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

Integrated Food Safety System Online Collaboration Development (U18)

Activity Code

U18 Research Demonstration – Cooperative Agreements

Announcement Type

New

Related Notices

None

Funding Opportunity Announcement (FOA) Number

RFA-FD-15-024

Companion Funding Opportunity

Not Applicable

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 Office of Regulatory Affairs, in coordination with FDA's Office of Foods, Center for Food Safety and Applied Nutrition, and Center for Veterinary Medicine, is soliciting a cooperative grant proposal to expedite program development to support critical federal-state collaboration necessary to plan and implement an integrated food safety system.

Key Dates

Posted Date

May 6, 2015

Open Date (Earliest Submission Date)

May 15, 2015

Letter of Intent Due Date(s)

Not Applicable

Application Due Date(s)

July 15, 2015, 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

July, 2015

Advisory Council Review

Not Applicable

Earliest Start Date

September 2015

Expiration Date

July 16, 2105

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.**

Apply for Grant Electronically

A compatible version of Adobe Reader is required for download. For Assistance downloading this or any Grants.gov application package, please contact Grants.gov Customer Support at http://www.grants.gov/contactus/contactus.jsp.

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Background

Food can become contaminated at many different points – on the farm, in processing or distribution facilities, during transit, at retail and food service establishments, and in the home. In recent years, FDA, in cooperation with other food regulatory and public health agencies, has done a great deal to prevent both intentional and unintentional contamination of food at each of these points. FDA has worked with other federal, state, local, tribal, territorial, and foreign counterpart food safety regulatory and public health agencies, as well as with law enforcement and intelligence-gathering agencies, and with industry, consumer groups, and academia, to strengthen the nation's food safety and food defense system across the entire distribution chain.

This cooperation has resulted in greater awareness of potential vulnerabilities, the creation of more effective prevention programs, new surveillance systems, and the ability to respond more quickly to outbreaks of foodborne illness. However, changes in consumer dietary patterns, changes in industry practices, changes in the U.S. population, and an increasingly globalized food supply chain and new pathogens and other contaminants pose challenges that are requiring us to adapt our current food protection strategies.

At the Federal level, a number of Agencies are working together to coordinate their efforts and develop short- and long-term agendas to make food safer. As the federal regulatory agency responsible for most of the nation's food supply,[1] FDA is committed to ensuring that the food[2] supply is among the safest in the world. This requires a systematic, integrated approach to effective risk control and enforcement strategies. Together with our federal, state, local, tribal, and territorial public health partners, FDA is working to plan and implement an inspection and enforcement program to ensure high rates of compliance with the Agency's food safety standards. FDA intends to establish a fully integrated national food safety system built on collaboration among all of these partners. This system will encompass inspections, laboratory testing, and outbreak response and will place priority on preventing foodborne illness, in both food for humans and animals. This collaboration will result in 1) better ability to assess potential risk at domestic food facilities and greater and more consistent inspectional coverage of these facilities across the entire food supply chain, 2) greater food surveillance through integration of food facility inspection and testing information, and 3) improved rapid response capacity and efficiency.

Current leveraging efforts have not been sufficient to ensure adequate oversight of the entire food supply chain. Food facilities are not uniformly inspected, data is not uniformly captured on a national basis, and the data that is collected is not systematically mined for intelligence. Neither FDA nor our regulatory or public health partners alone collect and analyze a sufficient number of surveillance samples per year to have confidence in to the ability to effectively identify potential areas of concern; combining the data from all public health partners would greatly enhance FDA's ability to detect potential problems. In addition, national response efforts are uneven. Throughout the years, numerous reports have concluded that FDA does not take full advantage of the inspectional and surveillance capabilities of our state, territorial, tribal and local regulatory and public health partners. This is due in large part to the varied standards and laws in each state as compared with the federal system, as well as to the lack of interoperable data systems and legal impediments to sharing data among partners.

These combined factors present a challenge in managing and responding to signals of public health concern in the food supply. The currently decentralized U.S. public health and agriculture system results in a situation in which responsibility for surveillance, detection, investigation, response and recovery to foodborne disease outbreaks is shared across federal, state, territorial, tribal, and local government agencies.

Various levels of government are working to improve the nation's food safety and defense system. At all levels, there is a call for greater integration and coordination between the Federal agencies and the regulatory and public health partners involved in food safety. An integrated food safety system will allow FDA to meet the White House Food Safety Working Group recommendation that the federal government ". . . prioritize crucial inspection and enforcement activity across the world, support safety efforts by States, localities, and businesses at home; and utilize data to guide these efforts and evaluate their outcomes." [3]

To be fully successful, the national food safety system must be built with continuous input from FDA's regulatory and public health partners. Efforts shall facilitate information sharing and communication among all partners, and include infrastructure for a national electronic information-sharing mechanism. These actions will result in a national food safety system that identifies sources of risk throughout the system and reduces time to detect and respond to foodborne outbreaks. A public health driven, collaborative, and leveraged approach to food safety activities and responsibilities will be reflected in improved public sector resource utilization at a national level, which provides additional capacity for ensuring a safe and secure food supply.

Objectives

The Office of Regulatory Affairs, in coordination with FDA's Office of Foods, Center for Food Safety and Applied Nutrition, and Center for Veterinary Medicine, is soliciting a cooperative grant proposal to expedite program development to support critical federal-state collaboration necessary to plan and implement an integrated food safety system. The intent is to fund proposals for the continued development and operations of collaborative online tools involving a range of stakeholders for the purposes of (information sharing in the development of an integrated food safety system, and developing and implementing a sustainable model for continued collaborative communication and information sharing. This grant opportunity is limited to organizations receiving funding under the current Integrated Food Safety System Online Collaboration Development cooperative agreement. The National Center for Food Protection and Defense (NCFPD), a Department of Homeland Security Center of Excellence, has unique expertise and capacity found nowhere else. It is the host/creator of FoodSHIELD, an inter-governmental collaborative project supporting information sharing at the federal, state and local levels. NCFPD is uniquely qualified to provide: Well-established and high-level access to Food/Ag Sector Organizations and coordination of electronic collaborative tools; collaborative support from the Department of Health and Human Services, the Department of Homeland Security, and the US Department of Agriculture. NCFPD also has past experience directly supporting the White House Food Safety Working Group Objectives to integrate the food safety system at all levels.

Proposals should provide a detailed plan for initiating, improving, and/or leveraging collaborative virtual partnerships to address topics that may include but are not limited to those listed below. Proposals should include a list of collaborators and their roles, as well as a proposed plan for developing a sustainable model for continued collaborative web-based communication and information sharing for regulatory health partners.

1. Leveraging among Federal, State, Local, Tribal, and Territorial Partners

The domestic food supply chain is currently overseen by a mix of multiple Federal, State, territorial, tribal, and local regulatory and public health agencies that often work independently from one another, work under different legislative authorities, and are driven by different objectives and priorities. More than 3,000 state, territorial, tribal, and local regulatory agencies have some responsibility to regulate the food and foodservice industries in the United States. Together, they are responsible for the inspection and oversight of over one million food establishments. At the federal level, FDA oversees more than 150,000 registered domestic food facilities including food manufacturers and processors, food warehouses, and grain elevators. Some of this oversight responsibility is shared with states. In addition, federal, state, territorial, tribal, and local authorities oversee more than 2 million farms.

2. Facilitating information sharing and communication for enhanced public health

FDA provides guidance, model codes, and other technical assistance to state, territorial, tribal, and local regulatory partners to assist them in carrying-out their regulatory responsibilities. Since 1972, FDA has also contracted or entered into partnership agreements with many state regulatory agencies to perform inspections and investigations. FDA currently has over forty (40) state food inspection contracts, providing over 10,000 inspections in the areas of Current Good Manufacturing Practices (CGMPs), sanitation, seafood, juice, and low-acid canned foods. In addition, FDA has over 30 state contracts providing over 4,000 yearly inspections in the areas of CGMPs for licensed medicated feed manufacturers and bovine spongiform encephalopathy (BSE) controls. FDA also has over 100 state grants/cooperative agreements in the areas of food protection, food emergency response networks, ruminant feed ban support, rapid response teams, and innovative food defense activities. These contracts and cooperative agreements have established, developed and maintained collaborative relationships with state,

territorial, tribal and local regulatory partners, and have been critical in leveraging FDA's food safety resources. These agreements have provided critical support to FDA in terms of regulatory oversight, but there are challenges related to the integration of resources and information sharing that need to be addressed.

Timelines should be provided for goals in each project. Intermediate and final goals should be clearly identified in the program description. Applicants should be able to describe specific short, medium, and long term outcomes of public health relevance that shall be reported as the program progresses.

It is expected that FDA will participate in the design of programs involving collaborative partnerships that may be formed as a result of this funding, and will provide oversight of the funded programs.

See Section VIII, Other Information - Required Federal Citations, for policies related to this announcement.

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.

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 Office of Regulatory Affairs intends to commit up to $680,000, for fiscal year 2015 in support of this grant program. Funding may be granted for additional years dependent on progress and federal budgets.

It is anticipated that up to one (1) award will be made, not to exceed $680,000 in total costs (direct plus indirect).

Awards are contingent upon FDA appropriations, and the submission of a meritorious application. Future year amounts will depend on annual appropriations and performance.

Award Budget

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

Year 1: $680,000
Year 2: $680,000
Year 3: $680,000
Year 4: $680,000
Year 5: $680,000

Award Project Period

The total project period for an application requesting support may not exceed 5 years. Recommended support beyond the first year will depend on the availability of funds and approved performance.

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

The following organizations/institutions are eligible to apply:

This cooperative agreement is only available to organizations receiving funding under the current Integrated Food Safety System Online Collaboration Development cooperative agreement. Competition is limited to NCFPD because it is uniquely qualified and has expertise and capacity found nowhere else. It is the host/creator of FoodSHIELD, an inter-governmental collaborative project supporting information sharing at the federal, state and local levels. NCFPD is uniquely qualified to provide: Well-established and high-level access to Food/Ag Sector Organizations and coordination of electronic collaborative tools; collaborative support from the Department of Health and Human Services, the Department of Homeland Security, and the US Department of Agriculture. NCFPD also has past experience directly supporting the White House Food Safety Working Group Objectives to integrate the food safety system at all levels.

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. **Late applications will not be accepted for this FOA.**

- 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

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

Applicants must download 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

Not Applicable

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

Planned Enrollment Report

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

PHS 398 Cumulative Inclusion Enrollment Report

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

3. Submission Dates and Times

Part I. Overview Information contains information about Key Dates. 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. 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.

4. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review.

5. 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*.

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

Funds are not to be utilized for new building construction.

A decrease in the amount of the non-competitive segment may occur if there is an unobligated balance from the prior year, in which case prior year funds can be used as an offset for the current year award.

Appropriated funds shall not be used to purchase promotional items when they are not a necessary expense.

Continued funding of a non-competitive segment is contingent upon satisfactory progress as determined by the FDA program/technical staff, the receipt of a non-competing continuation application, submission of an acceptable annual report and the availability of Federal funds.

Allowable costs (including but not limited to):

1) Audiovisual materials such as videotapes, DVDs, public service announcements, etc.
2) Consultant services
3) Employee salaries, wages and fringe benefits
4) Rental, purchasing, calibration, and maintenance of supplies and equipment
5) Indirect costs
6) Recruitment costs for hiring new employees
7) Registration fees
8) Purchase or development of IT equipment, software, and support
9) Shipping and mailing of equipment and supplies
10) Travel (shall not exceed coach class fare)
11) Speaker fees

Non-allowable costs:

1) Facilities, work, and training reimbursed under the FDA food safety inspection contract, the FDA feed safety inspection contract and other funding mechanisms shall remain distinct and separate from the cooperative agreement. The State shall be able to account separately for fund expenditures, including employee salaries, wages, and benefits, under the food safety inspection contract, the feed safety inspection contract and other funding mechanisms and this cooperative agreement.
2) Vehicle purchases are not permitted.
3) Cooperative agreement funds may not be utilized for new building construction; however, remodeling of existing facilities is allowed, provided that remodeling costs do not exceed 10% of the grant award amount.
4) Please also refer to the HHS Grants Policy Statement for additional information regarding costs.

Funding Plan:

Funding for years 2 through 5 will be non-competitive continuation of support and depend on performance, program progress, and the availability of Federal funds.

Funds should be requested in the budget for key project personnel to travel to meetings, on-site visits, and audits with FDA program staff to discuss the project. A portion of budgeted travel funds should also be set aside for key personnel to attend an annual face-to-face meeting (as determined by FDA/OP) and committee meetings supporting NCFPD. Training needs should also be anticipated and budgeted for accordingly.

6. 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.

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

Not Applicable

Section V. Application Review Information

1. Criteria

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

Scored Review Criteria

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

Significance (20 Points)

Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s) (20 Points)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Innovation (30 Points)

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach (20 Points)

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early

stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves human subjects and/or FDA-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of children, justified in terms of the scientific goals and research strategy proposed?

Environment (10 Points)

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall 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 five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. 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 Wide Association Studies (GWAS) /Genomic Data Sharing Plan.

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 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.

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.

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, the FDA purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and FDA as defined below.

Principal Investigator Rights and Responsibilities
The PD(s)/PI(s) shall have the primary responsibility for the scientific, technical, and programmatic aspects of the grant and for day-to-day management of the project or program. The PD/PI(s) shall 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 shall 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.

Awardees shall retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and FDA policies.

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.

3. Reporting

When multiple years are involved, awardees will be required to submit the annual Non-Competing Progress Report (PHS 2590 or RPPR) and financial statements.

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 30 days after the midyear point of the budget period. The annual Progress Report is required no later than 30 days after the end of the budget period. The mid-year and annual Progress Report should contain a description of project activities covering the applicable reporting period.

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

1. Detailed progress report on the grantee meeting the project goals identified in the proposal.

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

3. A strategic 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 support achievement of the objectives. The strategic plan should include significant goals or action items, anticipated completion dates, responsible personnel, and other required resources.

4. Description of program improvements

The final program progress report shall provide full written documentation of the project and summaries of accomplishments and goals, as described in the grant application. The documentation shall 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 accomplish the objectives as stated in this FOA and in the proposal.

5. An annual Financial Status Report (FFR) (SF-425) shall be sent to the FDA's grants management officer within ninety (90) days of the budget period end date of each twelve month cooperative agreement. Failure to file the annual FSR in a timely fashion will be grounds for suspension or termination of the cooperative agreement.

For continuing cooperative agreements, mid-year reports and annual program progress reports are also required.

Monitoring Activities

The program project officer will monitor grantees periodically. The monitoring may be in the form of telephone conversations, e-mails, or written correspondence between the project office/grants management office and the principal investigator. Periodic site visits with officials of the grantee organization may also occur. There may be other regular meetings with recipients to assist in fulfilling the requirements of the cooperative agreement. The results of these monitoring activities will be recorded in the official grant file and will be available to the grantee upon request consistent with applicable disclosure statutes and with 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 study will depend 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; (3) funds are being used to supplement, not supplant, the building of food safety capacity as described in the application; and (4) if necessary, there is an indication that adequate corrective actions have taken place to address any identified problems.

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 Commons Help Desk (Questions regarding eRA Commons registration, submitting and tracking an application, documenting system problems that threaten submission by the due date, post submission issues)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)
Finding Help Online: http://grants.nih.gov/support/index.html
Email: commons@od.nih.gov

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)

Nicola Areshenko
Food and Drug Administration (FDA)
Telephone: 253-987-7921
Email: nicola.areshenko@fda.hhs.gov

Objective Review Contact(s)

Daniel Lukash
Food and Drug Administration (FDA)
Telephone: 240-402-7596
Email: daniel.lukash@fda.hhs.gov

Financial/Grants Management Contact(s)

Daniel Lukash
Food and Drug Administration (FDA)
Telephone: 240-402-7596
Email: daniel.lukash@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 and 317R of the Public Health Service Act (42 USC 241 and 247b-20), section 1009 of the Federal Food, Drug, and Cosmetic Act (21 USC 399), 21 USC 2104, and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75.

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[1] FDA is the federal agency that is responsible for regulating most of the country's food supply, with the exception of most meat, poultry, and processed egg products, which are overseen by the U.S. Department of Agriculture (USDA).

[2] For purposes of this document, the term "food" includes human food, animal feed, components (i.e. ingredients) of both food and feed, and dietary supplements for humans, except as otherwise noted.

[3] White House Food Safety Working Group Key Findings Report submitted to President Obama on July 7, 2009

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see Help Downloading Files.