

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

U.S. Food and Drug Administration ([FDA \(http://www.fda.gov/\)](http://www.fda.gov/))

NOTE: The policies, guidelines, terms, and conditions stated in this announcement may differ from those used by the NIH. Where this Funding Opportunity Announcement (FOA) provides specific written guidance that may differ from the general guidance provided in the grant application form, please follow the instructions given in this FOA.

The FDA does not follow the NIH Page Limitation Guidelines or the NIH Review Criteria. Applicants are encouraged to consult with FDA [Agency Contacts](#) for additional information regarding page limits and the FDA Objective Review Process.

Components of Participating Organizations

Office of Regulatory Affairs ([ORA \(http://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/OR/default.htm\)](http://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/OR/default.htm))

Funding Opportunity Title

**Building an Integrated Laboratory System to Advance the Safety of Human and Animal Food (U18)
Clinical Trial Not Allowed**

Activity Code

[U18 \(//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=u18&Search.x=0&Search.y=0&Search_Type=Activity\)](https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=u18&Search.x=0&Search.y=0&Search_Type=Activity) Research Demonstration – Cooperative Agreements

Announcement Type

New

Related Notices

None

Funding Opportunity Announcement (FOA) Number

RFA-FD-20-013

Companion Funding Opportunity

None

Number of Applications

See [Section III. 3. Additional Information on Eligibility.](#)

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

93.103

Funding Opportunity Purpose

The intended outcome of this Funding Opportunity Announcement is to support and enhance human and animal food testing laboratory activities, specifically through the activities of an association that will offer trainings, workshops, meetings, and other educational resources; conduct research on national testing capability and capacity; prepare best practices and other guidance manuals; support ISO/IEC 17025 laboratory accreditation for non-accredited laboratories; and other activities to support human and animal food testing laboratories.

Key Dates

Posted Date

January 21, 2020

Open Date (Earliest Submission Date)

January 21, 2020

Letter of Intent Due Date(s)

February 21, 2020

Application Due Date(s)

March 23, 2020 by 11:59 PM Eastern Time.

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.

Applicants should be aware that on-time submission means that an application is submitted error free (of both Grants.gov and eRA Commons errors) by 11:59 PM Eastern Time on the application due date.

Late applications will not be accepted for this FOA.

AIDS Application Due Date(s)

Not Applicable

Scientific Merit Review

April 2020

Advisory Council Review

Not Applicable

Earliest Start Date

July 2020

Expiration Date

March 24, 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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=12000\)](https://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 \(//grants.nih.gov/grants/guide/\)](https://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.**

There are several options available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners. You **must** use one of these submission options to access the application forms for this opportunity.

1. Use the NIH ASSIST system to prepare, submit and track your application online.

[Apply Online Using ASSIST](#)

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and [eRA Commons \(http://public.era.nih.gov/commons/\)](#) to track your application. Check with your institutional officials regarding availability.
3. Use [Grants.gov \(http://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=RFA-FD-20-013\)](#) Workspace to prepare and submit your application and [eRA Commons \(http://public.era.nih.gov/commons/\)](#) to track your application.

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Office of Partnerships (OP) is announcing the availability of a cooperative agreement to be awarded under a Limited Competition for National Associations/Organizations to support both awardees under the Laboratory Flexible Funding Model (LFFM) cooperative agreement program and unfunded laboratories. Non-profit national Associations/Organizations that represent human and/or animal food testing laboratories have the membership, resources, structure, and expertise necessary to build national consensus amongst state and local agencies on key human and animal food safety and laboratory issues.

The intended outcome of this FOA is to advance the goal of a national food safety system by supporting and enhancing state human and animal food testing laboratories tasked with surveillance and emergency response testing, including investigations of foodborne disease outbreaks. The resulting cooperative agreement will provide the additional support to these laboratories through the activities of an association that will conduct research on national testing capability and capacity; develop best practices and other guidance manuals; offer trainings, workshops, meetings, and other educational resources; support ISO/IEC 17025 laboratory accreditation for non-accredited laboratories; and other activities to support human and animal food testing laboratories.

Program Goals:

State and local laboratories play a critical role in the identification, containment, and prevention of foodborne illness. FDA is committed to assisting these laboratories in building laboratory capacity and capability, maintaining and expanding the scope of ISO/IEC 17025 accreditation, and supporting the groundbreaking work achieved through the GenomeTrakr network. Effective leveraging of resources and harmonization of efforts will require extensive collaboration with relevant initiatives, including those of federal partners, national initiatives, associations/organizations, and State and local partners.

The intended outcome of this FOA is to assist laboratories with building laboratory capacity and capability, in addition to assisting FDA in the development of trainings, workshops, educational materials, and meetings in support of LFFM and unfunded laboratories conducting testing of human and animal food samples.

This cooperative agreement is only available to non-profit, national associations/organizations that represent state and local laboratories that conduct food and/or animal feed testing on behalf of state and local regulatory programs.

Project Objectives (progress assessed semi-annually):

1. Research into the development and implementation of trainings, workshops, and other educational materials and resources for use by laboratories in the LFFM, in addition to unfunded laboratories seeking to achieve, maintain, and enhance ISO/IEC 17025 accreditation. Areas in need include effective workshops and seminars on laboratory procedures, data transfer (to NCBI and FDA data systems), document control, quality management systems, continuous improvement, sample collection, and risk assessment.

- o Methods of delivery for training could include: webinars, teleconferences, workshops, on-site
- o technical sessions, face-to-face meetings, or information sharing through web-based resources.

Both individual laboratory and broad-based training needs should be considered and met by the grantee. Training programs developed shall be pre-reviewed and approved by FDA prior to delivery. FDA will periodically assess the trainer's performance by reviewing the course assessments and evaluations completed by students (individual and aggregated data).

2. Plan and host annual meetings, including scheduling, agenda planning, invitations, on-site logistics (meeting facilities and AV needs and support), registration, materials, and follow-up evaluations, for:

- a. The LFFM Face-to-Face Meeting, including breakout sessions for the various LFFM disciplines
- b. The GenomeTrakr face-to-face meeting.

Meeting agendas and materials shall be pre-reviewed and approved by FDA prior to distribution and execution.

3. Provide direct technical assistance to non-FDA funded state human and animal food testing laboratories seeking ISO/IEC 17025 accreditation.
4. Research, develop, and maintain a crosswalk of state and FDA regulations and standards regarding human and animal food-related illness and outbreak response. This crosswalk must include sample collection requirements, analytical methodology, and compliance standards and action levels, among other areas agreed upon with FDA. The association may need to utilize surveys or other means of communication with the state laboratories to develop this crosswalk. This crosswalk also must be made available to FDA in a format agreed upon by FDA.
5. Evaluate data collected from the crosswalk and identify areas of improvement that can be developed into best practices and utilized for training and other resources.
6. Assist states with National Food Safety Data Exchange (NFSDX) implementation, specifically with sample data exchange.
7. Promote Office of Regulatory Affairs Partners Portal (ORAPP), Laboratory Business Services (LBS), and NFSDX at conferences, including providing outreach and recruiting laboratories. This outreach should emphasize how ORAPP, LBS, and NFSDX allows partner organizations to send information to and receive information from the FDA, and other state agencies electronically, and demonstrate how that would be of benefit to such non-federal entities.
8. Integrate FDA-provided NFSDX training modules into existing training programs offered by the association, as appropriate.
9. Collaborate with the Partnership for Food Protection IT Working Group (PFP IT WG) to assist in data system transition activities.
10. Research, develop, and distribute best practices documents, protocols, and standard operating procedures for GenomeTrakr, in collaboration with FDA.
11. Evaluate activities across GenomeTrakr and PulseNet networks and provide a written report identifying the commonalities, differences, and areas of opportunity for collaboration.
12. Provide travel assistance to laboratorians of non-FDA funded organizations for:
 - o GenomeTrakr-contributing laboratorians to trainings, meetings and conference
 - o LFFM annual meeting FDA's Office of Training Education and Development (OTED) trainings
 - o InFORM meeting
 - o Other meetings, training courses, and educational opportunities, as determined by FDA, that are intended for federal, state and local public health and laboratory scientists.
13. Collaborate with Partnership for Food Protection Laboratory Working Group (PFP Lab WG) to support national laboratory initiatives, such as identifying best practices for data sharing and acceptability.

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

Section II. Award Information

Funding Instrument

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

Application Types Allowed

New

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

Clinical Trial?

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

[Need help determining whether you are doing a clinical trial? \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82370\)](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 FDA appropriations and the submission of a sufficient number of meritorious applications. Award(s) will provide one (1) year of support and include future recommended support for two (2) additional year(s) contingent upon annual appropriations, availability of funding and satisfactory awardee performance.

FDA/ Office of Regulatory Affairs intends to fund up to \$500,000, for fiscal year 2020 in support of this grant program.

It is anticipated that up to one (1) award will be made, not to exceed \$500,000 in total costs (direct plus indirect), per award.

Award Budget

Application budgets need to reflect the actual needs of the proposed project and should not exceed the following in total costs (direct and indirect):

YR 01: \$500,000

YR 02: \$500,000

YR 03: \$500,000

Award Project Period

The scope of the proposed project should determine the project period. The maximum project period is three (3) years.

HHS grants policies as described in the [HHS Grants Policy Statement \(https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf\)](https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf) will apply to the applications submitted and awards made from this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

This opportunity is only available to non-profit, food safety training entities that are national associations/organizations that represent State and local laboratories that conduct food and/or animal feed testing on behalf of State and local regulatory programs, and collaborates with one (1) or more institutions of higher education.

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.

Foreign components, as defined in the [HHS Grants Policy Statement \(https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf\)](https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf), **are not** 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. 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 \(DUNS\) \(http://fedgov.dnb.com/webform\)](http://fedgov.dnb.com/webform) - 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 \(SAM\) \(https://www.sam.gov/portal/public/SAM/\)](https://www.sam.gov/portal/public/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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11176\)](https://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.

- · [eRA Commons \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11123\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123) - 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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=82300\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82300) – 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 FDA 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

The funds provided by this cooperative agreement are available to applicants only to the extent that that the applicant funds its food safety program independently of any grant issued pursuant to this FOA in each year of the grant at a level equal to the level of such funding in the previous year, increased by the Consumer Price Index. Such non-Federal matching funds may be provided directly or through donations from public or private entities and may be in cash or in kind, fairly evaluated, including plant, equipment, or services.

The funds provided by this cooperative agreement shall be used to supplement, and not supplant, non-Federal funds and any other Federal funds available to carry out the activities carried out pursuant to this cooperative agreement.

3. Additional Information on Eligibility

Number of Applications

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

The FDA will not accept duplicate or highly overlapping applications under review at the same time. This means that the FDA 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.

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 Research (R) Instructions in the [SF424 \(R&R\) Application Guide \(//grants.nih.gov/grants/guide/url_redirect.htm?id=12000\)](https://grants.nih.gov/grants/guide/url_redirect.htm?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.

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 FDA 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:

- o · Descriptive title of proposed activity
- o · Name(s), email address(es), and telephone number(s) of the PD(s)/PI(s)
- o · Names of other key personnel
- o · Participating institution(s)
- o · Number and title of this funding opportunity

The letter of intent should be sent to:

Kiara Fowler

Telephone: 240-402-3099

Email: Kiara.Fowler@fda.hhs.gov (<mailto:xxxx@fda.hhs.gov>)

A technical session will be held for prospective applicants in February 2020. The conference call information will be provided to prospective applicants that submit a letter of intent. The technical session will provide an overview of the submission requirements and allow prospective applicants an opportunity to ask questions regarding the application process. Participation in the technical session is optional, but strongly encouraged.

Page Limitations

All page limitations described in the SF424 Application Guide and the [Table of Page Limits \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11133\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11133) must be followed, with the following exceptions or additional requirements:

For this specific FOA, the Research Strategy section is limited to 30 pages.

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 Budget

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

- Applications requesting multiple years of support must complete and submit a separate detailed budget breakdown and narrative justification for each year of financial support requested.
- If an applicant is requesting indirect costs as part of their budget, a copy of the most recent Federal indirect cost rate or F&A agreement must be provided as part of the application submission. This agreement should be attached to the RESEARCH & RELATED Other Project Information Component as line #12 'Other Attachments'.
- If the applicant organization has never established an indirect cost rate and/or does not have a negotiated Federal indirect cost rate agreement, a de minimis indirect cost rate of 10 percent (10%) of modified total direct costs (MTDC) will be allowed. MTDC means all direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel, and subaward and subcontracts up to the first \$25,000 of each subaward or subcontract. MTDC excludes equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs and the portion of each subaward and subcontract in excess of \$25,000.

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.

Research Strategy:

The research strategy submitted should include specific project milestones and metrics for each objective. In developing the research strategy, the applicant shall specifically address the ability to achieve the following objectives in the cooperative agreement:

1. Demonstrate ability to research, develop, and deliver trainings, workshops, meetings, and other educational materials and resources, including any online courses and in-person workshops or seminars. This shall include:
 - a. Evidence of technical knowledge of the Whole Genome Sequencing (WGS) specifically under the GenomeTrakr network; ISO/IEC 17025 accreditation; as well as sample collection and analysis of human and animal foods.
 - b. Experience in planning and hosting meetings and conferences with 100-200 attendees, including agenda planning, on-site logistics management, and the distribution and assessment of follow-up evaluations.
 - c. Process for researching, developing, and distributing best practices documents, protocols, and standard operating procedures, meeting materials and other project communications, in collaboration with FDA.
2. Show evidence of technical knowledge of ISO/IEC 17025 accreditation requirements, including the ability to assess and assist accreditation for achieving, maintaining, and expanding ISO/IEC 17025 accreditation.

Include efforts to research, design, develop, document, deliver, manage and implement support programs for ISO/IEC 17025 accreditation in non-FDA funded laboratories. Monitoring of the selected laboratories to ensure that they are on track and determine solutions to common barriers shall also be included.

3. Demonstrate ability to research, develop, and maintain a crosswalk between state and FDA regulations and standards regarding human and animal food-related illness and outbreak response, including identification of areas of improvement.
4. Demonstrate ability to assist states with National Food Safety Data Exchange (NFSDX) implementation, specifically with sample data exchange. This shall include:
 - a. Promoting Office of Regulatory Affairs Partners Portal (ORAPP), Laboratory Business Services (LBS), and NFSDX at conferences, including providing outreach and recruit laboratories.
 - b. Integrating FDA-provided NFSDX training modules into existing training programs offered by the association, as appropriate.
5. Demonstrate ability to collaborate with the Partnership for Food Protection IT Working Group (PFP IT WG) to assist in data system transition activities and Partnership for Food Protection Laboratory Working Group to national laboratory initiatives, such as data sharing and acceptability.
6. Demonstrate ability to evaluate activities across GenomeTrakr and PulseNet networks and provide a written report identifying the commonalities, differences, and areas of opportunity for collaboration.
7. Provide a properly detailed budget for the anticipated travel assistance the association will award to laboratorians for trainings, meetings and conferences.
8. Outline the plan, resources available, and qualifications of the personnel that will support this project.
9. Demonstrate the ability to satisfy the reporting requirements outlined in section VI.3 of this Announcement.

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:

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

PHS Human Subjects and Clinical Trials Information

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

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

Study Record: PHS Human Subjects and Clinical Trials Information

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

Delayed Onset Study

Note: [Delayed onset \(https://grants.nih.gov/grants/glossary.htm#DelayedOnsetHumanSubjectStudy\)](https://grants.nih.gov/grants/glossary.htm#DelayedOnsetHumanSubjectStudy) 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.

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.

Organizations must submit applications to [Grants.gov \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11128\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11128) (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the [eRA Commons \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11123\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123), FDA's electronic system for grants administration. eRA Commons 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. **Late applications will not be accepted for this FOA.**

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

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

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to [intergovernmental review](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11142). ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11142](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11142))

6. Funding Restrictions

All FDA awards are subject to the terms and conditions, cost principles, and other considerations described in the [HHS Grants Policy Statement](https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf) (<https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf>).

Pre-award costs are allowable only as described in the [HHS Grants Policy Statement](https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf) (<https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf>).

Facilities and work reimbursed under the FDA human or animal food safety inspection contract or other funding mechanisms must remain distinct and separate from the cooperative agreement.

Vehicle purchases are not permitted.

Cooperative agreement funds may not be utilized for new building construction; however, remodeling of existing facilities is allowed, provided that remodeling costs do not exceed 10% of the grant award amount.

Clothing and uniforms with the exception of personal protective equipment (PPE). PPE is defined as protective clothing or other outerwear required to mitigate a defined workplace hazard.

Additional funding restrictions may be part of the Notice of Award.

7. Other Submission Requirements and Information

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

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

For assistance with your electronic application or for more information on the electronic submission process, visit [How to Apply – Application Guide](https://grants.nih.gov/grants/how-to-apply-application-guide.html) (<https://grants.nih.gov/grants/how-to-apply-application-guide.html>). 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 FDA. 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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11146\)](https://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 assigned Grants Management Specialist and responsiveness by [components of participating organizations](#), FDA. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

Post Submission Materials

Post-submission materials are those submitted after submission of the grant application but prior to objective review. They are not intended to correct oversights or errors discovered after submission of the application. FDA accepts limited information between the time of initial submission of the application and the time of objective review. Applicants must contact the assigned Grants Management Specialist to receive approval, prior to submitting any post submission materials. Acceptance and/or rejection of any post submission materials is at the sole discretion of the FDA. Any inquiries regarding post submission materials should be directed to the assigned Grants Management Specialist.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process.

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit.

Significance (25 Points)

Does the project help support and enhance human and animal food testing laboratory activities, specifically through the activities of an association that will offer trainings, workshops, meetings, and other educational resources; conduct research on national testing capability and capacity; prepare best practices and other guidance manuals; support ISO/IEC 17025 laboratory accreditation for non-accredited laboratories; and other activities to support human and animal food testing laboratories?

Investigator(s) (25 Points)

Are the PD(s)/PI(s), collaborators, and other key personnel well suited to the project? Do they have previous experience implementing effective training programs, implementing effective national meetings, communicating with state and local laboratories, experience with ISO/IEC 17025, and experience with WGS and the GenomeTrakr network?

Approach (25 Points)

Is the overall strategy appropriate to support and enhance human and animal food testing laboratory activities? Does the rationale and design meet the goals of the cooperative agreement?

Environment (25 Points)

Will the environment in which the work will be done contribute to the probability of success? Has the applicant demonstrated the ability to effectively work with Federal and State partners to implement the goals and objectives of the cooperative agreement?

Additional Review Considerations

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

Protections for Human Subjects

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

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

Inclusion of Women, Minorities, and Individuals Across the Lifespan

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

Vertebrate Animals

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

Biohazards

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

Resubmissions

Not Applicable

Renewals

Not Applicable

Revisions

Not Applicable

Select Agent Research

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: (1) [Data Sharing Plan \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11151\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11151); (2) [Sharing Model Organisms \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11152\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11152); and (3) [Genomic Data Sharing Plan \(GDS\) \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11153\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11153).

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 Objective Review Committee, using the stated [review criteria](#).

As part of the objective review, all applications:

- Will receive a written critique.

Appeals of objective review will not be accepted for applications submitted in response to this FOA.

Applications will compete for available funds with all other recommended applications submitted in response to this FOA. The following will be considered in making funding decisions:

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

3. Anticipated Announcement and Award Dates

Successful applicants will be notified of additional information that may be required or other actions leading to an award. The decision not to award a grant, or to award a grant at a particular funding level, is discretionary and is not subject to appeal to any FDA or HHS official or board.

Section VI. Award Administration Information

1. Award Notices

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 in the [HHS Grants Policy Statement](#) (<https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf>), this FOA, and Notice of Award.

2. Administrative and National Policy Requirements

All FDA grant and cooperative agreement awards include the [HHS Grants Policy Statement](#) (<https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf>) as part of the NoA.

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.

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> (<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.html> (<https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html>); and <https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/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 <https://www.hhs.gov/civil-rights/for-individuals/disability/index.html> (<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> (<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> (<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), FDA 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 FDA grants and cooperative agreements.

FDA considers the sharing of research resources developed through FDA-sponsored research an important means to enhance the value and further the advancement of research. When research resources have been developed with FDA funds and the associated research findings published, those findings must be made readily available to the scientific community.

Upon acceptance for publication, scientific researchers must submit the author's final manuscript of the peer-reviewed scientific publication resulting from research supported in whole or in part with FDA funds to the NIH National Library of Medicine's (NLM) PubMed Central (PMC). FDA defines the author's final manuscript as the final version accepted for journal publication, which includes all modifications from the publishing peer review process. The PMC archive is the designated repository for these manuscripts for use by the public, health care providers, educators, scientists, and FDA. Please see the FDA Public Access Policy.

Certificates of Confidentiality – 42 U.S.C. 241(d)

Awardees are responsible for complying with all requirements to protect the confidentiality of identifiable, sensitive information that is collected or used in biomedical, behavioral, clinical, or other research (including research on mental health and research on the use and effect of alcohol and other psychoactive drugs) funded wholly or in part by the Federal Government. See 42 U.S.C. 241(d). All research funded by FDA, in whole or in part, that is within the scope of these requirements is deemed to be issued a "Certificate of Confidentiality" through these Terms and Conditions. Certificates issued in this manner will not be issued as a separate document.

Awardees are expected to ensure that any investigator or institution not funded by FDA who receives a copy of identifiable, sensitive information protected by these requirements, understand they are also subject to the requirements of 42 U.S.C. 241(d). Awardees are also responsible for ensuring that any subrecipient that receives funds to carry out part of the FDA award involving a copy of identifiable, sensitive information protected by these requirements understand they are also subject to subsection 42 U.S.C. 241(d).

Additional terms and conditions regarding FDA regulatory and ORA programmatic requirements may be part of the Notice of Award.

Cooperative Agreement Terms and Conditions of Award

The administrative and funding instrument used for this program is the cooperative agreement, an assistance instrument (rather than an acquisition instrument), in which substantial FDA programmatic involvement with the awardees is anticipated during the performance of the activities. Under the

cooperative agreement, FDA's objective is to support and stimulate the recipient's activities by involvement in and otherwise working jointly with the award recipient in a partnership role; it is not to assume direction, prime responsibility, or a dominant role of activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardee for the project although specific tasks and activities may be shared between the awardee and the FDA as defined below.

Project Director/Principal Investigator Rights and Responsibilities:

The Project Director/Principal Investigator (PD/PI) retains the primary responsibility and dominant role for planning, directing, and executing the proposed project, with FDA/ORA staff being substantially involved as a partner with the PD/PI, as described below.

The PD/PI will maintain general oversight for ensuring compliance with the financial and administrative aspects of the award, as well as ensuring that all staff have the necessary training and clearance to work on this project. This individual will work closely with designated officials within the recipient organization and with partner organizations to create and maintain necessary documentation, including both technical and administrative reports; prepare justifications; appropriately acknowledge Federal support in publications, announcements, news programs, and other media; and ensure compliance with other Federal, regulatory, and organizational requirements.

FDA Responsibilities:

The Grants Project Team may consist of a Grants Management Specialist, Program Official (PO), Project Manager (PM) and Technical Advisor. The Grants Project Team collaborates to review the progress of the grantee. The Grants Project Team may utilize the grantee's progress reports, site visits, audit reports and other supporting documentation to determine if the condition of the award was met and satisfactory progress is being made. Each team member works in consultation with each other, as needed, throughout the duration of the project. A description of each team member involved with the program are described below.

An FDA Grants Management Specialist (GMS) will be assigned and named in the Notice of Award. The GMS oversees the administrative, financial, business and other non-programmatic aspects of the program. These activities include, but are not limited to the following:

- Provides guidance on administrative, business, fiscal aspects of grants management to grantees and FDA program staff
- Monitors and manages applications and required reports on eRA Commons
- Monitors administrative and financial aspects of grantee activities
- Maintains the official grantee file

An FDA Program Official (PO) will be assigned and named in the Notice of Award. The PO is accountable for the programmatic oversight of the grant to include coordination, with the Project Manager, on the technical aspects of the grant. S/he ensures the budget of grantees are reasonable and costs are allowable and allocable. The PO reviews the progress reports to verify the budget proposed includes only allowable expenses that support the project goals and objectives. The PO also assists with post-award monitoring and establishing a corrective action plan, if necessary.

An FDA Project Manager (PM) will be assigned to the program. The FDA PM is the responsible official for the programmatic, scientific, and/or technical aspects of assigned applications and cooperative agreements. The FDA PM will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards as described below.

The PM will have substantial involvement in the design, implementation, and evaluation of program activities, and dissemination of program results and outcomes, above and beyond routine grant monitoring. Substantial involvement by FDA/ORA includes, but is not limited to, the following:

- Provide guidance, direction, and technical assistance in project planning, implementation, and evaluation;
- Provide subject matter expertise, programmatic assistance, and evaluation services to support program studies and activities;
- Actively monitor the supported program via telephone conversations, webinars, e-mails, written correspondence, or periodic site visits;
- Evaluate the supported program, including development of program-level performance measures, consistent data collection, and reporting procedures and protocols;
- Convene trainings, meetings, conference calls, and site visits with grantee to facilitate collaboration and information sharing;
- Participate in data analysis, interpretation of findings, and where appropriate, co-authorship of publications;
- Development of programs to meet the FDA mission;
- Provision of programmatic technical assistance;
- Post-award monitoring of project/program performance, including review of progress reports and making site visits; and other activities complementary to those of the FDA.

An FDA Technical Advisor(s) will be assigned to each enrolled program. The Advisor will work cooperatively with the PO to help monitor and report grantee status/progress including sharing of information and historical backgrounds. The FDA Technical Advisor will have programmatic involvement as described below including but not limited to the following:

- Provide guidance, direction, and technical assistance in project planning, implementation, and evaluation;
- Convene trainings, meetings, conference calls, and site visits with grantee to facilitate collaboration and information sharing;
- Provide subject matter expertise, programmatic assistance, and evaluation services to support program studies and activities;
- Provision of programmatic technical assistance;
- Post-award monitoring of project/program performance, including review of progress reports and making site visits; and other activities complementary to those of the FDA.

Unless another governance structure is mutually agreed upon, the PO will serve as the primary point of contact for the dissemination of FDA policy and milestones/objectives work planning.

Property rights (if the awardee develops something tangible):

The awardee will retain custody of, and have primary rights to, the data and software (including all source files) developed under these awards, subject to government rights of access consistent with current DHHS, PHS, and FDA policies. In all cases, FDA must be given a royalty-free, nonexclusive, and irrevocable license for the federal government to reproduce, publish, or otherwise use the material and to authorize others to do so for federal purposes. Curriculum and course content developed under this cooperative agreement grant such as objectives, learning outcomes, presentations,

manuals, scripts, exercises, handouts, reports, documents or other tangible materials produced by the awardee must be guaranteed free of copyrights from outside sources and be free domain for use by FDA. Any FDA curriculum or training course content provided by FDA will remain the property of FDA and any proposed changes are not to be made without concurrence from FDA.

Delineation of substantive involvement:

1. FDA will monitor and evaluate the overall performance of the awardee under this cooperative agreement grant
2. FDA will collaborate and work closely with awardee's continued development
3. FDA will take any action that may be necessary to ensure compliance with this cooperative agreement grant
4. FDA may choose not to have significant input or control on some projects/tasks as it may be deemed more suitable for the awardee to lead and control the design, methodology, analysis, development and/or delivery of work.

Monitoring Activities

Periodic program monitoring will be conducted by FDA on an ongoing basis which may include telephone conversations, emails, on-site visits, review of written progress reports, audit assessments, financial reports, etc.

The Project Manager and Technical Advisor conduct the monitoring of the grantee's performance, provide technical advice and assistance and, when necessary, investigate problems or deficiencies identified during review of reports.

The Grants Project Team (Grant Management Specialist, Program Official, Project Manager and Technical Advisor(s)) reviews the progress report to verify the satisfactory progress is being made toward the project objectives and goals in the project, proposed activities are allowable and within the guidelines of the FOA and budget proposed includes only allowable expenses that support project goals and objectives. When necessary, the Grants Project Team will investigate problems or deficiencies identified during review of reports and determine the corrective actions required. Performance deficiencies will be addressed by requiring a revised progress report, submission of a corrective action plan, increased reporting requirements, funding restrictions, and other methods, including up to suspension or termination of the award. The Annual Progress Report will be due as part of the Research Performance Progress Report (RPPR) and is due no later than 60 days prior to the start date of the next budget period.

Financial Reporting:

A. Cash Transaction Reports

The Federal Financial Report (FFR) has a dedicated section to report Federal cash receipts and disbursements. For recipients this information must be submitted quarterly directly to the Payment Management System (PMS) using the web-based tool. Quarterly reports are due 30 days following the end of each calendar quarter. The reporting period for this report continues to be based on the calendar quarter. Questions concerning the requirements for this quarterly financial report should be directed to the PMS.

B. Financial Expenditure Reports

A required Federal Financial Report (FFR) must be submitted annually. FDA now requires all annual financial expenditure reports to be submitted electronically using the Federal Financial Report (FFR) system located in the eRA Commons. This includes all initial FFRs being prepared for submission and any revised FSR/FFRs being submitted or re-submitted to FDA. Paper expenditure/FFR reports will not accepted.

Annual FFRs must be submitted for each budget period no later than 90 days after the end of the calendar quarter in which the budget period ended. The reporting period for an annual FFR will be that of the budget period for the grant; however, the actual submission date is based on the calendar quarter. Failure to submit timely reports may affect future funding.

C. Closeout Requirements (when applicable)

A Final Program Progress Activity Report, Final Federal Financial Report SF-425, Final Invention Statement HHS-568 (if applicable), Tangible Personal Property Report SF-428, and Statement of Disposition of Equipment (if applicable) must be submitted within 90 days after the expiration date of the project period.

D. Auditing

A non-Federal entity that expends \$750,000 or more during the non-Federal entity's fiscal year in Federal awards must have a single or program-specific audit conducted for that year in accordance with the provisions of 45 CFR 75, Subpart F-Audit Requirements. Audits must be completed and submitted electronically to the Federal Audit Clearinghouse (FAC) within 30 days after receipt of the auditor's report(s), or 9 months after the end of the audit period, i.e., the end of the organization's fiscal year, whichever is earlier. If you need information on your organization's obligations, please visit the following website: <http://harvester.census.gov/sac/>. Valuable information is included under the "Frequently Asked Questions" section of that website.

The grantee organization must comply with all special terms and conditions of the cooperative agreement. Future funding will be dependent on recommendations from the Project Manager and Program Official. The scope of the recommendation will confirm an acceptable level of performance and continued compliance with all FDA regulatory requirements and conditions of the award. Specific project milestones, reporting requirements, and other project deliverables may be included as a condition of your award. If FDA determines that the grantee is unable to make adequate progress, FDA may place them in special condition status and may require a corrective action plan.

If a recipient of multiple FDA awards (cooperative agreements, grants, contracts), the recipient must be able to account separately for fund expenditures, including employee salaries, wages, and benefits, under those funding mechanisms and this cooperative agreement.

A rebudgeting request covers reallocation of cooperative agreement funds and change of planned expenditures (compared to the existing budget on record for the grantee) either between budget categories (personnel, equipment, supplies, etc.) or within a single budget category. All rebudgeting requests that involve moving cooperative agreement funds between budget categories in excess of 10% of the total track award must be submitted and approved by FDA. A new NGA will only be issued when rebudgeting requests reach a cumulative total (during a single budget period) of 25% of the total award or more. Rebudgeting requests within a single budget category must be submitted and approved by FDA when they reach a cumulative (during a single budget period) total of \$10,000 or more.

Additional Terms and Conditions:

All meeting agendas, correspondences, trainings, and educational materials shall be pre-reviewed and approved by FDA prior to distribution and execution.

FDA reserves a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use for federal purposes any copyrighted works that are outcomes from these funding tracks, including curriculum, course content, objectives, learning outcomes, presentations, manuals, scripts, exercises, handouts, reports, documents or other tangible materials produced by the awardee. FDA may authorize others to reproduce, publish, or otherwise use such works for Federal purposes.

The grantee is required to utilize a minimum of ten (10) percent of the funds received under this award to support travel assistance for laboratorians of non-FDA funded organizations to meet the goals of this cooperative agreement.

The following are non-allowable costs under this project:

1. Facilities and work reimbursed under the FDA human or animal food safety inspection contract or other funding mechanisms must remain distinct and separate from the cooperative agreement.
2. Vehicle purchases are not permitted.
3. Cooperative agreement funds may not be utilized for new building construction; however, remodeling of existing facilities is allowed, provided that remodeling costs do not exceed 10% of the grant award amount.
4. Clothing and uniforms with the exception of personal protective equipment (PPE). PPE is defined as protective clothing or other outerwear required to mitigate a defined workplace hazard.
5. Other items listed in the HHS Grants Policy Statement or Notice of Award.

3. Reporting

When multiple years are involved, awardees will be required to submit the [Research Performance Progress Report \(RPPR\)](https://grants.nih.gov/grants/rppr/index.htm) ([//grants.nih.gov/grants/rppr/index.htm](https://grants.nih.gov/grants/rppr/index.htm)) annually and financial statements as required in the Notice of Award.

All progress reports shall contain certain elements as applicable to their approved cooperative agreement and award. These elements include, but are not limited to, the following:

1. Development status and projected timeline of completion of any trainings, workshops, meetings, and other educational materials and resources. This summary shall include activities related to:
 - a. Trainings, workshops, and other educational materials and resources for ISO/IEC 17025 accreditation, whole genome sequencing or GenomeTrakr. Examples include workshops and seminars on laboratory procedures, data transfer (to NCBI and FDA data systems), document control, quality management systems, continuous improvement, sample collection, and risk assessment.
 - b. Annual LFFM Face-to-Face and GenomeTrakr meetings.
 - c. Crosswalk of state and FDA human and animal food-related illness and outbreak response regulations and standards, and subsequent best practice training and resources.
 - d. Best practices documents, protocols, and standard operating procedures for GenomeTrakr, in collaboration with FDA.

2. Description of support being provided to laboratories to obtain, maintain, and enhance ISO/IEC 17025 accreditation requirements. This includes a summary of the monitoring activities and progress of the laboratories directly being supported through consultant services offered under this award.
3. Description of assistance provided to states with National Food Safety Data Exchange (NFSDX) implementation, specifically with sample data exchange. This description shall include activities related to:
 - a. Promoting Office of Regulatory Affairs Partners Portal (ORAPP), Laboratory Business Services (LBS), and NFSDX at conferences, including providing outreach and recruit laboratories. This outreach should emphasize how ORAPP, LBS, and NFSDX allows partner organizations to send information to and receive information from the FDA, and other state agencies electronically, and demonstrate how that would be of benefit to the non-federal entity.
 - b. Integrating FDA-provided NFSDX training modules into existing training programs offered by the association.
4. Description of collaborative work with the Partnership for Food Protection IT Working Group (PFP IT WG) and Partnership for Food Protection Laboratory Working Group (PFP Lab WG), including a summary of the relevant trainings being offered and other projects completed or supported.
5. Written report identifying the commonalities, differences, and areas of opportunity for collaboration across the GenomeTrakr and PulseNet networks. This should include the evaluation of standard operation procedures (SOPs) updated within each group and flagging potential conflicts.
6. Summary of travel scholarships awarded to laboratorians of non-FDA funded organizations for trainings, meetings and conferences. This summary must include the organization name, the number of scholarships awarded and the associated amounts of the scholarships.

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 terms and conditions of award and the [HHS Grants Policy Statement \(https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf\)](https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

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 FDA 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](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11170)) on all subawards over \$25,000.

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)

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)

Contact Center Telephone: 800-518-4726

Email: support@grants.gov (<mailto:support@grants.gov>)

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Section VIII. Other Information

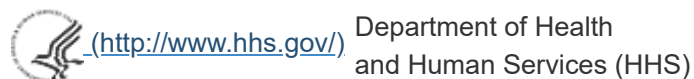
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Authority and Regulations

Awards are made under the authorization of section 1009 of the Federal Food, Drug, and Cosmetic Act (21 USC § 399).

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