Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	U.S. Food and Drug Administration (FDA) 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	**Egg Safety Regulatory Program Standards Development (U18)**
Activity Code	U18 Research Demonstration – Cooperative Agreements
Announcement Type	New
Related Notices	None
Funding Opportunity Announcement (FOA) Number	**RFA-FD-16-040**
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	This Funding Opportunity Announcement (FOA) is being issued to announce the availability of a cooperative agreement to be awarded under Limited Competition. This cooperative agreement is intended to advance efforts to improve the national egg safety programs through 1. Conducting an egg regulatory program self-assessment including a review of State egg laws and regulations in comparison to the current federal egg safety laws and regulations; 2. Developing and implementing an agreement and protocol for sharing egg regulatory inspections and information between States and the FDA; 3. Identifying gaps and areas of improvement between Federal and State egg programs and providing recommendations for national egg regulatory program standards for States.

Key Dates

Posted Date	
Open Date (Earliest Submission Date)	May 2, 2016
Letter of Intent Due Date(s)	May 20, 2016
Application Due Date(s)	July 1, 2016 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	August 2016
Advisory Council Review	Not Applicable
Earliest Start Date	September, 2016
Expiration Date	July 2, 2016
Due Dates for E.O. 12372	Not Applicable

Required Application Instructions

It is critical that applicants follow the 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.

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

The Food and Drug Administration (FDA), the Office of Regulatory Affairs (ORA), the Office of Partnerships (OP) is announcing the availability of a cooperative agreement to be awarded under Limited Competition. This cooperative agreement is intended to fund the self-assessment of State egg regulatory programs, provide recommendations for national egg regulatory program standards for State program to adopt, and share egg inspection data and program information between the grantee and FDA.

The goal of this cooperative agreement program is to facilitate long-term improvements to the national food safety system by strengthening interagency collaboration, and improving States' regulatory and surveillance protection programs for eggs, and development of national egg regulatory program standards for States. Under this cooperative agreement, the State agency shall make recommendations towards the establishment of national egg regulatory program standards for States to adopt. In addition, effective strategies for sharing egg inspection data between States and the FDA will be identified. Funds shall be used to conduct an egg program self-assessment, review State/Federal laws and regulations that pertain to eggs and identify or create an electronic system to facilitate sharing of egg inspection information.

This will be accomplished through the provision of funding for State egg regulatory programs to conduct a program assessment and to develop an improvement plan using the Manufactured Food Regulatory Program Standards (MFRPS) 2013 version and the Animal Feed Regulatory Program Standards (AFRPS) 2014 version, or most recent, as the foundation. In addition, the sharing of data related to the egg industry, such as firm, inspections, and compliance information, between FDA and the awardee will further advance food safety.

The outcome is the facilitation of long-term improvements to the national egg safety system and strengthening the national capacity and capability of egg safety regulatory entities to take appropriate action, including planning and otherwise preparing to take such action, to protect the public health.

MPRPS 2013 version:
http://www.fda.gov/downloads/ForFederalStateandLocalOfficials/PartnershipsContracts/Overview/UCM377447.pdf

AFRPS 2014 version:
http://www.fda.gov/downloads/ForFederalStateandLocalOfficials/AnimalFeedRegulatoryProgramStandardsAFRPS/UCM402506.pdf

The objectives of this funding opportunity include:

1. Determine the need for the establishment of national egg State regulatory program standards based upon performing a program assessment and developing an improvement plan using the MFRPS and AFRPS (Standard 11-Sampling Program) as models.

2. Identify gaps and areas of improvement between Federal and State programs, including voluntary egg safety programs, regulatory authorities and requirements.

3. Federal and State collaboration, to include but not be limited to, sharing of egg program data, such as inspections, sample analyses, firm inventory and individual firm information, collaborative work planning, and joint discussions around compliance actions.

Specific activities that shall be performed, working in collaboration with other awardees (required) to accomplish these objectives includes:

1. Conduct a baseline program self-assessment and develop an improvement plan using the MFPRS Standard 9 as the foundation. The program self-assessment requires the completion of the appendices and worksheets found in Standards 1- 8 and 10, or equivalent forms.

a. Describe the elements of the regulatory foundation used by the State program to regulate egg farms compared to Federal laws and regulations and any applicable voluntary quality regulatory programs. Refer to MFRPS Standard 1 and Appendix 1.

b. Define the essential elements of (including courses for) a training program for State and Federal inspectors including required coursework, field training, and continuing education to maintain an active status. Refer to MFRPS Standard 2 and Appendices 2.1 and 2.2.

c. Define and describe the elements of an effective inspection program for egg farms including: 1) Risk-based inspection program, 2) Inspection protocol, 3) Recall system, 4) Consumer complaints and egg industry inspection complaints system. Refer to MFRPS Standard 3 and Appendices 3.1 and 3.2.

d. Describe the inspection audit program by identifying the elements of the basic assurance reviews necessary to: 1) evaluate the effectiveness of the inspection program, 2) recognize trends in inspectional coverage, and 3) identify best practices used to achieve quality inspections and sample collections. Refer to MFRPS Standard 4 and Appendices 4.1 - 4.8 and Worksheets 4.2 and 4.3.

e. Describe the functions and related activities necessary to investigate egg-related illnesses and outbreaks as well as coordinating roles and responsibilities with other jurisdictions and notifying the public. Refer to MFRPS Standard 5 and Appendix 5.1.

f. Describe the State agency's strategies, procedures, and actions to enforce the laws and regulations to achieve compliance and to evaluate the effectiveness of its compliance and enforcement program. Refer to MFPRS Standard 6 and Appendices 6.1 and 6.2 and Worksheet 6.2.

g. Describe the elements of industry and community outreach activities developed and accomplished by the State program. Refer to MFRPS Standard 7 and Appendix 7.

h. Describe the elements for assessing the resources (staff, equipment, and funding) needed to support an egg safety program. Refer to MFRPS Standard 8 and Appendices 8.1 - 8.3.

i. Describe the elements of laboratory support for the State egg safety regulatory program. Refer to MFRPS Standard 10 and Appendix 10.

j. Describes the element of an effective egg sampling program. Refer to AFRPS Standard 11 and Appendix 11.

2. Make recommendations for elements of a national egg regulatory program standard for State egg regulatory programs, including identification of elements of the MFRPS and AFRPS that are not applicable to egg regulatory programs, elements that are appropriate, and additional elements that shall be included.

3. Develop and implement an agreement and protocol for electronically sharing all State and Federal egg regulatory information, such as inspections and findings, firm information, and compliance actions, between the State and FDA.

4. Schedule joint inspections between FDA and the State. Ideally, all State inspectors participate in a minimum of one joint inspection with FDA.

These cooperative agreement funds are not intended to replace current funding for program improvement and activities. Agencies funded under this cooperative agreement may be required to provide the previous and subsequent years of state, local, territorial, or tribal funding to demonstrate that these funds have not replaced previous allocations.

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.
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. Future year amounts will depend on annual appropriations, availability of funding and awardee performance. FDA/ORA intend to fund up to $750,000, for fiscal year 2016 in support of this cooperative program. It is anticipated that up to five (5) awards will be made, not to exceed $150,000 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: $150,000 YR 02: $150,000 YR 03: $150,000
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* will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

This opportunity is only available to State government agencies with egg safety regulatory programs. Priority is given to States that currently have or previously had an egg inspection contract with the FDA.

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) (formerly CCR) – Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
    - NATO Commercial and Government Entity (NCAGE) Code – 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 and SAM registration in order to complete the eRA Commons registration. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- 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

Only one application per institution (normally identified by having a unique TIN number) is allowed.

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

Applicants must obtain the SF424 (R&R) application package associated with this funding opportunity using the "Apply for Grant Electronically" button in this FOA or following the directions provided at Grants.gov.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide, including Supplemental Grant Application Instructions except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

For information on Application Submission and Receipt, visit Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications.

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 via electronic mail as a PDF file with the FOA Number and the Institution's Name in the message subject heading to:

Martin Bernard
Martin.Bernard@fda.hhs.gov

A technical session will be held for prospective applicants in May 2016. 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 20 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.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide, with the following modification:

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

Appendix: Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

PHS Inclusion Enrollment Report
When conducting clinical research, follow all instructions for completing PHS Inclusion Enrollment Report as described in the SF424 (R&R) Application Guide.

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*.

Non-allowable costs:

1) Facilities and work covered under current FDA egg inspection contracts shall not be counted towards fulfillment of the cooperative agreement and shall remain distinct and separate from the cooperative agreement. The State must be able to account separately for fund expenditures under the egg inspection contracts and this cooperative agreement.
2) Vehicle purchases are not permitted.
3) Subcontracting to third parties is limited to 25% of each year's award.
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 Applying Electronically. 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
Applicants are required to follow the instructions for post-submission materials, as described in NOT-OD-13-030.

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.

1. The rationale and design to meet the goals and objectives of the cooperative agreement and project proposed (weight = 40%).

2. Demonstration of effectiveness in working with federal, state, and other awardees (set regular meetings), etc. of this cooperative agreement to develop and share of ideas, techniques, and solutions (weight =30%)

3. Demonstration of adequate program resources (including staff) and infrastructure, or the ability to obtain the resources necessary, to complete the project needs (weight = 15%).

4. Presentation of a fair and reasonable budget. The application includes detailed budget line items with support justifications for each line item cost. The budget plan does not contain unnecessary expenditures and reflect the actual needs of the proposed project (weight = 15%).

Additional Review Criteria
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 six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

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

Inclusion of Women, Minorities, and Children

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 children to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the 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

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.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by an 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.
- Priority will be given to States that currently have or previously had an egg inspection contract with the FDA.

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 http://www.hhs.gov/ocr/civilrights/resources/laws/revisedlep.html. The HHS Office for Civil Rights also provides guidance on complying with civil rights laws enforced by HHS. Please see http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html; and

http://www.hhs.gov/ocr/civilrights/understanding/index.html. Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html. Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at http://www.hhs.gov/ocr/office/about/rgn-hqaddresses.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.

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.

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 Parts 75, and other HHS, PHS, and FDA grant administration policies.

Support will be in the form of a cooperative agreement. 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.

Work anticipated under this cooperative agreement may not be duplicated or funded by other cooperative agreements, contracts, or other funding mechanisms. Projects proposed under these cooperative agreements and the funding provided must remain distinct and separate from other projects and funding sources. The grantee must be able to account separately for funds expenditures, including employee salaries, wages, and benefits, received through contracts, cooperative agreements, grants, and other funding received by the grantee and these cooperative agreements.

Any equipment currently owned by FDA that is loaned out to parties as a result of a cooperative agreement will remain the property of FDA under loan to the awardee for a specified time period with a review every twelve months if applicable. FDA may terminate the loan at any time. Unless approved by ORA Office of Partnerships, the FDA provided equipment may not be transferred by the awardees 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 awardees.

The Government, via the PO, will have access to data generated under this cooperative agreement and may periodically review the data and progress reports. The PO may use information obtained from the data for the preparation of internal reports on the activities of the study. However, awardees shall retain custody of and have primary rights to all data developed under these awards.

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 Project Officer.

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 Officer. This person 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 and will be named in the award notice.

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 grants management officer and the program project officer.

The equipment purchased by FDA 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.

Monitoring Activities

The program project officer will monitor the recipient periodically. The monitoring may be in the form of telephone conversations, e-mails, or written correspondence between the project officer/grants management officer and the grantee. Periodic site visits with officials of the recipient organization may also occur. There may be other regular meetings with recipients to assist in fulfilling the requirements of the cooperative agreement.

The result 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 must 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 Project Officer.

Future funding will be dependent on recommendations from the Project Officer. 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 corrective action has taken place.

Program monitoring of recipients will be conducted on an ongoing basis and written report will be reviewed and evaluated by project officer and the grants management specialist.

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.

A final progress report, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in 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.

A mid-year Progress Report is required no later than 180 days after the award and beginning of the budget period. The mid-year Progress Report shall contain a description of project activities covering a six-month period.

A final report of the outcomes of the cooperative agreement program and a final Federal Financial Report (FFR) are required within 90 days of the expiration date of the project period. The report shall include full written document of the project, copies of any result, materials, and project deliverables as described in the grant application, and an analysis and evaluation of the result of the project.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons registration, submitting and tracking an application, documenting system problems that threaten submission by the due date, post submission issues)
Finding Help Online: 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 submission, downloading forms and application packages)
Contact CenterTelephone: 800-518-4726
Web ticketing system: https://grants-portal.psc.gov/ContactUs.aspx
Email: support@grants.gov

Scientific/Research Contact(s)

Meiying Li
Project Officer
FDA/ORA/Officer of Partnerships/Contracts and Grants
12420 Parklawn Drive, ELEM-3032
Rockville, MD 20857
301-796-5903
Email: meiying.li@fda.hhs.gov

Brenda Stewart-Munoz
Technical Advisor
FDA/ORA/Office of Partnerships

Telephone: 240-402-4806
Email: Brenda.Stewart-Munoz@fda.hhs.gov

Objective Review Contact(s)

Martin Bernard
Office of Acquisitions & Grants Services (OAGS)
Food and Drug Administration
Telephone: 240-402-7564
Email: Martin.Bernard@fda.hhs.gov

Financial/Grants Management Contact(s)

Martin Bernard
Office of Acquisitions & Grants Services (OAGS)
Food and Drug Administration
Telephone: 240-402-7564
Email: Martin.Bernard@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 Sections 301 of the Public Health Service Act as amended (42 USC 241) and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75.