Department of Health and Human Services
Part 1. Overview Information

Participating Organization(s)

U.S. Food and Drug Administration (FDA)

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)

Funding Opportunity Title

Implementation of the Animal Feed Regulatory Program Standards (U18 Clinical Trial Not Allowed)

Activity Code

U18 Research Demonstration – Cooperative Agreements

Announcement Type

New

Related Notices

None

Funding Opportunity Announcement (FOA) Number

RFA-FD-19-021

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 FOA is to advance efforts for a nationally integrated animal food safety system by assisting State animal food regulatory programs to achieve and maintain full implementation of the Animal Feed Regulatory Program Standards (AFRPS). The AFRPS Cooperative agreement will provide funding for State animal food regulatory programs that maintain a FDA animal food safety inspection contract to:

- Develop and implement the Standards (AFRPS)
- Enhance animal food safety, and
- Better direct their regulatory activities at reducing foodborne illness attributed to animal food safety hazards in facilities that manufacture, process, pack, or hold animal food materials/supplies.

In addition, this cooperative agreement may provide funding through regulatory animal food programs for accreditation of laboratories that support animal food programs and may pursue initial accreditation or seek to expand scope of accreditation under the international standard ISO/IEC 17025.

Key Dates

Posted Date

March 12, 2019

Open Date (Earliest Submission Date)

March 19, 2019

Letter of Intent Due Date(s)

April 1, 2019

Application Due Date(s)

May 20, 2019, 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

June, 2019

Advisory Council Review

Not Applicable

Earliest Start Date

September, 2019

Expiration Date

May 21, 2019

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, except where instructed to do otherwise (in this FOA or in a Notice from the *NIH Guide for Grants and Contracts*). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

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

1. Use the NIH ASSIST system to prepare, submit and track your application online.
   Apply Online Using ASSIST
2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA Commons to track your application. Check with your institutional officials regarding availability.
3. Use Grants.gov Workspace to prepare and submit your application and eRA Commons to track your application.

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Program Objectives

The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Office of Partnerships and Operational Policy (OPOP), Office of Partnerships (OP), is announcing the availability of up to $2,100,000 in FY 2019 to be awarded under Limited Competition to State animal food regulatory programs. The intended outcome of this FOA is to advance efforts for a nationally integrated animal food safety system through the implementation and advancement of the Animal Feed Regulatory Program Standards (AFRPS) by State animal food regulatory programs.

The AFRPS allows for the development of risk-based animal food safety programs by establishing a uniform basis for measuring and improving the performance of State animal food regulatory programs in the Unites States. By achieving and sustaining implementation of these program Standards, Federal and State food regulatory programs can better direct their regulatory activities toward reducing foodborne illness attributed to animal food safety hazards in animal food material/supply facilities. Consequently, the safety and security of the United States animal food supply will improve.

The AFRPS are comprised of eleven Standards which establish foundations for the critical elements that serve as an objective framework to evaluate and improve components of a State animal food program. These elements cover the State animal food program's regulatory foundation, training, inspection program, auditing, animal food-related illness or death and emergency response, enforcement program, outreach activities, planning and resources, laboratory services, sampling program, and assessment and improvement of Standard implementation.

Achieving and sustaining implementation of the program Standards will require comprehensive self-assessment on the part of a State program and will encourage continuous improvement and innovation. FDA recognizes that the time required for achieving full implementation of the AFRPS will vary between States. However, all State animal food regulatory programs will be expected to implement improvement plans to ensure continuous improvement and demonstrate that they are moving towards full implementation. State animal food regulatory programs receiving funds under this cooperative agreement will be expected to achieve full implementation by the conclusion of the cooperative agreement.

Grantees will achieve and maintain implementation with the AFRPS (most recent version).

For the purpose of this funding opportunity, "full implementation" is defined as the State animal food regulatory program has policies and procedures in place that meet all of the AFRPS program elements and

the program uses the policies and procedures as written for all program elements and documentation requirements within each Standard. If implementation is not achieved by the conclusion of the cooperative agreement, for those individual program elements that are not met, the State program has a detailed improvement plan on how the remaining AFRPS elements and documentation requirements not yet met will be fully implemented and demonstrated. The improvement plan will include: A detailed timeline including what needs to be accomplished to implement the element and/or documentation requirement, who will be doing the work, and when the work will be completed.

The outcomes of the work provided under this cooperative agreement are as follows:

1. State animal food regulatory programs will achieve and sustain implementation of the AFRPS, which is recognized as a critical element to creating a national, fully integrated food safety system.

2. State animal food regulatory programs will contribute to the continuous improvement of the AFRPS through attendance at an annual face-to-face meeting, active participation in committees, and other initiatives supporting the AFRPS.

3. Develop strategies for achieving and sustaining implementation of the AFRPS that can be duplicated on a national basis.

4. Provide FDA the foundation for pursuing regulatory action based upon the findings of State animal food regulatory programs.

5. For applicants that choose to support primary servicing laboratories to achieve or expand ISO/IEC 17025 accreditation, provide funding for State animal food regulatory programs to support primary servicing State regulatory laboratories in the ability to obtain or enhance, and maintain ISO/IEC 17025 accreditation including:

a. conduct chemical and microbiological analysis of animal food samples

b. produce valid and defensible testing data for possible regulatory action

c. maintain and enhance animal food testing laboratory's capabilities

d. improve lab capacity for animal food testing to further enhance public health

e. increase sharing of laboratory results

f. advance a nationally integrated animal food safety system

Only the following State animal food programs will be eligible to apply:

State animal food regulatory programs with current FDA animal food safety inspection contracts (providing funding to State agency animal food production regulatory programs), or those that apply for a FDA animal food safety inspection contract, at the earliest possible date, are eligible to apply for funding under this cooperative agreement. An animal food safety inspection contract must be executed prior to the cooperative agreement being awarded. A condition of the award will be maintaining a current FDA animal food safety inspection contract in satisfactory condition, as agreed upon by the State and FDA during contract negotiations, throughout the cooperative agreement project period.

The FDA will provide one year of funding with the possibility of up to four years of additional non-competitive support, contingent on performance and continued availability of federal funds.

Background

In the United States, Federal and State government agencies ensure the safety of animal food. The Food and Drug Administration (FDA) is responsible for ensuring that all human and animal foods moving in

interstate commerce, except those under the United States Department of Agriculture jurisdiction, are safe, wholesome, and labeled properly. State agencies are responsible for conducting inspections and regulatory activities that help ensure animal food produced, processed, and distributed within their jurisdictions are safe and in compliance with State laws and regulations. State agencies primarily perform inspections under their own regulatory authority. Some State agencies conduct inspections of animal food facilities under contract with the FDA. Because jurisdictions may overlap, FDA and States collaborate and share resources to protect animal food. To better facilitate a partnership among regulatory authorities, regulatory programs should be equivalent.

Maximizing resources between FDA and the States supports the ongoing work of the Partnership for Food Protection (PFP) to develop an Integrated Food Safety System (IFSS). The FDA and the Association of American Feed Control Officials (AAFCO) are members of the PFP. One of the Foundational principles of an IFSS is the implementation and uniform application of model standards so that Federal, State, territorial, tribal, and local regulatory agencies conduct inspections under the same set of standards. The Voluntary National Retail Food Regulatory Program Standards (VNRFRPS) and the Manufactured Food Regulatory Program Standards (MFRPS) are examples of such model standards. However, the VNRFRPS and MFRPS were developed for human food only and do not apply to animal food. As further development on the IFSS progressed, there was a recognized need to develop standards for animal food regulatory programs. One of the key recommendations that originated from the 2010 50-State workshop ("A United Approach to Public Health") was the development of standards for animal food regulatory programs. Standards provide a consistent, underlying foundation that is critical for uniformity across State and Federal agencies to ensure the credibility of all programs under an IFSS.

The FDA Food Safety Modernization Act (FSMA) provides further support for developing AFRPS. FSMA was signed into law in January 2011 and calls for enhanced partnerships and integration with Federal, State, local, tribal, and territorial partners. The enhanced partnerships and integration called for by FSMA will allow FDA to rely on inspections and data collected by other agencies to support regulatory activities and further the idea of an IFSS.

In 2011, FDA and AAFCO entered into a partnership to develop the AFRPS. These Standards are designed to promote uniformity and consistency among animal food regulatory programs. This is consistent with the principles of FSMA and the fundamental goal of AAFCO and FDA to provide a mechanism for developing and implementing uniform and equitable regulations, and standards to enhance the protection of the nation's animal food supply.

Objectives

Animal Feed Regulatory Program Standards (AFRPS)

All applicants must specifically address the ability to achieve the following objectives in the cooperative agreement:

1. Demonstrate the ability to develop and implement a comprehensive improvement plan that will result in full implementation of the AFRPS and maintenance of the AFRPS after the cooperative agreement.

2. Demonstrate the ability to fully participate in initiatives supporting the AFRPS, such as a required annual face-to-face meeting and any required training (as determined by FDA/OP), committees, OP/AFRPS conference calls, sharing of best practices, annual visits, program assessment verification audits.

3. Demonstrate the availability of adequately trained staff and the criteria and ability to hire and/or train personnel to meet the goals and deliverables of the cooperative agreement

4. Provide a properly detailed budget (one for each of the five years) that is intended to achieve

implementation of the AFRPS. For applicants that choose to support ISO/IEC 17025 Accreditation or expansion for a primary servicing laboratory, a separate budget is required. The applicant must consult with the primary servicing laboratory they choose to support for ISO/IEC 17025 Accreditation or expansion, when developing a separate budget to include for this purpose.

5. Demonstrate the ability to satisfy the reporting requirements outlined in section VI.3 of this announcement.

6. Outline a detailed methodology for program assessment, improvement, and collaboration to accomplish the work, as described in this announcement, and ensure program sustainability.

7. Provide justification for hiring new staff, including qualifications, training needs, and new equipment needs.

8. Demonstrate capacities and capabilities for animal food sample collection and analysis for chemical and microbiological hazards for emergency response and surveillance and compliance efforts - an annual estimate of capacity and capability should be provided for sample collection for chemical and microbiological testing, based on recent sample data from the program and laboratory included with the estimate.

Animal Feed Regulatory Program Standards (AFRPS) Goals:

The project goals provided below are based on new programs enrolling in the AFRPS and are applicable to all applicants. The FDA recognizes that achieving to full implementation of the AFRPS will vary by program based on multiple factors, such as previous enrollment in the AFRPS and current level of implementation. Applicants should adjust their project goals to reflect their previous accomplishments and current implementation level with the AFRPS.

Technical assistance may available upon request for State animal food regulatory programs and/or laboratories funded by the program through this CAP to achieve or expand ISO/IEC 17025 Accreditation.

Project Goals:

Year 1:

1. If not under a current animal food safety inspection contract, the State animal food program must apply for an animal food safety inspection contract with the FDA, at the earliest possible date. An animal food safety inspection contract must be executed prior to the cooperative agreement being awarded. A current animal food safety inspection contract must be maintained in satisfactory condition throughout the cooperative agreement, as agreed upon by the State and FDA during contract negotiations, throughout the cooperative agreement project period.

2. Participation in a visit consisting of key State animal food regulatory program and FDA personnel to discuss the implementation of program elements of the AFRPS. Participation includes providing meeting space, accessibility of key State animal food regulatory program management and staff, and access to records, databases, and other materials supporting AFRPS implementation.

3. Attendance and participation of key State animal food program managers and staff in an annual face-to-face meeting, committee meetings, and other initiatives supporting national and program specific implementation of the AFRPS.

4. Conduct a comprehensive baseline self-assessment/baseline evaluation, including completion of all applicable appendices, worksheets, and other documents (or equivalent documents), required in each Standard.

5. Following the baseline evaluation, develop improvement plan(s) that will result in implementation of the AFRPS by the completion of Year 5 of the cooperative agreement. Review and update improvement plan(s) on an annual basis. Documentation related to the evaluation and improvement plan(s) must be maintained.

Improvement plan(s) must include the following, at a minimum:

a. The individual element or documentation requirement for the Standard that was not fully met.

b. Improvements needed to fully implement the program element or documentation requirement(s) of the Standard.

c. Lists of individual tasks that will be used to address the needed improvement(s).

d. A projected completion date for each task.

e. An assigned AFRPS Project Coordinator with the overall responsibility for implementing the improvement plan(s).

Year 2:

1. Participation in a verification assessment conducted by FDA/ORA/OHAFO Audit Staff. Participation includes providing meeting space, accessibility of key State animal food program management and staff, and access to records, databases, and other materials supporting AFRPS implementation.

2. Participation in a visit consisting of key State animal food regulatory program and FDA personnel to discuss the implementation of program elements of the AFRPS. Participation includes providing meeting space, accessibility of key State animal food regulatory program management and staff, and access to records, databases, and other materials supporting AFRPS implementation.

3. Attendance and participation of key State animal food regulatory program managers and staff in a required annual face-to-face meeting and any required training, committee meetings, and other initiatives supporting national and program specific implementation of the AFRPS.

4. Implementation of the improvement plan(s). The improvement plan(s) should be updated to accurately reflect when specific objectives and tasks have been met and when new objectives and tasks are identified to achieve full implementation of the AFRPS. Progress achieved should indicate that implementation of the AFRPS can be expected by the completion of Year 5.

5. Review and updated improvement plan(s) on an annual basis. Documentation related to the evaluation and improvement plan(s) must be maintained. The improvement plan(s) must include the following, at a minimum:

a. The individual element or documentation requirement for the Standard that was not fully met.

b. Improvements needed to fully meet the program element or documentation requirement(s) of the Standard.

c. Lists of individual tasks that will be used to address the needed improvement(s).

d. A projected completion date for each task.

e. An assigned AFRPS Project Coordinator with the overall responsibility for implementing the improvement plan(s).

Year 3:

1. Participation in a verification assessment conducted by FDA/ORA/OHAFO Audit Staff (may be scheduled for year 4, based on state and audit staff availability). Participation includes providing meeting space, accessibility of key State animal food regulatory program management and staff, and access to records, databases, and other materials supporting AFRPS implementation.

2. Participation in a visit consisting of key State animal food regulatory program and FDA personnel to

discuss the implementation of program elements of the AFRPS. Participation includes providing meeting space, accessibility of key State animal food regulatory program management and staff, and access to records, databases, and other materials supporting AFRPS implementation.

3. Attendance and participation of key State animal food regulatory program managers and staff in a required annual face-to-face meeting and any required training, committee meetings, and other initiatives supporting national and program specific implementation of the AFRPS.

4. Implementation of the improvement plan. The improvement plan should be updated to accurately reflect when specific objectives and tasks have been met and when new objectives and tasks are identified to achieve full implementation of the AFRPS. Progress achieved should indicate that implementation of the AFRPS can be expected by completion of Year 5.

5. Review and update improvement plan(s) on an annual basis. Documentation related to the evaluation and improvement plan(s) must be maintained. The improvement plan must include the following, at a minimum:

a. The individual element or documentation requirement for the Standard that was not fully met.

b. Improvements needed to fully meet the program element or documentation requirement(s) of the Standard.

c. Lists of individual tasks that will be used to address the needed improvement(s).

d. A projected completion date for each task.

e. An assigned AFRPS Project Coordinator with the overall responsibility for implementing the improvement plan(s).

Year 4:

1. Participation in a visit consisting of key State animal food regulatory program and FDA personnel to discuss the implementation of program elements of the AFRPS. Participation includes providing meeting space, accessibility of key State animal food regulatory program management and staff, and access to records, databases, and other materials supporting AFRPS implementation.

2. Attendance and participation of key State animal food regulatory program managers and staff in a required annual face-to-face meeting and any required training, committee meetings, and other initiatives supporting national and program specific implementation of the AFRPS.

3. Implementation of the improvement plan. The improvement plan should be updated to accurately reflect when specific objectives and tasks have been met, and when new objectives and tasks are identified to achieve full implementation of the AFRPS. Progress achieved should indicate that full implementation of the AFRPS can be expected by completion of Year 5.

4. Review and update improvement plan(s) on an annual basis. Documentation related to the evaluation and improvement plan(s) must be maintained. The improvement plan must include the following, at a minimum:

a. The individual element or documentation requirement for the Standard that was not fully met.

b. Improvements needed to fully meet the program element or documentation requirement(s) of the Standard.

c. Lists of individual tasks that will be used to address the needed improvement(s).

d. A projected completion date for each task.

e. An assigned AFRPS Project Coordinator with the overall responsibility for implementing the improvement

plan(s).

Year 5:

1. Participation in a comprehensive assessment by the FDA/ORA/OHAFO Audit Staff of the State animal food program to verify implementation status of the AFRPS. Participation includes providing meeting space, accessibility of State key animal food program staff, and access to records, databases, and other materials supporting the State program's implementation of the AFRPS. Nonconformities identified in the audit should be addressed in the subsequent self-assessment and improvement plan.

2. Participation in a visit consisting of key State animal food regulatory program and FDA personnel to discuss the implementation of program elements of the AFRPS. Participation includes providing meeting space, accessibility of key State animal food regulatory program management and staff, and access to records, databases, and other materials supporting AFRPS implementation.

3. Attendance and participation of key State animal food regulatory program managers and staff in a required annual face-to-face meeting and any required training, committee meetings, and other initiatives supporting national and program specific implementation of the AFRPS.

4. Development of a plan identifying personnel, funding, and resources necessary to sustain implementation of the AFRPS.

Exit Strategy for Sustainability (Maintenance):

State animal food programs are expected to achieve full implementation of the AFRPS by the completion of year 5 of the cooperative agreement and must develop and submit an ESS with the Year 5 mid-year report, for FDA review and approval. The ESS will outline the State program's plans to sustain implementation of the AFRPS and ensure progress continues within their agency to achieve full implementation of the AFRPS.

The ESS must detail:

Strategy to sustain AFRPS implementation, including identifying personnel/FTEs, current funding sources for these personnel, and plans to sustain those personnel using grantee resources to the best of the grantee's ability.

Animal food program data (all data should be pulled from a recent 12-month period): Number of animal food (AF) inspectors (FTE), Number of animal food facilities in inventory, Number of routine animal food inspections conducted, number of animal food-related emergency response events investigated, number of animal food compliance actions taken (embargo, disposal, emergency closures, re-inspections and fines issued).

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

Clinical Trial?

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

Need help determining whether you are doing a clinical trial?

Funds Available and Anticipated Number of Awards

The number of awards is contingent upon 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 four (4) additional year(s) contingent upon annual appropriations, availability of funding and satisfactory awardee performance.

FDA/ORA intends to fund up to $2,100,000.00, for fiscal year 2019 in support of this grant program.

It is anticipated that up to seven (7) awards will be made, not to exceed $300,000.00 in total costs (direct plus indirect), per award per year.

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: $300,000

YR 02: $300,000

YR 03: $300,000

YR 04: $300,000

YR 05: $300,000

Award Project Period

The scope of the proposed project should determine the project period. The maximum project period is five (5) years.

HHS grants policies as described in the *HHS Grants Policy Statement* will apply to the applications submitted and awards made from this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Governments

- State Governments

This opportunity is only available to the following State animal food safety programs:

State animal food regulatory programs with current FDA animal food safety inspection contracts (providing funding to State agency animal food protection regulatory programs), or those that apply for an animal food safety inspection contract with FDA at the earliest possible date, are eligible to apply for funding under this cooperative agreement. An animal food safety inspection contract must be executed prior to the cooperative agreement being awarded. The animal food safety inspection contract must be maintained in satisfactory condition, as agreed upon by the State and FDA during contract negotiations, throughout the cooperative agreement project period. Competition is limited to these State animal food regulatory programs because the foundational work conducted under the current FDA animal food safety inspection contracts is necessary for the completion of significant improvements in a nationally integrated animal food safety system.

Only primary servicing laboratories are eligible to receive funds through the awardee, in order to help the State animal food regulatory program to implement the AFRPS. Primary servicing laboratories are defined as State funded regulatory laboratories, funded by the same State as the State animal food regulatory program, which perform 51% or more of the analyses on all samples collected by the State animal food regulatory program.

Current award recipients under cooperative agreements awarded under RFA FD-15-021 or RFA-FD-16-022 are ineligible to apply for this cooperative agreement.

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*, **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) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- System for Award Management (SAM)– Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
    - NATO Commercial and Government Entity (NCAGE) Code – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- eRA Commons - Applicants must have an active DUNS number to register in eRA Commons. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration, but all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov – Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

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

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

Eligible Individuals (Program Director/Principal Investigator)

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

This FOA does not require cost sharing as defined in the HHS Grants Policy Statement.

3. Additional Information on Eligibility

Number of Applications

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

The 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, 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:

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

The letter of intent should be sent to:

Gordana Zuber
Telephone: 301-348-1747
Email: gordana.zuber@fda.hhs.gov

A technical session will be held for prospective applicants in April 2019. 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 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.

- Applicants may also apply for personnel, training, and surveillance sample analysis if they have the necessary equipment and it will be available for these projects.
- Where personnel costs are requested, documentation must be provided to associate these costs with the specific goals and deliverables.
- Funds should be requested in the budget for key project personnel to travel to meetings, on-site visits, assessments and audits with FDA program staff to discuss the State self-assessment and implementation of the AFRPS. All anticipated meetings for attendance should be listed and referenced by name in the application.
- A portion of budgeted travel funds should also be set aside for key personnel to attend required annual face-to-face meeting and any required training (as determined by FDA/OP) and committee meetings supporting the AFRPS.
- All anticipated meetings and trainings, to include the required annual meeting and required training, for attendance should be listed and referenced by name in the application.

Funding Plan: Grantees whose State human or animal food regulatory program receives funding from a FDA Rapid Response Team (RRT) cooperative agreement are required to participate in the RRT and should ensure that their efforts to meet the program elements of the AFRPS Standard 5 are aligned/integrated with the existing RRT and their participation therein. Funds from the AFRPS Cooperative Agreement are to be used for the program elements indicated under each Standard. RRT-specific activities support the program elements under Standard 5, but it is not a requirement of Standard 5

R&R Subaward Budget

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

PHS 398 Cover Page Supplement

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

PHS 398 Research Plan

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

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

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

Study Record: PHS Human Subjects and Clinical Trials Information

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

Delayed Onset Study

Note: Delayed onset does NOT apply to a study that can be described but will not start immediately (i.e., delayed start).

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

PHS Assignment Request Form

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

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 (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, 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.

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*.

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

Selected list of allowable costs that have limitations specific to this announcement (including but not limited to):

1) Audiovisual materials such as videotapes, DVDs, public service announcements, etc. when identified as a necessary expense that directly impacts the goals and deliverables of this award.

2) Travel and per diem to trainings, exercises and meetings with AFRPS members (other State agencies, local agencies, FDA Divisions and Districts), FDA Headquarters, and annual AFRPS meetings.

3) Subcontracting to third parties (other than local/county/tribal agencies conducting work on behalf of the State animal food regulatory agency) is allowed but limited to 25% of each year's award.

Non-allowable costs:

1) Pre-award costs are not allowable for this announcement.

2) Facilities, work, and training reimbursed under the FDA animal food safety inspection contract and other funding mechanisms must remain distinct and separate from the cooperative agreement. The State must be able to account separately for fund expenditures, including employee salaries, wages, and benefits, as well as sub-contractor and/or primary servicing laboratory expenditures, under the animal food safety inspection contracts and other funding mechanisms and these cooperative agreements.

3) Vehicle purchases are not permitted.

4) 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.

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. If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Dealing with System Issues guidance. For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF424(R&R) Application Package**.** Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to 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 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.

Rational and Design (40 Points)

Demonstrates ability to achieve the goals and project goals of the cooperative agreement and project proposed.

Cooperation (20 Points)

Demonstration of effectiveness in working with federal, State, and local partners and other appropriate organizations to implement the goals of the cooperative agreement.

Integration (20 Points)

Demonstration of plans to facilitate the incorporation and sustainability of project developed capabilities into the entity's animal food safety system. Expected challenges are documented and addressed.

Resources (20 Points)

Demonstration of adequate program resources (including staff) and infrastructure, or the ability to obtain the resources necessary, to complete the project.

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.

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.

Vertebrate Animals

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

Biohazards

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

Resubmissions

Not applicable.

Renewals

Not applicable.

Revisions

Not applicable.

Applications from Foreign Organizations

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

Authentication of Key Biological and/or Chemical Resources:

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

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

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate 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.

2. Administrative and National Policy Requirements

All FDA grant and cooperative agreement awards include the *HHS Grants Policy Statement* 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. 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; and 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. Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at https://www.hhs.gov/ocr/about-us/contact-us/index.html or call 1-800-368-1019 or TDD 1-800-537-7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at https://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 following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Part 75, and other HHS, PHS, and FDA grant administration policies.

FDA Responsibilities

The administrative and funding instrument used for this program will be the cooperative agreement, an “assistance” mechanism (rather than an “acquisition” mechanism), in which substantial 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 as a whole, although specific tasks and activities may be shared between the awardee and the FDA as defined below.

Substantive involvement by the awarding agency is inherent in the cooperative agreement award. Accordingly, FDA will have substantial involvement in the program activities of the project funded by the cooperative agreement.

The PO and Project Manager/Technical Advisors 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. Substantive involvement may include, but is not limited to, the following:

- Provide guidance, direction, and technical assistance in project planning, implementation, and evaluation;
- Provide subject matter expertise, programmatic technical assistance, and evaluation services to support program studies and activities;
- Actively monitor the supported program via telephone conversations, e-mails, written correspondence, or periodic site visits;
- Evaluate the supported program, including development of program-level performance measures, consistent data collection, and reporting;
- FDA hosting annual face-to-face meetings for programs enrolled in the AFRPS, and participating in the meetings with awardees.
- FDA conducting technical sessions with the grantee, as deemed necessary by FDA.
- Post-award monitoring of project/program performance, including review of progress reports and conducting visits and verification assessments to verify grantee progress in achieving implementation

of the AFRPS.
- FDA hosting monthly (or at a frequency chosen by FDA) conference calls/webinar meetings with all programs enrolled in the AFRPS.
- FDA assistance in the sharing of information developed by the grantee and collaboration to achieve implementation of the AFRPS with other programs enrolled in the AFRPS in addition to FDA and other federal agencies. Examples may include SOPs, MOUs, training programs, and record keeping systems.
- Development of programs to meet the FDA mission; and
- FDA assistance in coordinating multi-program pilot projects.

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

The purpose of this cooperative agreement is to advance efforts for a nationally integrated animal food safety system by assisting State animal food regulatory programs to achieve and maintain full implementation of the AFRPS. The AFRPS are intended to ensure that State animal food regulatory programs develop and maintain best practices for a high-quality regulatory program. The

cooperative agreements will provide funding for additional personnel, equipment, supplies, and training to support activities related to achieving implementation of the AFRPS.

The grantee must maintain an animal food safety inspection contract with the FDA throughout the cooperative agreement. Key personnel (minimum of 2) will attend a required annual face-to-face meeting and any required training (as determined by FDA/OP) as a condition of the award. Facilities, work, and training reimbursed under the FDA animal food safety inspection contract and other funding mechanisms must remain distinct and separate from the cooperative agreement. The grantee must be able to account separately for fund expenditures, including employee salaries, wages, and benefits, as well as sub-contractor and/or primary servicing laboratory expenditures, under the animal food safety inspection contracts and other funding mechanisms and these cooperative agreements. Future funding will be dependent on recommendations from the Project Officer. The scope of the recommendation will confirm that acceptable progress has been made in achieving implementation of the AFRPS, continued compliance with all FDA regulatory requirements, and, if necessary, a corrective action plan has been implemented.

State animal food regulatory programs that provide funding to such laboratories should commit to continued support of the laboratory as necessary to accomplish project goals, for the life of the project. Ideally the primary servicing laboratory will support the awardee with report data to demonstrate progress in achieving the project goals listed, as applicable. Continued funding may be subject to adequate program support toward other FDA Cooperative agreements that support laboratory accreditation, testing, method development, and/or other relevant initiatives.

Principal Investigator Rights and Responsibilities

The PD(s)/PI(s) will have the primary responsibility for the scientific, technical, or programmatic aspects of the grant and for day-to-day management of the project or program. The PD/PI(s) will maintain general oversight for ensuring compliance with the financial and administrative aspects of the award, as well as ensuring that all staff has sufficient clearance and/or background checks to work on this project or program. This individual will work closely with designated officials within the recipient organization 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 and organizational requirements.

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

Overall management of the study and agree to work cooperatively with FDA.

Developing and implementing systems necessary for communications among the various study organizational components. All data and samples to be shared freely by methods and within time periods to be specified by the Program Official.

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

The awardees agree to accept assistance from the designated FDA Project Manager/Technical Advisors. These persons will participate in the monitoring of issues relating to recruitment, follow-up, and adherence to protocols and will assist in the development and/or adjustment of project activity.

Additionally, an agency Program Official may be responsible for the normal scientific and programmatic stewardship of the award.

The reporting and monitoring activities may include a review of budget modification requests from the grantee. The grantee and any sub-grantees are expected to utilize the approved funding respectively as indicated in the original submitted separate budget and cost estimates. The letter of agreement will be submitted by the grantee with the aforementioned budget modification request to the Program Official and Project Manager.

Equipment may be loaned by FDA to an awardee pursuant to FDA policy. Such equipment will remain the property of FDA under loan to the awardee for a specified time period with a review every twelve months. FDA may terminate the loan at any time. Unless approved by ORA/OP, the FDA provided equipment may not be transferred by the awardee to a third party, and the awardee assumes full responsibility and liability for any claims that may arise as a result of operation of this equipment for the period it is in the possession of the awardee

Mid-year reports are required. The Research Performance Progress Report (RPPR) will be considered the annual program progress report for the budget period.

Mid-year and annual progress reports shall contain the elements below as applicable to the grantee proposal and award, but are not limited to, the following:

1. Detailed progress report on the grantee meeting the project goals detailed in the cooperative agreement and identified in the application.

2. Status report on the hiring and training of animal food program personnel.

3. Certification of current State appropriation funding levels for the State animal food regulatory program.

4. Submission of the following documents in the most current version of the AFRPS. These documents must be current and fit for use.

Appendix 1.1 or alternate form that is equivalent

Appendix 2.1 or alternate form that is equivalent

Appendix 3.1 or alternate form that is equivalent

Appendix 4.1, 4.3, 4.6, 4.8, 4.10, 4.11 or alternate forms that are equivalent

Appendix 5.1 or alternate form that is equivalent

Appendix 6.1 or alternate form that is equivalent

Appendix 7.1 or alternate form that is equivalent

Appendix 8.1 or alternate form that is equivalent

Appendix 9.1, 9.2, and 9.3 or alternate forms that are equivalent

Appendix 10.1 or alternate form that is equivalent

Appendix 11.1 or alternate form that is equivalent

Annual progress reports must contain the elements below as applicable to their application and award, but are not limited to, the following:

1. An improvement plan that accurately reflects when specific objectives and tasks have been, or will be, completed and/or implemented and when new objectives and tasks are identified to achieve full implementation of the AFRPS. Progress achieved should indicate full implementation of the AFRPS can be expected by completion of Year 5. Review and update improvement plan(s) on an annual basis. Documentation related to the evaluation and improvement plan(s) should be maintained.

Submission of an improvement plan will include the following at the minimum to demonstrate program advancement in achieving implementation of the AFRPS:

- The individual element or documentation requirement for the Standard that was not fully met.
- Improvements needed to fully meet the program element or documentation requirement(s) of the Standard.
- Lists of individual tasks that will be used to address the improvement
- A projected completion date for each task.
- An assigned AFRPS Project Coordinator with the overall responsibility for implementing the improvement plan(s).

Note: For programs with less than 12 months of enrollment in the AFRPS, this information will be required after 12 months of enrollment in the AFRPS, with the annual progress report.

2. Description of program improvements and demonstration of measurable implementation of the AFRPS.

Note: For programs with no previous enrollment in the AFRPS, this information will not be required until Year 2.

3. An estimate (in total dollars) of in-kind contributions toward accomplishing the goals of the cooperative agreement during the reporting period.

Additional reporting requirements: For programs with less than 12 months of enrollment in the AFRPS, submission of the baseline self-assessment, including applicable appendices, worksheets, and other documents required for each Standard, or equivalent alternate forms, and an improvement plan is required to be submitted after 12 months of enrollment in the AFRPS, with the first annual progress report.

The final program progress report must provide full written documentation of the project and summaries of accomplishments and goals, as described in the grant application. The documentation must be in a form and contain sufficient detail such that other State, local, and tribal governments could reproduce the final project. The final program progress report should also detail the strategy, including commitment of personnel, resources, and funding, to sustain implementation of the AFRPS (current and future versions). An independent audit of the program by FDA should verify the program is in implementation of the AFRPS.

Monitoring Activities

The Program Official and Project Manager/Technical Advisor(s) will monitor award recipients periodically. The monitoring may be in the form of face-to-face meetings, telephone conversations, e-mails, or written correspondence between the Program Official/Grants Management Officer/Technical Advisor(s) and the

principal investigator. In addition, periodic site visits with officials of the recipient organization may also occur to assess progress. The results of these monitoring activities will be recorded in the official cooperative agreement file and will be available to the grant recipient, upon request, consistent with applicable disclosure statutes and FDA disclosure regulations. Also, the grantee organization shall comply with all special terms and conditions of the cooperative agreement, including those which state that future funding of the project will depend on recommendations from the Program Official and Project Manager/Technical Advisor(s).

The scope of the recommendation will confirm that:

(1) There has been acceptable progress on the project; (2) there is continued compliance with all FDA regulatory requirements; and (3) if necessary, there is an indication that adequate corrective actions have taken place to address any identified problems.

The evaluation of performance includes, but is not limited to: technical meeting and annual face-to face meeting attendance and participation, implementation progress of the AFRPS according to the work and schedules identified in the application and improvement plan submissions, verification of implementation progress through FDA verification audits, responsiveness to FDA, conference call participation, and the general progress of the cooperative agreement deliverables as determined by FDA.

3. Reporting

When multiple years are involved, awardees will be required to submit the Research Performance Progress Report (RPPR) annually and financial statements as required in the Notice of Award.

Mid-year reports are required.

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*.

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 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

Scientific/Research Contact(s)

Isaiah Isakson
Food and Drug Administration
Telephone: 406-465-9363
Email: isaiah.isakson@fda.hhs.gov

Objective Review Contact(s)

Gordana Zuber
Office of Acquisitions & Grants Services (OAGS)
Food and Drug Administration
Telephone: 301-348-1747
Email: gordana.zuber@fda.hhs.gov

Financial/Grants Management Contact(s)

Gordana Zuber
Office of Acquisitions & Grants Services (OAGS)
Food and Drug Administration
Telephone: 301-348-1747
Email: gordana.zuber@fda.hhs.gov

Section VIII. Other Information

All awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement.

Authority and Regulations

Awards are made under the authorization of section 1009 of the Federal Food, Drug, and Cosmetic Act (21 USC 399), 21 USC 2104, and section 301 of the Public Health Service Act (42 USC 241) and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75.

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