# 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)
Center for Food Safety and Applied Nutrition (CFSAN)

## Funding Opportunity Title

Integrated Food Defense & Emergency Response Cooperative Agreement Program IFD&ER(U18)

## Activity Code

U18 Research Demonstration – Cooperative Agreements

## Announcement Type

New

## Related Notices

None

## Funding Opportunity Announcement (FOA) Number

**RFA-FD-15-022**

## 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 Integrated Food Defense & Emergency Response Cooperative Agreement Program (IFD&ER CAP) grant awards are designed to generate food defense tools and resources that are easily replicated and can complement, aid in the development of, and/or improve State, local, Tribal and territorial (SLTT) food defense programs through unique, innovative, and reproducible projects .

The known overlap between food safety (unintentional contamination) and food defense (intentional contamination) is extensive. And the pools of resources available are vast and sometimes difficult to locate and implement.

As the Food Safety Modernization Act (FSMA) recognizes the evolution of the relationship between food safety and food defense, it is critical that these programs be integrated to the maximum extent possible in order to ensure the most efficient use of resources, as well as to optimize responses to incidents and events.

## Key Dates

### Posted Date

May 4, 2015

### Open Date (Earliest Submission Date)

May 8, 2015

February 1, 2016

February 1, 2017

February 1, 2018

February 1, 2019

### Letter of Intent Due Date(s)

June 15, 2015,

March 1, 2016

March 1, 2017

March 1, 2018

March 1, 2019

### Application Due Date(s)

July 9, 2015

April 2, 2016

April 2, 2017

April 2, 2018

April 2, 2019

by 11:59 PM Eastern Time.

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

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

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

### AIDS Application Due Date(s)

Not Applicable

### Scientific Merit Review

July 2015

April 2016

April 2017

April 2018

April 2019

### Advisory Council Review

Not Applicable

### Earliest Start Date

September 2015

May 2016

May 2017

May 2018

May 2019

### Expiration Date

April 3, 2019

### 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.

# Table of Contents

# Part 2. Full Text of Announcement
# Section I. Funding Opportunity Description

The Food and Drug Administration (FDA or Agency) is announcing the availability of grant funds for the support of the development of Integrated Food Defense & Emergency Response Cooperative Agreement Program (IFD&ER CAP) grant projects. FDA will support projects covered by this notice under Title III of the Public Health Service Act, Section 317R (42 U.S.C. 247b20) and Section 1004 of the Food and Drug Administration Amendments Act of 2007 (21 U.S.C. 2104).

Successful projects may be utilized by the Agency to forward mission objectives. Previous projects have been successfully replicated by our stakeholders and applicants are expected to provide necessary materials and resources produced as a result of this project to the Grant Program Officials for further Agency use. Several applicants' projects have been successfully integrated into FDA resources and others have successfully promoted these resources within the food defense community.

FDA's program is described in the Catalog of Federal Domestic Assistance, No. 93.103, and applicants are limited to food safety regulatory agencies of State, local, tribal, and territorial (SLTT) governments. Internet viewers should proceed to “Publications”.

The Public Health Service (PHS) strongly encourages all award recipients to provide a smoke-free workplace and to discourage the use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

## Background

Food defense is a term used to describe activities associated with protecting the nation’s food supply from intentional adulteration.  FDA has adopted 4 broad strategies that encompass its food defense activities:

(1) Preparedness:  Increase awareness among federal, state, local, Tribal and territorial governments, and the private sector, to better understand where the greatest vulnerabilities lie, and to develop effective protection/mitigation strategies to shield the food supply from intentional adulteration.

Examples include:

(i) vulnerability assessments checklists for the agriculture and food system;
(ii) improving/refining communication and training relating to the FD&ER system;
(iii) develop exercises to test and conduct decontamination and disposal plans;
(iv) develop modeling tools to improve event consequence assessment and decision support; and
(v) prepare risk communication tools and enhance public awareness through outreach.

(2) Detection: Improve upon agriculture and food system detection capabilities.

Examples include:

(i) how to identify contamination in food products at the earliest possible time; and

(ii) conduct an analysis (assessment) of surveillance systems to determine areas for improvements.

(3) Response:  Ensure an efficient response to agriculture and food emergencies.

Examples include:

(i) guidance on how to immediately investigate animal disease outbreaks by suspected food contamination;
(ii) prevent additional human illnesses through spread of contaminated food;
(iii) create tools to help organize, train, and equip animal, plant, and food emergency response teams; of the Federal, State, local, and tribal governments levels;
(iv) databases/tools to design, develop, and evaluate training and exercises carried out under agriculture and food defense/emergency response  plans; and
(v) develop procedures to ensure consistent and organized risk communication to the public by the Federal, State, local, and tribal governments; and the private sector.

(4) Recovery: Secure agriculture and food production after an agriculture or food emergency.

Examples include:

(i) develop business recovery plans to rapidly resume agriculture, food production, and international trade;

(ii) develop training exercises with the goal of long-term recovery results;
(iii) create databases/tools/guides to assist with rapidly removing, and effectively disposing of contaminated agriculture and food products; and infected plants and animals; and
(iv) processes/steps on how to decontaminate and restore areas affected by an agriculture or food emergency.

Stakeholders must determine how to most effectively apply resources within this continuum of activities to best protect the food supply chain and consumers. With regard to prevention and preparedness tools and information, the FDA has provided numerous documents, tools, links and references on the Center for Food Safety and Applied Nutrition's (CFSAN) Food Defense & Emergency Coordination Staff (FDECS) website at www.fda.gov/FoodDefense.

As the FDA continues to move forward our food defense goals by increasing preparedness, encouraging the development of response plans, and ensuring we have the tools to facilitate recovery; we must also integrate these approaches into our existing food safety infrastructure. The known overlap between food safety (unintentional contamination) and food defense (intentional contamination) is extensive. And the pools of resources available are vast and sometimes difficult to locate and implement. Food safety and food defense are ongoing issues and it is critical that these programs be integrated to the maximum extent possible in order to ensure the most efficient use of resources as well as to optimize response to an event.

FDA is committed to this approach in order to make optimal use of both human and financial resources to protect public health. As a result, FDA and State field forces may weave components of food defense awareness and education into food safety inspections. The FDA encourages our regulatory stakeholders to consider the possibilities of incorporating food defense ideas into their food safety related programs.

FDA has relied on our SLTT and other partners to assist with the Food Safety activities through formal contracts, partnership agreements, and other arrangements. Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, and the FDA Food Safety Modernization Act of 2011, the demands on both the agency and the States have increased. Procedures need to be reviewed and innovative changes need to be made. These changes should increase effectiveness and efficiency and conserve resources. CFSAN will continue to support food defense and emergency response programs by providing high quality, science-based work that result in maximizing consumer protection.

FDA continues to believe that these grants will be able to generate innovative and integrated Food Defense & Emergency Response tools and resources that will benefit Federal, State, local, Tribal and territorial governments, industry, and the general public in the area of food defense, as stakeholders have benefited from the Innovative Food Defense Program (IFDP) grant projects in the past.

It is anticipated that innovative and integrated food defense programs and concepts that are developed at the State and local levels could enhance programs that are developed at the Federal level. These grants must have national implications or applications that can enhance Federal, SLTT food regulatory programs and are likely to impact food defense preparedness, response, and/or recovery. At the discretion of FDA, successful project formats will be made available to interested Federal, SLTT food safety regulatory agencies.

To view past innovative food defense program accomplishments that have been generated out of this work you can visit the following link to a PDF document containing summaries of various completed projects:
http://www.fda.gov/downloads/ForFederalStateandLocalOfficials/CooperativeAgreementsCRADAsGrants/UCM281368.pdf

Additional information can be found on the ORA website at:
http://www.fda.gov/ForFederalStateandLocalOfficials/CooperativeAgreementsCRADAsGrants/ucm234305.htm#IFDP.

**Project Goals, Definitions, and Examples**

The specific goal of this program is to generate innovative integrated food defense and emergency response/coordination tools and resources that complement, develop, or may improve State, local, tribal and territorial food defense programs and which may then be applied to food defense programs nationwide. Examples of food defense oversight team tools and resources that are available publicly, online at www.FDA.gov/FoodDefense include: Employees FIRST programs, the Food Defense Mitigation Strategies Database, the Food Related Emergency Exercise Boxed set (FREE-B), Food Defense 101 (ALERT), Food Defense

Plan Builder, among others. Previously CFSAN/FDECS has participated in programs addressing food defense including Food Defense Surveillance Assignments (FDSA); Food Emergency Response Network (FERN) for federal and state laboratories; and the Strategic Partnership Program Agroterrorism (SPPA) Initiative.

Applications that convey unique and innovative, integrated food defense and emergency response/coordination projects and fulfill the following specific project objectives will be considered for funding.

**Application resources may be found** on the Office of Regulatory Affairs, Office of Partnerships website at http://www.fda.gov/ForFederalStateandLocalOfficials/CooperativeAgreementsCRADAsGrants/default.htm.

The "Resources for You" panel is located to the left of the page and contains FAQs and application resources.

**Each application must address only one project.** Applicants may apply for more than one project area, but must submit a separate application for each project. If an applicant should receive a fundable score on more than one topic area only the application with the highest score will be awarded.

There are five (5) key project areas identified for this effort:

**1. Innovative Food Defense & Emergency Response Plan Integration**

One key project area is the development of innovative template food defense plans and associated programs that could be integrated with established food safety programs; including continuous improvement plans for the protection of various food establishments in order to improve food defense effectiveness and efficiency. Innovative/Integrated food defense and emergency response programs and methodology projects must propose to effect factors that contribute to preparedness, detection, response, and recovery in all, or a segment of, food industry programs. For example, projects could address key elements from the Food Defense 101 (ALERT) Initiatives. These proposals should focus on providing efficient and effective food defense and emergency response/coordination awareness communications and/or have an effect on factors that contribute to a potential intentional food adulteration.

**2. Education and Awareness Information Dissemination**

Another key project area is the development of innovative food defense and emergency response/coordination awareness education projects and materials for SLTT regulatory officials. They:

- should foster consistency and uniform application of State and local food regulations
- should be reproducible by other State and local food safety regulatory agencies
- may incorporate concurrent education of both State and local food safety and food defense regulatory agencies and the food industry
- may attempt to compile, evaluate and catalogue into a searchable dataset the myriad of existing food safety and defense related exercises and training opportunities and after action reports that are publicly available, to assess, without attribution to the source of the strength or area of improvement:
- commonality of strengths and areas of improvement needed within regulatory program food emergency response (capturing food safety and food defense) planning efforts,
- resources (human and material) gaps and weaknesses identified, and
- illustration of capability gaps and weaknesses.
- must be consistent with the Food Defense 101 (ALERT)/See Something Say Something Initiatives messages.

**3. Integrated Food Defense & Emergency Response Training**

FDA recognizes that there are a number of new technologies and methods for distance learning and training that may be applicable to the food industry and relevant stakeholders in relation to food defense & emergency response. These should not be duplicative of the basic elements contained within the FD 101 (ALERT) initiatives messages. Unique and innovative Integrated Food Defense & Emergency Response training projects being submitted under this section may include:

- training industry representatives and / or SLTT officials to identify, in a general sense, potential vulnerabilities and risks in relation to food defense in food industry establishments
- training industry representatives and / or SLTT officials to encourage food defense awareness in the employees and management of food industry establishments
- helping to ensure that all stakeholders will have an increased awareness of the threat of intentional contamination of the US food supply
- educating industry representatives and / or SLTT stakeholders to understand their unique responsibilities in reducing the

risk of intentional contamination of the food supply
- Enlisting the use of the Food Related Emergency Exercises (FREE-B) for a series of workshops, seminars and/or tabletop exercises to develop integrated food defense & emergency response capacities or to improve existing food defense & emergency response capacities.

**4. Information Technology / Database Development**

Using current technology is obviously important in facilitating necessary communication, coordination, and information sharing during the response to and recovery from a food emergency. To that end, the focus of this project should be on:

- the creative/novel use of existing technologies; or
- improving existing IT systems, platforms or systems to address the myriad of food defense considerations within the surveillance, recall, traceback/traceforward, GIS mapping
- to the extent possible, the development of information sharing technologies; and/or,
- developing a database to assist other food regulators to be able to view, share, post, and observe the process of the response to and recovery from the incident.

**5. Vulnerability Assessments using FDA's Vulnerability Assessment Software Tool**

The FDA is interested in SLTT regulatory agencies use of the Vulnerability Assessment software tool to conduct vulnerability assessments (VAs). Utilizing the software to conduct these assessments will assist in the identification of vulnerabilities within the farm-to-table continuum and assist in the development of potential mitigation strategies. Sharing the vulnerability and mitigation strategies attained during these can assist the FDA in targeting educational and awareness campaigns, to decrease the likelihood of an intentional adulteration event on the food supply. Sensitive information can be shared through the Department of Homeland Security's Protected Critical Information Infrastructure (PCII) program. These VA's should not be misconstrued as to replace the need for traditional food safety inspections.

## 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 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/CFSAN and ORA intends to fund up to $200,000, for fiscal year 2015 in support of this grant program.

In FY's 2016, 2017, 2018, and 2019:

It is anticipated that up to two (2) will be made, not to exceed $100,000 in total costs (direct plus indirect), per award. The length of support will be for one (1) year from the date of the award. Because the nature and scope of the proposed activities will vary from application to application, the size of each award may also vary.

### 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):

Not to exceed $100,000 per award.

### Award Project Period

One (1) Year

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

Governments

- State Governments
- County Governments
- City or Township Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- U.S. Territory or Possession

Only one grant under this FOA will awarded per State, Tribal Government, Territory, or Possession. Agencies within a State, Tribal Government, Territory, or Possession are urged to collaborate among themselves to submit a single application.

Grantees with a currently funded grant under the Innovative Food Defense Program are not eligible to apply under this FOA.

### 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.
- 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

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), 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 by email to:

Dan Lukash
240/402-7596
Email: daniel.lukash@fda.hhs.gov

## 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 10 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:

Applications must include the following information in the Research Strategy attachment not to exceed 10 pages in length:

- A detailed, sound rationale and appropriate grant design to address the objectives of the FOA.
- The project MUST be generic enough in nature to be used by other SLTT food regulatory agencies.
- A detailed explanation of the desired goals and outcomes of the project.

- A full description of the project design, a detailed implementation plan, methods of execution, and a timeline for completion and provide for a description of the sustainability of the tool or resource that will be developed through this FOA.
- A detailed description of measures of effectiveness and a description of the source documents or data collection methods for establishing the baseline for measurement.
- The adequacy of facilities, equipment, databases, and support services and the expertise of project staff needed for the project.

Applicants should also consider the application scoring criteria (Significance, Investigator(s), Innovation, Approach and Environment) in Section V. when completing the Research Strategy attachment.

**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.

### 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*.

No more than 50% of the total award may be used to conduct food defense exercises. Food Safety agencies may subcontract up to 25% of the award to educational institutions for assistance with developing food defense awareness education projects and materials and training. Subcontract amounts of greater than 25% of the award may be permissible upon program review and approval from the technical review panel and program staff.

Non-allowable costs: Include but are not limited to: (1) Purchase of equipment (defined as an item of property that has an acquisition cost of $5,000 or more); (2) transportation costs exceeding coach class fares; (3) entertainment; (4) tips; (5) bar

charges; (6) personal telephone calls; (7) laundry charges; (8) travel or expenses other than local mileage for local participants; (9) organization dues; (10) honoraria or other payments for the purpose of conferring distinction or communicating respect, esteem or admiration; (11) alterations or renovations; and (12) travel or per diem costs for federal employees. Please also refer to the HHS Grants Policy Statement for additional information regarding costs.

Funds may not be used to offset or to conduct regulatory food inspections for food safety regulatory agencies.

### 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.

For this particular announcement, note the following:

Only the review criteria described below will be considered in the review process. All applications submitted to the FDA in support of this announcement are evaluated for scientific and technical merit through the FDA objective review system.

Applications submitted in response to this FOA 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:

Programmatic merit of the proposed project is determined by objective review, availability of funds, and relevance of the proposed project to program priorities.

## Scored Review Criteria

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

Significance and Relevance (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 the nation's food defense (preparedness, detection, response, and recovery) be improved? How will

successful completion of the project goals support the agency's objectives for the nation's food defense?

Is the purpose of the project plan and its relevance to FDA's mission clear? Is the project plan timely in terms of currency of the issues to be addressed and the amount of interest that may be generated in response? Are milestones clear, defined, applicable, and timely as projected?

Project Staff and Resources (15 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 the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; do their leadership approach, governance and organizational structure seem appropriate for the project?

Does the experience, training, or other indication of competence support the selection of the principal investigator/director as the key person to manage this particular project? Does the proposed team bring complementary and integrated expertise to the project (cross functional)? Is the support staff adequate to complete the project successfully? Does the project appear to have adequate resources to implement their project plan? Does the project team appear to have the necessary institutional support, equipment, and other physical resources available?

Integration and Innovation (30 Points)

The applications should present sufficient information to demonstrate that such work develops or employs novel concepts, approaches, methodologies, tools, or technologies for food defense preparedness, detection, response, and recovery within the respective state. Is the work plan original and clearly stated? Are the innovative ideas attainable and reasonable? How collaborative is the approach at an intra-state level? Does the project promote the integration of food defense into existing infrastructure? Is the project proposal unique and does it identify only one of the project areas?

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?

Reproducibility (15 Points)

Does the project plan address how to generate innovative integrated food defense and emergency response/coordination tools and resources that complement, develop, or may improve State, local, tribal and territorial food defense programs and which may then be applied to food defense programs nationwide? Do the tools and resources proposed from this project appear to be easily reproducible by other parties? Does the plan clearly explain how they will present the final outputs of the project for future use by other parties?

## 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.

> Does the amount requested from FDA appear reasonable as partial support of the total work plan, facilities, staff, etc.? Is the budget organized, reasonable, and clearly stated? Does the budget account for the proposed work plan?
>
> Budget area should be considered by the reviewers, but they will not give scores for these items, and should not consider them in providing an overall impact/priority score.

## 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.

All conference material (promotional materials, agenda, publications and internet sites) related to this project must include an acknowledgement of FDA grant support and a disclaimer stating the following:

"Funding for this conference was made possible [in part] by [insert grant number] from [insert FDA Center/Office name]. The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services; nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government."

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

**Project outputs will be made available to the Agency in full, for use at its discretion.**

Cooperative Agreement Terms and Conditions of Award

The administrative and funding mechanism used for this program is cooperative agreement, an "assistance" mechanism in which substantial FDA programmatic involvement with the awardees is anticipated during the performance of the activities.

Under the cooperative agreement, FDA's 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, although specific tasks and activities may be shared among the awardees and FDA as defined below.

a. All awardees are required to participate in a cooperative manner with FDA.

b. Awardees will 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 polices.

c. An agency program official or a Center program director will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice. FDA staffs have substantial programmatic involvement that is above and beyond the normal stewardship role in awards as described below.

Principal Investigator(s) (PI)/Program Director (PD) responsibility

The Principal Investigator (PI)/Program Director (PD) will have 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) 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 prepare justifications; appropriately acknowledge Federal support in publications, announcements, news programs, and other media; and ensure compliance with other Federal and organizational requirements.

The awardee is responsible for submitting interim progress reports (e.g. at specified intervals), when requested, to the FDA Project Officer (PO) and the Grants Management Specialist (listed as contacts on the Notice of Grant Award) including summary data on progress and expenses to date.

The awardee is encouraged to publish and publicly release and disseminate results, data and other products of the cooperative agreement, concordant with the governance and the approved plan for making data and materials available to the scientific community and FDA. Awardee will work with the appropriate FDA staff to develop and implement an appropriate rapid data release policy.

Manuscripts shall be submitted to FDA Project Officer within two weeks of submission for publication. Publications or oral presentations of work performed under this Cooperative Agreement will require appropriate acknowledgement of FDA support. Timely publication of major findings is encouraged

The awardee is responsible for obtaining approval for the development and design of FDA projects prior to execution.

FDA Project Officer Responsibility

An FDA Project Officer (PO) with scientific/technical expertise and other members of the FDA staff will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

The responsibilities of the PO include involvement during conduct of the activity, through technical assistance, advice, coordination, and/or other assistance activities.

As appropriate, the PO will participate in the definition of objectives and approaches, and in planning, conducting, and publishing resulting work from activities under this cooperative agreement. However, the dominant role and prime responsibility for the activity reside with the awardees(s) for the project.

The PO will be responsible for the administration and general programmatic stewardship of the award and have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

The FDA through the PO will have access to data generated under this Cooperative Agreement and may periodically review the data and progress reports. The FDA PO may use information obtained from the data for the preparation of internal reports on the activities of the cooperative agreement. However, awardees will retain custody of and have primary rights to all data developed under these awards or as stated in the terms and conditions of award.

Retain the right to have prior approval on the appointment of all key personnel substantially supported by the grant.

Be directly involved in the guidance and development of the program and the collaborative structure of for the program.

Participate with the grantee in determining and carrying out the approaches to be used. Collaboration will also include identifying topics, agendas, participants, and dissemination of findings and where appropriate, co-authorship of publications.

Arrange to have professional scientific and administrative/clerical personnel working in collaboration with the grantee as required.

Collaborative Responsibilities

As relevant, the PD/PIs in collaboration with PO will work collaboratively in evaluating the most appropriate methods, publication and dissemination of findings. Projects require FDA approval prior to implementation/initiation.

During performance of the award, the PO, with assistance from other program staff, designated based on their relevant expertise, may provide appropriate assistance, advice and guidance. The role of the PO will be to facilitate and not to direct the activities. It is anticipated that decisions in all activities will be reached by consensus between the PD/PI and the PO and that the FDA programmatic staff will be given the opportunity to offer input into this process. The PO will facilitate liaison activity for partnerships, and provide assistance with access to FDA supported resources and services.

The FDA will work collaboratively to identify and coordinate training, professional development and training-related scientific exchange opportunities.

Dispute Resolution Process

Any disagreements that may arise in technical or programmatic matters (within the scope of the award) between award recipients and the FDA may be brought to Dispute Resolution. A Dispute Resolution Panel composed of three members will be convened. It will have three members: a designee of the FDA staff, one recipient designee, and a third designee with expertise in the relevant area that is chosen by the other two; in the case of individual disagreement, the first member may be chosen by the individual awardee. This special dispute resolution procedure does not alter the awardees' right to appeal an adverse action that is otherwise appealable in accordance with PHS regulation 42 CFR Part 50, Subpart D and DHHS regulation 45 CFR Part 16.Disallowance of Cost.

Copyright

Except as provided in the conditions of the award, when a publication or similar copyrightable material is developed from work supported by HHS, the author is free to arrange for copyright without approval of the FDA. Such copyrighted materials are subject to a royalty-free, nonexclusive, and irrevocable license to the Federal government to reproduce them, translate them, publish them, and use and dispose of them, and to authorize others to do so for Federal government purposes.

### 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.

Awardees have primary authorities and responsibilities to define objectives and approaches, and to plan, conduct, analyze, and publish results, interpretations, and conclusions of their work.

An agency Program Official or Project Officer will be responsible for the normal technical and programmatic stewardship of the award and will be named in the NoA.

A mid-year Progress Report is required no later than thirty (30) days after the initial six (6) months of the budget period. The mid-year Progress Report should contain a description of project activities covering a six-month period. A report template will be provided to grantees by the Grants Management staff.

A final report of the outcomes of the grant and a final Financial Status Report (FSR) are required within 90 days of the expiration date of the project period as noted on the Notice of Grant Award, and in the HHS Grants Policy Statement. The report should include full written documentation of the project, copies of any results, materials, and project deliverables, as described in the grant application, and an analysis and evaluation of the results of the project. The documentation must be in a form and contain sufficient detail such that other State and local food safety regulatory agencies could reproduce the final tool or resource.

Program monitoring of recipients will be conducted on an ongoing basis and written reports will be reviewed and evaluated by the project officer. Project monitoring may also be in the form of telephone conversations between the project officer/grants management specialist and the principal investigator and/or a site visit with appropriate officials of the recipient organization. The results of these monitoring activities will be recorded in the official file and may be available to the recipient upon request. Quarterly conference calls and web meetings are also conducted, and recipients are expected to participate in these information sharing opportunities.

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.

## 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 Center Telephone: 800-518-4726
Web ticketing system: https://grants-portal.psc.gov/ContactUs.aspx
Email: support@grants.gov

### Scientific/Research Contact(s)

Carrol Burgundy
Food and Drug Administration (FDA)
Telephone: 240-402-2158
Email: carrol.burgundy@fda.hhs.gov

Graham N. Giesen
Food and Drug Administration (FDA)
Telephone: 214-790-4986
Email: graham.giesen@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 42 USC 247b20 and 21 UCS 2014.) and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75.

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Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

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National Institutes of Health
*Office of Extramural Research*

Department of Health
and Human Services (HHS)


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