#### 3. Additional Information on Eligibility

#### Number of Applications

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

The NIH will not accept duplicate or highly overlapping applications under review at the same time. 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 <a href="NOT-OD-11-101">NOT-OD-11-101</a> (//grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html)).

### Section IV. Application and Submission Information

### 1. Requesting an Application Package

Buttons to access the online ASSIST system or to download application forms are available in <u>Part 1</u> 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 Research (R) Instructions in the <u>SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url\_redirect.htm?</u> id=12000), 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.

For information on Application Submission and Receipt, visit <u>Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications</u> (//grants.nih.gov/grants/guide/url\_redirect.htm?id=41137).

### 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:

Louis A. Rosenthal, Ph.D. Telephone: 240-669-5070 Fax: 301-480-2408

Email: rosenthalla@niaid.nih.gov (mailto:rosenthalla@niaid.nih.gov)

### Page Limitations

All page limitations described in the SF424 Application Guide and the <u>Table of Page Limits (//grants.nih.gov/grants/guide/url\_redirect.htm?id=11133)</u> 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 Guid

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

- Include a biosketch for the PD/PI for this application indicating the individual's institutional responsibilities and authorities, as well as qualifications
  to serve as the senior administrator or scientist at the applicant institution. The PD/PI should be the person who travels to and receives training in
  the US. If a multiple PD/PI application, the contact PD/PI will be the senior administrator at the LMIC and will be the person who travels to and
  receives training in the US.
- For the PD(s)/PI(s) a business degree or equivalent qualification is desirable, although not required.

Include a biosketch that indicates the expertise of any additional senior administrators requesting support to travel and receive training that demonstrates sufficient institutional responsibilities and authority to develop and implement strategies for strengthening the research administration and support mechanisms at their home institution as well as administrative and professional leadership qualities to enhance and implement the training/mentoring.

### R&R Budget

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

- Justification for the administrative, training or teaching responsibilities and time commitment for salaried foreign senior administrators.
- Justification for travel expenses for up to two foreign grants administrators including the PD/PI.
- Justification for the consulting fees by the host US institution. Funds for US institutions will be limited to consultant fees at the host institution.
- Justification for the products/services needed for sustainability initiatives.

Applications requesting funds to promote distance learning including webinar training or videoconferencing may include \$5000 of direct costs.

After 10 months of the project period, and submission of the program's progress to the program officer, up to \$10,000 of direct cost may be used to support "sustainability initiatives".

#### 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:** Briefly describe the specific aims of the proposed training program, including the overall goals, critical gaps in grants administration, objectives including the process for making sustainable business process changes, and how the program will meet the objectives outlined in this FOA.

Research Strategy: Applicants should describe their training strategy and implementation of related business processes and must include the following:

Research Grants Administration/Financial Management Plan:

- Describe the ways that the administrators trained under this award will support faculty researchers performing NIAID funded research within the context of the research grant life cycle (receipt of award and budget implementation, and managing grant awards).
- Describe the current grants administration/financial management process used at your institution.
- Identify which aspects of the grants administration-related services the proposed Research Grants Administration/Financial Management Plan will
  address (i.e., post-award expenditure tracking, financial reporting, or other NIH funding requirements) and explain how the current
  administration/plan will be improved.
- Identify the US host and describe how the PD/PI and host administrators/business officials will interact to achieve the training and business practice goals of the program.
- Describe the overall strategy and methodology to be used to accomplish the specific aims and include a timeline.
- Outline the processes and work tools that will be developed and/or acquired to address gaps in existing research grants administration support services (i.e., pre-award services, post-award services, compliance, preparation for Federal funding related audits etc.).
- Indicate how the proposed program of activities will be integrated into the institution's grants management functions.

#### Staff Training Plan:

- Mentoring and development of junior grants management staff should be included in the application. The staff training plan should include a viable plan, based on allowable activities at the local institution, for senior grants management staff to train current and future institutional grants management leaders; essentially a "Train-the-Trainer" plan.
- The staff training plan may also include grants management training opportunities or expertise that will be made available to other institutions that receive NIAID/NIH funding in the local area.
- For applicants that plan to provide training to other local in-country institutions, describe how this activity will be developed and executed.

#### Sustainability Initiative:

- Applicants should describe plans and procedures to develop and implement (including a timeline) grants management or related best business
  practices that could continue after the grant funding period ends. Sustainability initiatives may include the development of a grants management
  training program at the college level to ensure a pipeline of grants management specialists, establishing an institutional sponsored research program
  office, or other activities that may result in sustainable changes. Applicants must describe the initiative, as well as how and when it will be
  implemented.
- Describe the level of authority needed within the institute to implement and maintain grants management changes that result from the sustainability initiative. Indicate who has the authority and whether that person or entity has agreed to make changes, if needed.

**Letters of Support:** Applicants should provide the following letters of support:

Letters of recommendation: Applicants must provide three letters of support from colleagues who have worked with the PD/PI and/or have the knowledge to describe and comment on his or her role in grants administration, effectiveness in working with a team and ability to successfully communicate and coordinate across organizational boundaries. Each letter must also include the referee's name, title, institutional affiliation, address, telephone and fax numbers, and email address.

Institutional Commitment Letter: A letter of commitment must be provided by the President or designated high-ranking official (i.e., Provost, Vice-President for Research, Dean, etc.) of the LMIC Institution as evidence of institutional commitment to enhancing research grants administration. The letter should highlight the provision of adequate staff, facilities, authority to implement changes to the grants management process and resources that can contribute to the planned efforts to improve training in research grants administration. It should also include a commitment to the proposed sustainability initiative project described in the application. In addition, the letter should affirm that the applicant institution has current NIAID funding and include the grant number(s) and total amount in U.S. dollars for all NIH grant and/or cooperative agreement support (direct awards) received in the last 5 years at the time of application submission.

US Institutional Commitment Letter: A letter of commitment must be provided by the business office of the US institution as evidence of institutional commitment to provide at least two grants management best practices training sessions at their institution. It should also include a commitment to provide one senior grants manager with NIH grants management experience to oversee the two grants management training events, and to review the grantees proposed local grants management/business plans. The letter should affirm that the US host institution, at the time of submission, has received at least \$5 million per year in total NIH research grant and/or cooperative agreement support each year over the last 10 years.

**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, with the following modification:

Generally, Resource Sharing Plans are expected, but they are not applicable for this FOA.

### Appendix:

Do not use the Appendix to circumvent page limits. 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 follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with the following additional instructions:

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

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

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

### Delayed Onset Study

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.

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### Foreign Institutions

https://grants.nih.gov/grants/guide/pa-files/PAR-18-335.html

Foreign (non-U.S.) institutions must follow policies described in the <u>NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url\_redirect.htm?id=11137)</u>, 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

<u>Part I. Overview Information</u> 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 <u>Federal holiday (https://grants.nih.gov/grants/guide/url\_redirect.htm?id=82380)</u>, the application deadline is automatically extended to the next business day.

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

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

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

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

This initiative is not subject to intergovernmental review. (//grants.nih.gov/grants/guide/url\_redirect.htm?id=11142)

#### 6. Funding Restrictions

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

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

#### 7. Other Submission Requirements and Information

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

Applicants must complete all required registrations before the application due date.

Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit <u>Applying Electronically</u> (<u>//grants.nih.gov/grants/guide/url\_redirect.htm?id=11144</u>). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the <u>Guidelines for Applicants Experiencing System Issues</u>

(<u>//grants.nih.gov/grants/ElectronicReceipt/support.htm#guidelines</u>). For assistance with application submission, contact the Application Submission Contacts in <u>Section VII</u>.

#### 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 (//grants.nih.gov/grants/guide/url redirect.htm?id=11146) for avoiding common errors.

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

#### **Post Submission Materials**

Applicants are required to follow the instructions for post-submission materials, as described in <a href="mailto:the-policy">the policy (//grants.nih.gov/grants/guide/url redirect.htm? id=82299)</a>.

### Section V. Application Review Information

Important Update: See NOT-OD-18-228 (/grants/guide/notice-files/NOT-OD-18-228.html) for updated inclusion and human subjects review language for due dates on or after January 25, 2019.

#### 1. Criteria

Only the review criteria described below will be considered in the review process. As part of the NIH mission (//grants.nih.gov/grants/guide/url redirect.htm?id=11149), all applications submitted to the NIH in support of biomedical and behavioral research 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 improve oversight of NIAID grants or cooperative agreement awards and compliance with NIH funding policies; and to exert a sustained, grants management/business practice change including training at the applicant's institution, 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? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or grants administration practices be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Is the proposed project well justified in terms of addressing deficiencies or gaps in the existing research grants administration/financial management infrastructure? Are processes and/or work tools identified that need to be developed, facilitated, or acquired to address current gaps in the infrastructure? Does the staff training plan facilitate the strengthening of grants administration at the grantee institution and, where proposed, other incountry institutions?

### Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? 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?

Does the PD/PI, senior grants manager (if not the PD/PI) have the ability to provide administrative leadership and direction? Has he/she demonstrated the ability to perform in a team environment to accomplish objectives that require coordination across multiple organizational entities? Does the PD/PI have the requisite authority to implement the proposed institutional grants administration/management training plan? Does the PD/PI or senior grants manager have an appropriate level of skills and experience? Does the PD/PI or senior grants manager have sufficient authority or relative areas of responsibility to implement research grants administrative changes?

Does the US consultant have the appropriate skills and experience in managing NIH awards to train a foreign senior administrator? Is the plan for communication between the U.S. consultant and the foreign senior grants manager adequate?

### Innovation

Does the application challenge and seek to shift current research grants administration 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 grants management or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Does the application identify creative ways to address critical research administration needs (i.e., effective information dissemination; staffing and grants management function, training grants management staff), and seek to address those needs?

For applications that propose a sustainability initiative, does the initiative propose a new idea or strategy for improving institutional grants management training or business practices?

### **Approach**

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? 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?

Do the plans for research grants administration and the training of local grants administrators adequately identify specific needs within the applicant's existing research grants administration, establish reasonable specific aims, as well as identify best practices (i.e., interventions, work tools, and processes) that can effectively address and eliminate targeted deficiencies and gaps? Are the plans for mentoring junior grants management staff and providing competency-based training in grants administration adequate? Is there a plan for institutional grants management practice changes as needed? Does the application describe plans for training grants specialists at other in-country institutions that manage NIH awards, if applicable? Does the application adequately describe how and when the sustainability initiative will be implemented? Does the plan present reasonable goals for sustainable management of NIH awards after the project funding has ended?

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 children, justified in terms of the scientific goals and research strategy proposed?

### **Environment**

Will the administrative 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 administrators adequate for the project proposed? Will the project benefit from unique features of the scientific and business environment, subject populations, or collaborative arrangements?

Does the applicant's high-level leadership exhibit strong support for strengthening the institution's research administration training capability?

Does the LMIC Institutional commitment reflect the provision of adequate staff, facilities, training, and resources that can contribute to the planned efforts to improve training in research grants administration? Are the requested resources appropriate based on the goals of the institution's sustainability initiative?

Does the US institution have the appropriate grants management staff and environment to adequately train a foreign senior grants manager? Is the site for training in the US appropriate?

#### **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 six 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 six 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 <u>Guidelines for the Review of Human Subjects</u> (//grants.nih.gov/grants/guide/url\_redirect.htm?id=11175).

#### Inclusion of Women, Minorities, and Children

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 children 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 <u>Guidelines for the Review of Inclusion in Clinical Research (//grants.nih.gov/grants/guide/url\_redirect.htm?id=11174)</u>.

#### **Vertebrate Animals**

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

#### **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

Not Applicable

#### **Additional Review Considerations**

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

#### Applications from Foreign Organizations

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

#### **Select Agent Research**

Not Applicable

### **Resource Sharing Plans**

Not Applicable.

### 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 (//grants.nih.gov/grants/guide/url redirect.htm?id=11154), using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications:

- May undergo a selection process in which only those applications deemed to have the highest administrative 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. Following initial peer review, recommended applications will receive a second level of review by the National Advisory Allergy and Infectious Diseases Council. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Scientific and technicAvailability 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 <u>eRA Commons (//grants.nih.gov/grants/guide/url\_redirect.htm?id=11123)</u>. 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 <u>NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url\_redirect.htm?</u> id=11156).

### 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 <u>NIH Grants Policy</u> <u>Statement (//grants.nih.gov/grants/guide/url\_redirect.htm?id=11157)</u>.

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 <u>Section IV.5</u>. <u>Funding Restrictions</u>. 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 <u>Award Conditions and Information for NIH Grants</u> (//grants.nih.gov/grants/guide/url redirect.htm?id=11158) 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 <u>NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url\_redirect.htm?id=11120)</u> as part of the NoA. For these terms of award, see the <u>NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (//grants.nih.gov/grants/guide/url\_redirect.htm?id=11157)</u> and <u>Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities (//grants.nih.gov/grants/guide/url\_redirect.htm?id=11159)</u>. More information is provided at <u>Award Conditions and Information for NIH Grants (//grants.nih.gov/grants/guide/url\_redirect.htm?id=11158)</u>.

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

PAR-18-335: Global Infectious Disease Research Administration Development Award for Low-and Middle-Income Country Institutions (G11-Clinical Trial Not Allowed) where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research.

For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this FOA. 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/forindividuals/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 http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html

(http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html); and https://www.hhs.gov/civil-rights/for-providers/laws-regulationsguidance/index.html (https://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 http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html (http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html). Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at <a href="https://www.hhs.gov/ocr/about-us/contact-us/index.html">https://www.hhs.gov/ocr/about-us/contact-us/index.html</a> (<a href="https://www.hhs.gov/ocr/about-us/contact-us/contact-us/contact-us/contact-us/contact-us/contact-us/contact-us/contact-us/contact-us/contact-us/contact-us/contact-us/contact-us/contact-us/contact-us/contact-us/contact-us/con 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 (http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53).

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.

#### **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) (//grants.nih.gov/grants/rppr/index.htm) annually and financial statements as required in the NIH Grants Policy Statement.

(//grants.nih.gov/grants/guide/url\_redirect.htm?id=11161) An Evaluation Plan is required. At the end of 10 months of the award period, awardees must submit a strategy for improving grants management oversight and business practices at their institution. The U.S. host institution must sign-off on the draft. By the end of 16 months of the award period, the awardee must provide a report that states what changes have been initiated or made to the local business practices of the grantee and staff training plan. The host U.S. institution must sign the report.

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 (//grants.nih.gov/grants/guide/url redirect.htm?id=11161).

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 (//grants.nih.gov/grants/guide/url\_redirect.htm?id=11170) on all subawards over \$25,000. See the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url redirect.htm?id=11171) 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 registration, submitting and tracking an application, documenting system problems that threaten submission by the due date, post submission issues) Finding Help Online: <a href="http://grants.nih.gov/support/">http://grants.nih.gov/support/</a> (//grants.nih.gov/support/) (preferred method of contact)

Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

Grants.gov Customer Support (//grants.nih.gov/grants/guide/url redirect.htm?id=82301) (Questions regarding Grants.gov registration and submission, downloading forms and application packages)

Contact Center Telephone: 800-518-4726 Email: <a href="mailto:support@grants.gov">support@grants.gov</a>)

GrantsInfo (Questions regarding application instructions and process, finding NIH grant resources) Email: GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov) (preferred method of contact)

Telephone: 301-945-7573

### Scientific/Research Contact(s)

Paula S. Strickland, Ph.D., MPH National Institute of Allergy and Infectious Diseases (NIAID) Telephone: 240-669-2922

Email: pstricklan@mail.nih.gov (mailto:pstricklan@mail.nih.gov)

#### Peer Review Contact(s) Louis A. Rosenthal, Ph.D.

National Institute of Allergy and Infectious Diseases (NIAID) Telephone: 240-669-5070

Email: rosenthalla@niaid.nih.gov (mailto:rosenthalla@niaid.nih.gov)

### Financial/Grants Management Contact(s)

Tseday Girma, MPA

National Institute of Allergy and Infectious Diseases (NIAID)

Telephone: 240-747-7388

Email: Tseday.girma@nih.gov (mailto:Tseday.girma@nih.gov)

### Section VIII. Other Information

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

### **Authority and Regulations**

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

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?11-03-17) NIH Funding Opportunities and Notices (/grants/guide/index.html)



https://grants.nih.gov/grants/guide/pa-files/PAR-18-335.html 7/8



(http://www.hhs.gov/) Department of Health



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

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