

Managing National Institutes of Health (NIH) Awards with Foreign Components

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Meeting: Harnessing Data Science for Health Discovery and Innovation in Africa (DS-I Africa)

Monday, Aug. 10, 2020 (10 – 10:30) AM



Fogarty International Center

Current Funding Opportunities

Title	NIH Guide	RFA Number	Common Fund Contact	Application Receipt Date
Harnessing Data Science for Health Discovery and Innovation in Africa (DS-I Africa) Research Hubs (U54 – Clinical Trial Optional). Additional information for applicants.	July 24, 2020	RFA-RM-20-015	Brad Newsome brad.newsome@nih.gov (link sends e-mail) 301-480-8389	Letter of Intent: 11/9/2020 Receipt Date: 12/8/2020
Harnessing Data Science for Health Discovery and Innovation in Africa (DS-I Africa) Research Training Program (U2R – Clinical Trial Optional)	July 24, 2020	RFA-RM-20-016	Laura Povlich laura.povlich@nih.gov (link sends e-mail) 301-827-2227	Letter of Intent: 10/23/2020 Receipt Date: 11/24/2020
Harnessing Data Science for Health Discovery and Innovation in Africa (DS-I Africa): Ethical, Legal, and Social Implications Research (U01 – Clinical Trial Not Allowed)	July 24, 2020	RFA-RM-20-017	James D. Churchill churchillj@mail.nih.gov (link sends e-mail) 301-443-3621	Letter of Intent: 11/2/2020 Receipt Date: 12/1/2020
Harnessing Data Science for Health Discovery and Innovation in Africa (DS-I Africa) Open Data Science Platform and Coordinating Center (U2C – Clinical Trial Not Allowed)	July 24, 2020	RFA-RM-20-018	Tiffani Lash DS-I_AfricaFOA-Inqry@mail.nih.gov (link sends e-mail) 301-496-4778	Letter of Intent: 11/3/2020 Receipt Date: 12/3/2020

Definition of the Mechanisms

U54	Cooperative Agreements	Specialized Center--Cooperative Agreements	To support any part of the full range of research and development from very basic to clinical; may involve ancillary supportive activities such as protracted patient care necessary to the primary research or R&D effort. The spectrum of activities comprises a multidisciplinary attack on a specific disease entity or biomedical problem area. These differ from program project in that they are usually developed in response to an announcement of the programmatic needs of an Institute or Division and subsequently receive continuous attention from its staff. Centers may also serve as regional or national resources for special research purposes, with funding component staff helping to identify appropriate priority needs.
U2R	Cooperative Agreements	International Research Training Cooperative Agreements	Cooperative agreement mechanism for D43 to support research training programs for US and foreign professionals and students to strengthen global health research and international research collaboration.

Definition of the Mechanisms

U01	Cooperative Agreements	Research Project--Cooperative Agreements	To support a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing his or her specific interest and competencies.
U2C	Cooperative Agreements	Resource-Related Research Multi-Component Projects and Centers Cooperative Agreements	To support multi-component research resource projects and centers that will enhance the capability of resources to serve biomedical research. Substantial federal programmatic staff involvement is intended to assist investigators during performance of the research activities, as defined in the terms and conditions of the award.

ROLES AND RESPONSIBILITIES

- 2.1 The **Chief Grants Management Officer CGMO** is the focal point for receiving and acting on requests for NIH prior approval or for changes in the terms and conditions of award, and is the only NIH official authorized to obligate NIH to the expenditure of Federal funds or to change the funding, duration, or other terms and conditions of award
- **Grants Management Specialist, GMS.** The GMS whose name appears in the NoA is an agent of the GMO and is assigned responsibility for the day-to-day management of a portfolio of grants.
- **Program Official.** The PO is responsible for the programmatic, scientific, and/or technical aspects of assigned applications and grants.
- **Scientific Review Officer.** SROs are health science administrators who manage the activities of SRGs, including CSR study sections

2.1.2 Recipient Staff (Grantee)

- Overall responsibility for successfully implementing an NIH grant is a shared responsibility of the PD/PI(s), the AOR, and the Research Administrator. As key members of the grant team, they respectively lead the scientific and administrative aspects of the grant.
- **Authorized Organization Representative.** The AOR is the designated representative of the recipient organization in matters related to the award and administration of its NIH grants, including those that require NIH approval.
- **Program Director/Principal Investigator.** A PD/PI is an individual designated by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program supported by the award.
- **Research Administrator.** The Research Administrator acts as a local agent of the AOR and/or PD/PIs providing day-to-day grant-related support

PRE-AWARD

FORMS-F Grant Application Forms & Instructions Must be Used for Due Dates On or After May 25, 2020- New Grant Application Instructions Now Available

This notice reminds the NIH and AHRQ applicant and recipient community that applicants must use FORMS-F application packages for due dates on or after May 25, 2020

- **Additional Updates:**
 - ❖ FORMS-F Grant Application Instructions are now posted on the [How to Apply - Application Guide](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.120-significant-changes.htm) page. All significant changes to form instructions are listed at: <https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.120-significant-changes.htm>.
 - ❖ FORMS-F application packages are currently being posted to active Funding Opportunity Announcements (FOAs).
 - ❖ All [Parent Announcements](#) will be reissued for due dates on or after May 25, 2020. Consequently, FORMS-F application packages will not be added to the existing [Parent Announcements](#) with FORMS-E application packages.

Upcoming FORMS-F and Inclusion Across the Lifespan Requirements for NIH Applicants and Recipients Submitting Post-Submission Updates Using the Human Subjects System (HSS) Notice Number: NOT-OD-20-125

Key FORMS-F Changes to the PHS Human Subjects and Clinical Trials Information Form:

As of June 13, all applicants and recipients submitting post-submission updates in the Human Subjects System (HSS) will use the FORMS-F PHS Human Subjects and Clinical Trials Information Form for the submission.

For a full list of significant FORMS-F changes, see

<https://grants.nih.gov/grants/electronicreceipt/files/high-level-form-change-summary-FORMS-F.pdf>.

PRE-AWARD – FUNDING OPPORTUNITY ANNOUNCEMENT (FOA)

RFAs found at : [Grants.gov/FIND](https://grants.gov/FIND) and in the [*NIH Guide for Grants and Contracts*](#).

Indicates who should apply/eligibility

- Program Announcement
- Request for Applications

Indicate whether collaboration with a *Foreign Component* is allowed

ELIGIBILITY BOTH FOR INSTITUTIONS AND PRINCIPAL INVESTIGATORS (PI's)

Check the FOA (Funding Opportunity Announcement)

- Institutions: Governments & Federal Institutions, Academic Institutions, Other Non-Profit orgs and Hospitals
- PI's – Educational requirements, Citizenship requirements and Qualifications/expertise – Again check the FOA

NIH APPLICATION PROCESS AND REGISTRATION

- Start **EARLY**
- 4 weeks prior to the application due date is recommended
- Read your FOA, download the instructions
- Submit through ASSIST, and/or Grants.gov
- Organizations must submit applications to [Grants.gov](https://www.grants.gov) (the online portal to find and apply for grants across all Federal agencies) using ASSIST or other electronic submission systems.
- The Application Submission System & Interface for Submission Tracking (ASSIST) is a web-based system used to prepare applications using the SF424 Research & Related form set and to submit electronically through Grants.gov to NIH and other participating agencies.

NIH APPLICATION PROCESS and REGISTRATION (CONT.)

- 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.

Foreign Inst. interested in conducting business with the United States (U.S.) Federal Government must complete the following

How to Obtain A Commercial and Government Entity (CAGE)/North Atlantic Treaty Organization (NATO) CAGE (NCAGE) Code:

Companies located outside the U.S.: http://www.dlis.dla.mil/Forms/Form_AC135.asp

1. Register with [NATO Support Agency \(NSPA\)](#)
2. If you wish to do business with the U.S. you must:
 - a. Register with [Dun & Bradstreet \(D&B\)](#).
 - b. Register with [System for Award Management \(SAM\)](#).
 - c. Review [Business Identification Number Cross-reference System \(BINCS\)](#):
a search engine (help with SAM registration)for foreign and domestic manufacturers, suppliers and potential contractors supporting the Federal supply chain.

Companies located in the U.S.:

1. Register with [Dun & Bradstreet \(D&B\)](#).
2. Register with [System for Award Management \(SAM\)](#).

Note: Approximately 4-5 business days after your SAM application is approved, NCAGE/CAGE Codes will be assigned and delivered by e-mail.

3. Review [Business Identification Number Cross-reference System \(BINCS\)](#), a search engine for foreign and domestic manufacturers, suppliers and potential contractors supporting the Federal supply chain.

U.S. territories (Guam, Puerto Rico, Virgin Islands, American Samoa and Northern Mariana Islands, etc.) will be assigned by the U.S and must register in SAM.

NIH APPLICATION PROCESS AND REGISTRATION (cont.)

- All Institutions must be registered with DUN & Bradstreet, have a Data Universal Numbering System (DUNS) number and have an active Systems Award Management (SAM) account.
- PI's must be registered in the ERA Commons with a commons ID#. 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.
- PI and Signing Official (SO) need separate accounts in eRA Commons because each has different privileges.

NIH APPLICATION PROCESS AND REGISTRATION (cont.)

- 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 (SAM).

Notification of Upcoming Change in Federal-wide Unique Entity Identifier Requirements

Notice Number: NOT-OD-19-098

- The purpose of this Guide Notice is to alert NIH recipients of the Federal-wide transition from the DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) to a new Government-owned unique entity identifier (UEI). Effective December 2020, the system for Award Management (SAM) will become the central repository for the new SAM Managed Identifier (SAMMI) that will be incorporated into an institution's SAM registration.
- The assignment of the SAMMI will be incorporated into the SAM registration process, eliminating the need for applicants to seek external identifiers in order to register.
- The transition from DUNS to SAMMI is ongoing, and GSA will provide details to agencies related to the full implementation by December 2020. NIH will provide updates and guidance to recipients on changes to policies and procedures as additional information becomes available.

SAM.gov FAQs for Foreign Organizations

- **I am an international registrant and cannot access the SAM website. Why and what do I do?**

A technical or security issue may be preventing you from accessing the SAM website. Please visit this Federal Service Desk FAQ for guidance on how to proceed: <https://www.fsd.gov/app/answers/list>.

- **I am an international registrant and cannot access the NATO CAGE Code website. Why and what do I do?**

In certain circumstances, specific locations may be blocked for technical or security reasons. If you cannot access the website, please visit this Federal Service Desk FAQ for guidance on how to proceed: https://www.fsd.gov/app/answers/detail/a_id/564/kw/international.

- **I am an applicant who lives outside the U.S. and am unable to access the System for Award Management (SAM) site. What should I do?**

A few countries may have trouble accessing the [SAM](#) website. The applicant should send an email to security@bpn.gov and copy the NIH Electronic Submission mailbox at NIHElectronicSubmiss@mail.nih.gov.

- **Are International Organizations required to hold a DUNS and register in Grants.gov?**

Yes.

- **Can I register my organization in Commons in my native language?**

We can accept any foreign names that use the English alphabet. Unfortunately our systems cannot accept special characters.

- **Are there any tips to assist foreign organizations while registering in eRA Commons?**

Keep these handy pointers in mind while registering in eRA Commons. Applicant organizations:

- Must have a DUNS number before registering in the eRA Commons. This DUNS number must match the DUNS number provided at the SAM registration with Grants.gov.
- Must have a valid e-mail and should ensure that any filters on their email do not interfere with NIH email. Must also keep in mind that the sooner they reply to emails, the faster NIH can complete their registration.

FAQs Foreign Organizations

- **Some of the data fields in the 424 (R&R) do not really apply to foreign organizations. How will this be handled?**

For some of the data, special instructions are included in the Application Guide for foreign organizations.

- **Are International organizations required to obtain an EIN number as part of the grant submission process?**

NIH does not require international organizations to obtain an EIN number for application submission. International organizations may use 44-4444444 for the Employer Identification field in the SF424 (R&R) Cover Component of the application package. [See [NIH eSubmission Tips for International Applicants](#) (PDF - 343 KB)].

- **How do I know if a foreign organization is eligible to apply?**

Each funding opportunity has a section for Eligibility. In that section there will be a clear statement about whether foreign institutions are eligible to apply

- **Which budget form should I use if I am a foreign organization?**

Foreign institutions must use the Research and Related Budget form.

- **On the SF424 (RR) application the field for "state" appears to be required. What do I do?**

Make sure you select your country first. If you select a country other than the US or Canada, the state field will become optional. Inclusion of Providence is required for Canada.

- **How does the system handle phone numbers in different formats?**

The phone number field on the SF424 (RR) application has a 25 character limit, but no specific format requirements.

- **What should I include in the Congressional District filed?**

Foreign institutions should use 00-000 for the Congressional District.

F&A for Grants to Foreign and International Organizations

NIH continues to provide F&A costs under grants to foreign and international organizations will be funded at a rate of 8 percent of total direct costs, less only equipment, tuition and related fees, and subawards in excess of \$25,000.

In addition, NIH has **removed** the requirement that only allows F&A costs to be recovered in order to support the costs of compliance with NIH requirements. This policy change will be reflected in the NIH GPS and will apply retroactively as of December 26, 2014.

Reference: 45 CFR 75.414(c)(1) /NIH Grants Policy Statement (Chapter 7.4 - Reimbursement of Facilities and Administrative Costs)

Consortium/Subcontract

- A formalized agreement whereby a research project is carried out by the recipient and one or more other organizations that are separate legal entities.
- Under the agreement, the recipient must perform a substantive role in the conduct of the planned research and not merely serve as a conduit of funds to another party or parties
- These agreements typically involve a specific level of effort from the consortium organization's PD/PI and a categorical breakdown of costs, such as personnel, supplies, and other allowable expenses, including F&A costs.
- The relationship between the recipient and the collaborating organizations is considered a subaward relationship

Consortium/Subcontract

The following information must be provided to NIH as part of a competing application that proposes consortium arrangements:

- Include all proposed performance sites; those of the applicant organization and the consortium participant(s); and
- Non-modular grant applications must include complete detailed budgets for each consortium participant.
- Modular grant applications must include an estimate of consortium total costs ([direct costs](#) plus [F&A costs](#)) each year as part of the budget narrative justification (see [Modular Applications and Awards](#) chapter).

Consortium vs. Fee For Service Contract

- **Consortium/Subcontract:**
 - The consortium carries out grant supported programmatic (scientific) activity.
 - The consortium investigator provides scientific input which could affect the direction of the project.
 - The consortium research makes an intellectual contribution to the project aims.
 - Consortium work is both scientific and administrative
 - **Parent grantee closely monitors activities at the consortium institution.**
- **Fee for Service Contracts** are used to provide a routine service to the grantee such as equipment fabrication or repair, data processing, routine analytical testing services, or management services. The service is not a programmatic activity.

Points of Contact

- General NIH Application Questions:
 - E-Mail: GrantsInfo@nih.gov
 - Phone: 301-435-0714
- Grants.gov Customer Support:
 - E-Mail: support@grants.gov
 - Webpage: <http://grants.gov/>
 - Phone: 800-518-4726
- eRA Commons Helpdesk:
 - Web: <http://era.nih.gov/help/>
 - Toll-free: 1-866-504-9552
 - Phone: 301-402-7469
 - Hours: Mon-Fri, 7a.m. to 8 p.m. Eastern Time

Points of Contact

- NIH Division of Grants Policy:
 - E-Mail: GrantsPolicy@mail.nih.gov
 - Phone: 301-435-0949
- NIH Division of Grants Compliance and Oversight:
 - E-Mail: GrantsCompliance@mail.nih.gov
 - Phone: 301-435-0949
- SAM.gov HelpDesk- The Federal Service Desk:
 - Webpage/Electronic Helpdesk Ticket: <https://fsd.gov/fsd-gov/home.do>
 - **U.S. Calls:** 866-606-8220
International Calls: 334-206-7828
DSN: 866-606-8220
 - Hours: Monday – Friday 8 a.m. to 8 p.m. Eastern Time

Thank you! Any questions?



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