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)
Office of Foods and Veterinary Medicine (OFVM)

Funding Opportunity Title

Food Protection Rapid Response Team (RRT) (U18)

Activity Code

U18 Research Demonstration – Cooperative Agreements

Announcement Type

New

Related Notices

None

Funding Opportunity Announcement (FOA) Number

RFA-FD-15-020

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 goal of these cooperative agreements is to facilitate long-term improvements to the national integrated food safety system by unifying and coordinating federal/state/local food/feed emergency response efforts including:

1) Strengthening the link among epidemiology, lab and environmental health/regulatory components;

2) Improving States' regulatory and surveillance food/feed protection programs to include using Incident Command System (ICS)/National Incident Management System (NIMS) principles and a Unified Command structure to conduct integrated responses to all-hazards food/feed emergencies, rapidly identifying and removing tainted food from commerce, and conducting root cause investigations to inform future prevention efforts; and

3) Addressing supporting components, such as training, data sharing, data analysis, communications, continuous process improvement, and development of best practices and other resources to support national capacity/capability development.

This will be accomplished through the provision of funding to support multi-jurisdictional, multi-disciplinary Rapid Response Teams (RRTs) for program improvement and will require extensive cooperation and coordination with FDA District Offices and other FDA program offices.

Key Dates

Posted Date

May 6, 2015

Open Date (Earliest Submission Date)

May 15, 2015 and January 5, 2016

Letter of Intent Due Date(s)

May 28, 2015 and January 15, 2016, by 11:59 PM Eastern Time.

Application Due Date(s)

July 15, 2015 (FY2015) and March 8, 2016 (FY2016), by 11:59 PM Eastern Time.

The application requirements/content, as described in this RFA, shall be the same for all application due dates, with the exception that applications from State food safety agencies who are currently receiving funding under RFA-FD-12-013 are eligible to apply in FY15 and FY16, and State food safety agencies who are currently receiving funding under RFA-FD-13-006 are eligible to apply only in FY16. Applications submitted for the July 1,2015 due date may include budgets for a maximum three (3) year project period, and applications submitted for the March 8, 2016 due date may only include budgets for a maximum two (2) year project period.

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 and March 2016

Advisory Council Review

Not Applicable

Earliest Start Date

September 1, 2015 and September 1, 2016

Expiration Date

March 9, 2016

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide, except where instructed to do otherwise (in this FOA or in a Notice from the *NIH Guide for Grants and Contracts*). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

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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Section I. Funding Opportunity Description
Program Objectives

The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Office of Partnerships (OP), in collaboration with the Office of Foods and Veterinary Medicine (OFVM), is announcing the availability of up to 18 cooperative agreements to be awarded under a Limited Competition (up to 9 awards in fiscal year 2015 and up to 9 awards in fiscal year 2016).

The goal of these cooperative agreements is to facilitate long-term improvements to the national integrated food safety system by unifying and coordinating federal/state/local food/feed emergency response efforts including:

1) Strengthening the link among epidemiology, lab and environmental health/regulatory components;

2) Improving States' regulatory and surveillance food/feed protection programs to include using Incident Command System (ICS)/National Incident Management System (NIMS) principles and a Unified Command structure to conduct integrated responses to all-hazards food/feed emergencies, rapidly identifying and removing tainted food from commerce, and conducting root cause investigations to inform future prevention efforts; and

3) Addressing supporting components, such as training, data sharing, data analysis, communications, continuous process improvement, and development of best practices and other resources to support national capacity/capability development.

This will be accomplished through the provision of funding to support multi-jurisdictional, multi-disciplinary Rapid Response Teams (RRTs) for program improvement and will require extensive cooperation and coordination with FDA District Offices and other FDA program offices.

Effective leveraging of resources and harmonization of efforts shall require collaboration with relevant initiatives, including those of federal partners (e.g., FDA, the Centers for Disease Control and Prevention (CDC) and the US Department of Agriculture (USDA) Food Safety and Inspection Service), national initiatives (e.g., the FDA Food Safety Modernization Act, the Integrated Food Safety System (IFSS), the National Response Framework, and the Partnership for Food Protection (PFP)), and relevant associations, state, and local partners.

The funding opportunity purpose, program objectives and yearly goals are in accordance with the RRT Program 5 Year Plan. The RRT Program 5 Year Plan (posted in the RRT Program Workgroup in FoodSHIELD) consists of 6 Program Objectives, summarized in the below table.

Program Objective	**Goals & Outcomes**
	Propagate Best Practices & Lessons Learned
Mentorship	1) Develop a national RRT mentorship program (incorporating regional elements), including establishment of basic expectations for mentors/mentees and mechanisms to facilitate mentorship match-ups and track and evaluate progress.
	2) Develop programmatic infrastructure to support implementation of the RRT Concept and Best Practices Manual by funded and non-funded RRTs.
RRT Capability Data Capture & Assessment	Measure Current Performance and Meaningful Success
	1) Measure process improvement, increases in efficiency/effectiveness and success at the individual RRT level and across the RRT Program.
Communication	Transparency & Information Sharing
	1) Ensure transparency of objectives and outcomes for the RRT Program.
	2) Actively promote and justify sustainment of the RRT Program and individual RRTs through strategic application of capability data capture/assessment and enhanced communications, to include promotional materials.
Post Response & Prevention	Lessons Learned, Corrective Actions & Continuous Improvement
	1) Ensure documentation and follow up for lessons learned to support prevention and facilitate continuous process improvement.
	2) Operationalize models to analyze outcomes from concluded responses, identify causing factors and develop and effectively communicate recommendations for prevention.
RRT Maturity & Maintenance	Maintenance & Maturity of the RRT Concept: Innovation and Integration
	1) Develop multi-jurisdictional RRTs (minimum District/State) that operate under ICS/NIMS to support integrated all-hazards prevention, response and recovery efforts for food/feed.
	2) Ensure continual improvement of the RRT Concept through investment in new models, capabilities and methodologies to improve and enhance response.
	3) Ensure adequate training opportunities to support development and maintenance of RRT capabilities.
Sustainability	Program Evolution, Viability & Relevance
	1) Document and support successful efforts on the part of RRT state components towards sustainability of capabilities developed under the RRT cooperative agreement.
	2) Formalize and make operational the RRT Program's role within a national, cohesive approach to response capacity and capability building (standards, best practices, innovation).
	3) Obtain management support and begin to implement a strategy to align the structure, function and capabilities of RRTs within the context of the National Response Framework, including development of

infrastructure to support coordination of inter-RRT surge capacity, such as regional support structures.

The projects funded under these cooperative agreements shall be in alignment with the RRT Program 5 Year Plan and must be specifically designed by the grantee to help their respective RRT meet the yearly goals as outlined in this RFA.

Additionally, these cooperative agreement funds are intended to supplement, not replace, State funding for food protection program improvement and activities. States funded under these cooperative agreements may be required to provide the previous and subsequent years of State funding to demonstrate that these funds have not replaced State allocations for the food protection program.

I) All-Hazards Food/Feed Rapid Response Teams (RRT) Concept

I.A) Background

The complex challenges in the food safety arena require new, creative responses. However, no greater challenges exist than in our ability to swiftly investigate and take appropriate measures to control foodborne outbreaks. The scope and complexity of each outbreak varies significantly, and routine GMP inspection procedures are ineffective in understanding how and why foodborne outbreaks occurred. In some cases, extensive in-plant inspection and environmental investigation including environmental and human or animal sampling from a single facility may be required. In other cases, data/invoices from a web of inter-related firms throughout the State may be needed. Moreover, the inclusion of epidemiologically based environmental investigations is needed. In light of these new, complex challenges in food safety, there is a continued need for an integrated rapid response team concept that facilitates effective, coordinated responses, starting within hours of the verification of a foodborne outbreak or other food protection emergencies.

To address these concerns, this Cooperative Agreement seeks to develop, implement, improve, and integrate rapid response capabilities (both innovative/unique and those considered to be core capabilities) into a resource (the “RRT Concept”) that can effectively and rapidly respond to food/feed incidents. This effort integrates with related FDA components and other national programs, such as the FDA Coordinated Outbreak Response and Evaluation Network (CORE), Centers for Disease Control and Prevention (CDC) Integrated Food Safety Centers of Excellence, CDC Foodborne Diseases Centers for Outbreak Response Enhancement (FoodCORE) and Environmental Health Specialists Network (EHS-Net), to collaboratively improve the various, interdependent facets of food incident response. RRTs are also encouraged to use the Guidelines and Toolkit developed by the Council to Improve Foodborne Outbreak Response (CIFOR), which has provided recommendations for program policies in foodborne outbreak response.

I.B) The RRT Concept Framework and Best Practices Manual

The RRT Concept and these cooperative agreements focus on the development and maintenance of rapid response infrastructure and capabilities within the five phases of food/feed incident response: preparedness, surveillance/detection, investigation, control/mitigation, and post-response/prevention. The framework also delineates four core elements (collaboration, communication, written policies and procedures, and resources) that are essential to having an effective capability for each of these phases; and lastly, this framework identifies how continuous improvement and sustainability must be involved throughout the entire system.

The RRT Best Practices Manual is a collection of best practices (e.g., lessons learned, tools) identified by the RRTs that are considered foundational for conducting effective multiagency responses. Each chapter within the RRT Manual represents a unique rapid response capability that falls within one of the five phases of response, and incorporates each of the four core elements as described above, as well as a series of achievement levels for measuring and assessing continuous improvement of that rapid response capability.

For the purposes of these cooperative agreements, sustainability is considered to be the development of mechanisms to support or maintain a portion of products, outcomes or accomplishments achieved under funding provided by these cooperative agreements. A requirement of these cooperative agreements is that the grantee creates and maintains a sustainability plan (See Section III, Goals). Approaches to sustainability can vary widely, and may include incorporation of RRT processes and procedures into state/local program SOPs or IT systems, transfer of a portion of cooperative agreement supported personnel onto state or local program funds over time to secure a FTE, or cross-training of staff external to those funded by this agreement (to support RRT activities in routine or surge capacity scenarios). Innovative sustainability approaches are encouraged.

The RRT Concept is described in detail within the RRT Manual (available upon request to FDA OP at OP-ORA@fda.hhs.gov).

I.C) Rapid Response Team Members

1) RRT Members

Although RRT Structure will vary on a case-by-case basis, the following components must be represented on the RRT. It is permissible that projects funded under these cooperative agreements have the aim of furthering incorporation of these components within the RRT.

a) FDA District Office

The nucleus of the RRT is considered the grantee state agency and the corresponding FDA District Office. The FDA District Office will designate one or more persons to be the main point of contact representing the District Office on the RRT, and designate other personnel to participate in RRT activities as appropriate (e.g., joint trainings, joint inspections, joint investigations, etc.).

b) Food Program

This should represent the grantee agency, and is deemed the 'lead' state agency within the RRT. It is a requirement of eligibility for this award for the grantee to be enrolled in the Manufactured Food Regulatory Program Standards. In addition, state regulatory agencies with authority over meat, shellfish, Grade A milk and retail should also be included within the RRT.

c) Feed Program

Each Rapid Response Team should include at least one person representing the State's feed regulatory program. The definition of "food" in section 201(f) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) includes human food, animal feed, and ingredients used in each of those classes of products. Many animal feeds contain food processing byproducts, many firms make ingredients for both types of products and, often, salvaged food products are used as animal feed. As a result, it is important that each RRT be able to work with the State feed regulatory program to prevent food emergencies from becoming feed emergencies and vice-versa. Consideration should be given to collaboration with animal health veterinarians and other food animal programs.

d) Epidemiologists

Each Rapid Response Team should ensure inclusion of epidemiological representatives, specifically, an epidemiologist representing the State's entity with primary responsibility for surveillance and epidemiological investigations of foodborne outbreaks. It is important that there is an intentional and effective partnership between the regulatory/environmental health, surveillance, epidemiology, and laboratory components of the public health system to ensure optimal communication and collaboration during responses to foodborne illness outbreaks.

e) Laboratory

For laboratory support, the RRT shall develop the proper protocols and agreements with both the FDA and/or other federal or State labs for analytical support during foodborne outbreak investigations. The labs would support existing technology for field-based analytical methods like temperature, adenosine triphosphate (ATP) measurements (luminometers), residual chlorine, quaternary ammonium indicators, microscopy, pH, water activity, ORP, and salt content that could be used on-site. Additionally, as approved, real-time technologies could be pilot-tested during actual outbreak investigations.

All lab participants on the response team should be fully trained in team inspections. Lab SMEs (e.g. microbiologists, chemists) shall provide current information on emerging pathogen analytical methodology and servicing lab capability. Lab SMEs shall also keep current information on the best shipping methods to the servicing lab. Purchase of laboratory and investigation sampling equipment (with approval of awarding Agency) and supplies should be considered in the budget for the application. Appropriate development and storage of sampling kits for use in a rapid response should be incorporated.

Uniformity in sample collection is essential to achieve consistent results with multiple serving laboratories. The RRT investigators could use the FDA Investigations Operation Manual (IOM) and compliance program guides or equivalent State procedures to standardize sample size and collection methods. Coordination between the RRT and laboratories is essential to maximize the outcome of foodborne illness response.

f) Local Health Partners

Each RRT should develop a strategy to incorporate key local health department partners in appropriate RRT activities (e.g., situational awareness, coordination for targeted activities, such as recalls, investigations involving the retail point of service,

etc.). The move towards a nationally integrated food safety system requires effective integration across all levels of government. As the RRT concept develops, it is important to develop effective models of collaboration in food emergency response to include local partners. It is encouraged that all local health partners involved in the RRT also enroll in the Voluntary National Retail Food Regulatory Program Standards (as well as those state agencies with authority over retail foods).

2) RRT Responsibilities

All members must be familiar with procedures (and any updates to the procedures) associated with the RRT, including but not limited to Joint Investigations/Inspections, Communication Standard Operating Procedures (SOPs), Environmental Assessment Inspections, After Action Reviews, Food Emergency Response Plans, etc.

Other duties/responsibilities of the RRT members could include:

a) Training

Complete detailed training in subjects according to the RRT Training plan (should be aligned with and meet the minimum requirements of the Training Chapter of the RRT Best Practices Manual). Important training areas include: foodborne illness investigations; ICS (100, 200, 300, 400, position specific); sampling techniques; tracebacks; farm investigations; and commodity-specific investigations such as sprouts, eggs, leafy greens, etc. It is important that the RRT delineate in their training plan what training requirements are applicable to which types of RRT members.

RRT members should also provide response-based training for other local, state or federal investigators and industry groups, as appropriate. Additional staff in the food and feed protection programs and in other relevant organizations (e.g., other RRT member agencies, as appropriate) should be trained as a resource to provide surge capacity to the RRT in the event that additional assistance is needed. In particular, a train the trainer approach for response-based activities (such as sampling, recall effectiveness/audit checks, traceback/traceforward, etc.) that reaches the local responder level is highly encouraged.

Unless circumstances mandate otherwise, RRT members (especially state and District investigators) should engage in joint training. This is in accordance with one of the key principles laid out in the Training Chapter of the RRT Best Practices Manual, and helps provide a uniform foundation for rapid response as a team. When true joint training is not possible and separate training courses must be offered in order to reach the full target audience, every effort should be made to coordinate training offerings so as to provide equivalent training content/materials for team members.

All training efforts related to the RRT that promote the training of personnel external to those funded exclusively on this cooperative agreement should be considered to be in support of sustainability of the RRT concept.

Where feasible, RRTs should consider inviting or including other RRTs to participate in training events and/or make available these training materials to other RRTs through FoodSHIELD or other appropriate avenues.

b) “Expertise” Development:

Each RRT investigator should become an "expert" in at least one core component of rapid response (e.g., commodity-specific agricultural practices, manufacturing processes, water, wildlife, soil amendments, ICS/NIMS). This investigator would then be responsible for training other staff in this area so that there is at least one back-up for each area of expertise on the team.

Records related to the RRT expertise development plan and current summary of team member expertise should be included in the RRT Training Plan.

I.D) RRT Functions

This section describes essential or high-interest RRT functions (as per OP), and a base level of accomplishment (as outlined and assessed in the yearly RRT Capability Assessment) is required by all grantees. As such, it is permissible that projects funded under these cooperative agreements have the aim of accomplishing one or more of these RRT functions.

As 'high-interest' RRT functions, the following topics should also be considered as potential areas for special projects under these cooperative agreements by RRTs that wish to further enhance and build their capability to perform these functions.

Although multiple RRT members (including those outside of the grantee agency) might work on and contribute to special projects focused on these topics or other RRT functions, at least one representative from the grantee agency must be routinely involved

in the special project or otherwise be part of a regular communication channel. The grantee agency is encouraged to submit budget items in their application that support a state or local RRT member agency outside of their own in accomplishing special projects or carrying out other RRT functions, including prevention efforts.

This listing is not inclusive of all rapid response capabilities.

1) Team Development, Maintenance and Response

This “RRT” resource within the state should have the appropriate authority, expertise, and training to investigate foodborne illness outbreaks and other food hazards/emergencies (e.g., natural disasters, bioterrorism, and power outages) from “farm to table.” Although the RRTs involved in this cooperative agreement all have varied circumstances and needs, each RRT will include relevant partner organizations (including FDA District Offices, other state agencies [i.e. those with epidemiological, laboratory and environmental health/regulatory responsibilities for food and feed]) in the decision-making process and optimize the use of resources while aligning with preparedness plans. When appropriate or necessary, the RRT (representing all component agencies) will use expandable ICS protocols and structures to respond to an outbreak, and mitigate the problem (e.g., remove the contaminated product from commerce). When appropriate, RRTs will work to identify sources of contamination and contributing factors/antecedents for the outbreak, reaching conclusions and identifying possible interventions for the prevention of future incidents whenever possible. The RRT Best Practices Manual will help to support the development and maintenance of rapid response capabilities and is expected to be incorporated into existing state and local programs so that they may remain viable beyond the project period of this cooperative agreement. Additionally, in accordance with the RRT Best Practices Manual CIFOR Chapter, RRTs should incorporate the CIFOR Guidelines and Toolkit into their RRT development/improvement process.

2) Traceback Capabilities

As part of the RRT concept, State and federal partners should continuously improve the effectiveness, standardization, and coordination of their traceback capabilities for investigating foodborne illness outbreaks. Accomplishing improvements in this area could include training of State and local resources in conducting tracebacks; implementing best practices identified by RRTs and other relevant initiatives (e.g., the Council to Improve Foodborne Outbreak Response [CIFOR] Guidelines); and addressing areas of improvement based on after action reviews of responses and exercises. RRTs should continue to identify best practices in tracebacks, including exploration of different approaches and tools (e.g., industry resources, new information technology (IT) options, working with epidemiologists). Routine traceback investigations require skilled, highly trained staff to ensure rapid, accurate collection and analysis of relevant records. Traceback investigations will occasionally be needed to help inform and guide epidemiologic investigations where traditional approaches are unable to pinpoint the specific food responsible for illnesses or outbreaks.

3) Recalls and Market Withdrawals of Food Products/Foodborne Illness Reporting

As part of the RRT concept, State and federal partners continuously improve the effective use of resources to quickly notify consumers and ensure prompt removal of suspect or contaminated products from commerce. This optimizes the ability of the RRT to function within “mitigation/control” phase of a food/feed incident and plays a critical role in maximizing food protection. Accomplishing improvements in this area (which could be demonstrated by quantifying accomplishments and timeframes for each incident) could include: training of State and local resources; working with industry groups and major retailers/distributors to understand distribution patterns in advance of incidents; and considering use of RRT partners, emergency response resources and other innovative concepts to facilitate the effective removal of product from sale or distribution. The RRT should work with partners at the state, federal and local levels to facilitate better and more rapid communications for national, local, or regional recalls that could be the model for use with other RRTs. Transparency in results and efforts should be a goal in recalls and illness reporting.

4) Environmental Assessment Inspections (EAs)

Important note: the term 'EA inspection' is used consistently throughout this RFA in order to align with FDA's policy that EAs in which FDA is involved be conducted under FDA's inspection authority. FDA fully recognizes and acknowledges that EAs are not necessarily a routine inspection and could require a completely different mindset and process, depending on the context in which they are conducted. The 'inspection' portion of this term refers solely to the need to conduct the EA under the appropriate regulatory authority and should not be interpreted otherwise or used in any other way to qualify, describe or classify an EA.

A purpose of an EA inspection is to identify potential contributing factors and environmental antecedents to foodborne illness outbreaks to provide a regulatory program/agency and industry with information to inform prevention efforts and

compliance/regulatory policies.

In the context of RRT activations or any RRT initiated activities, EA inspections are carried out by Subject Matter Experts (SMEs), which should include representatives from all relevant members (agencies) of the RRT, as appropriate (e.g., the state food regulatory program and the District Office). EA inspections that are conducted under FDA's inspection authority may only include participants who are authorized to conduct inspections under FDA's authority (e.g., FDA employees, commissioned/credentialed individuals, special government employees). Depending on the scenario, representatives from FDA Centers or academic experts may also be included, as appropriate. All agencies and personnel participating in joint EA inspections (particularly joint District-State EA inspections) must coordinate inspection activities in advance. EA inspection activities when any FDA component is involved (including appointing the lead agency for the EA inspection) must be done in accordance with current FDA policy. During a joint EA inspection, SMEs perform EA activities complementary to and in conjunction with each other.

The data and information collected during an EA inspection are more extensive and detailed than what is typically possible to obtain during a routine regulatory inspection and are critical to understand the contributing factors and environmental antecedents that caused a foodborne illness outbreak or food contamination event.

5) Exercises

In the absence of a RRT activation (under ICS/NIMS and Unified Command) involving an after action review and development and subsequent implementation of recommendations during a given grant year, the RRT must complete at least one annual exercise that incorporates the use of ICS and all members of the RRT to promote team building of the RRT and continuous improvement. In either case (activation or exercise), at a minimum, an after action review should be conducted and the following documentation should be maintained and shared with other RRTs as requested by OP:

1. An incident summary which, at a minimum, defines and describes the size, scope and distribution of the incident.
2. A list of recommendations and appropriate tracking of subsequent implementation of recommendations

Should a national RRT exercise be held during this funding opportunity's project period, RRTs (at a minimum the funded agency and FDA District Office) shall be required to participate.

6) Communication and Coordination with Industry and Other Stakeholders

The RRT should initiate and maintain contacts with: major food manufacturers, processors, wholesalers, distributors, warehouses, and retail chains; city or county environmental health officers and county public health officers; and academic or private experts in selected areas of interest/need (e.g., surface water, well construction, wildlife, etc), university researchers and extension programs. It is also important to obtain 24-hour emergency phone numbers for contact persons and become familiar with strengths and weaknesses of existing databases for tracebacks and for locating growers, shippers, packers, wholesalers, and retailers. This is in line with concepts outlined in MFRPS Standard #7 - Industry and Community Relations.

These contacts can and should be leveraged for a host of preventive and preparedness activities, as appropriate, to include training and outreach. At a minimum, the maintenance of these contacts will increase the efficiency and effectiveness of the RRT when responding to incidents requiring communication and coordination with these stakeholders.

RRTs are encouraged to leverage State Food Safety/Defense/Protection Task Forces, where appropriate, to achieve these goals, provided that funding streams are kept separate if the grantee agency is also a recipient of a FDA Food Protection Task Force Conference Grant. Online collaborative and information sharing resources, such as FoodSHIELD or the in development Task Force Mobile App, can also be a valuable asset in achieving these goals.

For example, the applicant could propose using a State Food Protection Task Force as a mechanism to facilitate new interventions, methods, communication strategies, and other tools to expedite recalls and foodborne illness reporting. See Program Announcement FD 09-005 or PAR-09-123 located at http://www.grants.gov/.

Desired areas of inter-program coordination include with CDC programs such as FoodCORE, EHS Net, FoodNet; the Food Emergency Response Network (FERN), a nationally integrated network of food-testing laboratories that can support emergency responses; and with partners at the US Department of Agriculture (USDA) and the Department of Homeland Security (DHS). In addition, RRTs are encouraged to develop relationships with one or more of the five existing Food Safety Centers of Excellence which were established, per FSMA, to identify new approaches to surveillance and response. These programs have relevant and overlapping goals and activities for food incident response that should be coordinated with

RRT activities whenever possible.

Information on some of these initiatives can be located at: http://www.cdc.gov/ncezid/dfwed/orpb/index.html; http://www.cdc.gov/nceh/ehs/default.htm; http://www.cifor.us/; http://www.fernlab.org/

II) Regulatory Program Standards

A portion of the infrastructure necessary to develop and sustain rapid response capabilities is established using regulatory program standards, to include the Manufactured Food Regulatory Program Standards (MFRPS), the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS) and the Animal Feed Regulatory Program Standards (AFRPS). These Regulatory Program Standards provide the foundation with which to assess and continually improve the infrastructure of a State food regulatory program. Standard 5 within each of the Regulatory Program Standards is focused on response. Although the RRT Concept and the Regulatory Program Standards are separate and distinct, both programs contain elements that complement each other in achieving a common goal (strengthening food/feed regulatory program infrastructure to enhance the ability to respond to food/feed incidents). The RRT program plays a vital role in establishing innovative best practices that may be incorporated into the regulatory program standards. As such, you will notice references to specific sections of regulatory program standards throughout this RFA.

Each partner state that is awarded funding through the RRT cooperative agreement must be enrolled and actively working towards conformance/implementation of at least the MFRPS. However, it is vital for all grantees to understand that funding streams must be kept separate and non-duplicative if the grantee is a recipient of multiple funding agreements, such as the MFRPS, AFRPS or VNRFRPS Cooperative Agreements.

For more information on the Regulatory Program Standards, please visit the following resources:

1) MFRPS: http://www.fda.gov/ForFederalStateandLocalOfficials/PartnershipsContracts/Overview/default.htm.

2) VNRFRPS: http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ProgramStandards/default.htm.

3) AFRPS: http://www.fda.gov/ForFederalStateandLocalOfficials/AnimalFeedRegulatoryProgramStandardsAFRPS/default.htm.

III) Expected Goals

These goals represent yearly requirements for grantees receiving these cooperative agreements. Goals are aligned with the Program Objectives as outlined in the RRT 5 Year Plan (described above in this RFA).

Applicants must address how they plan to meet these yearly goals in their application. Grantees shall be required to report out the status of accomplishments for each goal in mid-year and annual reports.

As applicants may request up to three years of funding through this cooperative agreement, one set of goals is provided that shall apply to each grant year. FDA has a strong desire to promote a long-term working relationship in order to provide to each project ample time to fully develop and implement its desired goals and outcomes. The activities proposed by each applicant should demonstrate evolution/growth over the duration of the project period, providing a timeline to fully develop, build, and achieve sustainable outcomes for the applicant's RRT.

Expected Goals **(RRT Base Award):**

Mentorship: 1. A. All RRTs: RRTs may mentor non-funded RRTs (as assigned by FDA Office of Partnerships (OP)) in RRT development as per the RRT Capacity Building Process and Mentorship Framework. Note that 1.A, 4.B, 4.C, 5.B and 5.C are voluntary goals. However, grantees must elect to address at least two of these voluntary goals each grant year.

Mentorship: 1. B. All RRTs: (Innovation and National Capacity/Capability Development): RRTs will participate in individual, multi-state or national initiatives to undertake innovative approaches to response and/or create and provide tools and resources to help others enhance their ability to effectively respond to food/feed contamination incidents (e.g., develop a capability/implement best practices, increase capacity, enhance communications/information sharing).

- Examples of innovative approaches/projects envisioned include: use of emerging/new technology or use of existing technology in a new way, piloting a new process or innovative elements to an existing activity/process. At its conclusion, innovative projects should undergo a cost/benefit analysis, which should include an assessment of its impact on the period of time between agency notification of an incident and implementation of effective control measures. Other suggested projects include:
  1) On-site evaluation of a “high risk” (as identified under MFRPS Standard #3) food, commodity, or specific type of

producer, manufacturer or processor (such as LACF/Acidified Foods, and including high-risk animal feed and produce/farms as well), or participation in a special study and assessment to provide additional insights into how food may become contaminated within the farm to fork continuum (non-retail point of service focus). The evaluation/exercise/study should be done in collaboration with the FDA District Office and other relevant RRT member agencies/partners, and RRTs are encouraged to use a HACCP and/or CARVER + Shock approach. Results should be documented in the form of a final report, programmatic paper, and/or technical document to identify specific hazards and critical control points, strengths of the response team efforts, recommendations and needed improvements.
2) Creation of coordinated District-State surveillance (sampling) assignments for products and contaminants of concern. Assignments should involve coordination of District-State sampling and laboratory testing capacity, and incorporate appropriate measures so as to ensure District and/or State regulatory or compliance action throughout all components of the assignment. Assignments should be targeted (e.g., risk-based; aimed at identifying points of contamination for a product within the farm to fork continuum or to address other strategic needs; and innovative approaches are encouraged). These projects may complement or augment, but not be duplicative of, other cooperative agreement requirements held by the laboratory (e.g., ISO, FERN).

- Examples of the types of tools/resources envisioned include: functional SME centers (accessible remotely and in real-time; could provide SME input for specific types of investigations [commodity specific, especially high risk commodities] or investigation activities [e.g., tracebacks and data analysis], could also serve as a surge capacity resource to others); seminar series; webinar or classroom-based trainings (especially those to address high risk product investigations or other national/regional gaps/needs; collaborations with academic institutions to develop/host courses are encouraged; other encouraged courses to host are ER220, ICS305 and other food/feed specific ICS courses); information sharing processes/mechanisms; template SOPs; detailed procedural/process documents.
- Specific capabilities and activities of interest (for innovation and tools/resources) include: response data capture/tracking/analysis/reporting/sharing, regulatory and informational tracebacks, high risk product investigations (e.g., sprouts, soft cheese, produce/farms, etc.), environmental assessments, recall audit checks, response management structure (e.g., ability to implement ICS/Unified Command), multi-jurisdictional/multi-disciplinary communications, conducting multi-jurisdictional/multi-disciplinary after action reviews, writing after action reports and developing improvement plans to address lessons learned/gaps/other needs.
- Note that capability building efforts should follow the NIMS preparedness cycle (plan ® organize, train & equip ® exercise ® evaluate & improve).
- Multi-disciplinary, multi-jurisdictional projects are encouraged.
- This goal can be accomplished via individual RRT projects, collaborative multi-RRT workgroups or RRT participation in national food/feed workgroups (e.g., PFP WGs [Surveillance, Response and Recalls WG projects], CIFOR initiatives, collaborations with the Food Emergency Response Network, collaborations with CDC FoodCORE or Integrated Food Safety Centers of Excellence), so long as the product produced meets the purpose/intent of this goal.

RRT Capability Data Capture & Assessment: 2.A. All RRTs: RRTs shall: 1) complete/submit the Capability Assessment Tool; and 2) develop an improvement plan based on the results of the assessment.

Communication: 3.A. All RRTs: RRTs shall conduct at least two presentations per year (oral or poster) about the development of the RRT or documenting a specific RRT investigation and share a copy of the presentation within the RRT Program Workgroup in FoodSHIELD. At least one of these two presentations must be at a regional or national meeting. RRTs are encouraged to write and submit peer reviewed journal articles (the publication of which would count against the 2 presentation minimum for this goal).

Communication: 3.B. All RRTs: RRTs shall prepare reports of significant investigations, successful prevention efforts, or other RRT actions taken to protect public health to be posted on a Food Protection Task Force webpage, a state agency webpage or other public webpage and shall notify RRT Program Coordinators to allow cross-linking from the FDA RRT webpage. If the grantee's attempts to post these reports to a public webpage are fruitless, we will accept posting to the RRT Program Workgroup in FoodSHIELD (please provide a justification in your progress report).

Post Response & Prevention: 4.A. All RRTs: RRTs shall conduct an after action review and complete subsequent documentation requirements for all RRT exercises, responses and activations as per RRT SOPs (i.e. creation of incident/event summary and documentation of recommendations/tracking of follow up action [Improvement Plan]). Documentation shall be made available to other RRTs through the secure RRT Program Workgroup in FoodSHIELD. Key issues/items for improvement related to team performance are incorporated into an improvement plan or into future trainings, as applicable. See RRT CAT, Part III, section 5.4.2. After action reviews/reports should include a calculation and assessment of the time intervals between key response activities to identify opportunities for improvement (most importantly, assessing the interval between FDA and state food/feed regulatory program notification and implementation of effective control measures; but ideally inclusive of lab and epi activities as

well, where applicable). Use of the baseline response data in the RRT Manual Metrics Chapter (2013 Edition) and CIFOR Guidelines (2nd Edition) Performance Indicators are recommended. Note: An annual exercise is required in the absence of a RRT activation during a given grant year (see goal 5.A, below).

Post Response & Prevention: 4.B. All RRTs: RRTs may work with others (other RRTs, federal partners, etc.) to develop and pilot a collaborative, multi-state approach to conducting after action reviews and developing after action reports and improvement plans, including identifying and proposing solutions to regional/national needs/gaps and working with relevant partners to propose outreach, education, legislative and other activities to prevent incident/contamination recurrence. Note that 1.A, 4.B, 4.C, 5.B and 5.C are voluntary goals. However, grantees must elect to address at least two of these voluntary goals each grant year.

Post Response & Prevention: 4.C.All RRTs: RRTs may develop, implement and enhance capacity and capability to participate in coordinated post response and prevention/recovery activities with partners (e.g., RRT members (Dept. of Ag, Dept. of Health, FDA District Office) and federal response coordination groups, such as FDA CORE), specifically conducting environmental assessments for FDA regulated food/feed commodities (e.g., manufactured foods, animal feed/pet food and farm/produce commodities), following best practices outlined in the RRT Environmental Assessment (EA) Workgroup Final Report and other information provided by FDA Office of Partnerships (OP). This shall include demonstrating implementation of environmental assessment procedures by trained personnel, to include identification, documentation and sharing of contributing factors/environmental antecedents, as well as working with relevant partners to propose recommendations for industry or other preventive measures based on the EA findings. Submission of EA data to NVEAIS for EAs at retail/food service establishments is encouraged. RRTs shall use the FDA FIQ for on-farm/produce EAs. Contributing factors identified during EAs related to foodborne illness outbreaks should be included in the NORS report. Note that 1.A, 4.B, 4.C, 5.B and 5.C are voluntary goals. However, grantees must elect to address at least two of these voluntary goals each grant year.

RRT Maturity & Maintenance: 5.A.

New RRTs: RRTs shall operate within Phase 2 or 3 of the RRT Capacity Building Process & Mentorship Framework. If in Phase 2, the RRT must identify a plan to complete development of all required SOPs and other elements (so as to transition to Phase 3) by the end of this 3 year award and demonstrate adequate progress against that plan each year. If the RRT is in phase 3, then an update on key areas of Phase 3 would be provided in each progress report (follow guidance for Original RRTs, below).

Original RRTs: RRTs shall operate within Phase 3 of the RRT Capacity Building Process & Mentorship Framework. Please describe activities/special projects undertaken by the RRT to support meeting the key areas of Phase 3. Many of the other goals cover key areas of Phase 3, as such, please scope your activities under this goal to the following key areas of Phase 3:

- Maintain a Written Framework: Describe updates to existing SOPs/creation of new SOPs, efforts to coordinate SOPs among RRT member agencies/partners; any efforts to pursue and complete necessary documents, SOPs and agreements to support Unified Command; any efforts to update/create an operational RRT Data Management System (e.g., FoodSHIELD), with capability for use by all RRT member agencies, as needed/appropriate. There shall be at least an annual review/update of most SOPs (see the RRT CAT, Part III (Metrics), Section 5.2.1).
- Execute the Training Plan: Describe efforts to provide/procure training opportunities for the RRT according to the RRT training plan, particularly trainings where attendance (or the course itself) was funded using RRT grant funds. There shall be at least an annual review of the RRT training plan (see the RRT CAT, Part III (Metrics), Section 5.2.2).
- Maintain and Coordinate the Team: Demonstrate routine engagement of core RRT member agencies/partners (state food regulatory program, FDA District Office, state feed regulatory program, epi and laboratory) and auxiliary RRT member agencies/partners. These may be routine teleconferences of the core RRT team, RRT steering committee or equivalent; as well as scheduled face to face meetings with all RRT members (and may include training components). See RRT CAT Part V (RRT Characterization Data), Section 5.1.1-5.1.3.
- Equip the team: Describe efforts to procure the equipment and supplies necessary to support the RRT during investigations; or efforts to identify/procure/evaluate new equipment to determine if it has a positive impact on RRT performance. There shall be at least an annual evaluation of key response equipment/supplies (see the RRT CAT, Part III (Metrics), Section 5.2.4).
- RRT Exercises: The state food regulatory program (RRT grantee) and relevant RRT member agencies/partners (at a minimum the FDA District Office) complete at least one exercise or response to a real time event to test/implement RRT procedures under ICS/Unified Command System (UCS) (including use of Incident Action Plans) every grant year (see the RRT CAT, Part III (Metrics), Section 5.3.1). Additionally, at least one exercise must be conducted during this award (2 or 3 year project period) involving an intentional food or feed contamination incident, involving relevant RRT member agencies/partners and other stakeholders as appropriate (e.g., emergency managers, law enforcement, etc.).
- RRT Improvement plan: Provide examples of accomplishment of past RRT CAT Improvement Plan (goal 2.A) and RRT

exercise/response/activation AAR/Improvement plan (goal 4.A) items. Note that the RRT may want to maintain a single improvement plan, inclusive of AAR and CAT improvement items; RRT improvement plan items may also be integrated with a MFRPS improvement plan, if desired by the RRT.

RRT Maturity & Maintenance: 5.B. All RRTs: RRTs may contribute to revision and revision of the RRT Manual (2016-2017 grant year only). Activities include: serving as a reviewer, serving on a chapter revision workgroup and creating/ contributing content (templates, model processes, etc.). Note that 1.A, 4.B, 4.C, 5.B and 5.C are voluntary goals. However, grantees must elect to address at least two of these voluntary goals each grant year.

RRT Maturity & Maintenance: 5.C. All RRTs: RRTs may undertake efforts to enhance/improve collaboration with local health departments during RRT responses and activations, taking into consideration the resource constraints and other needs specific to these audiences. Suggested activities include: joint trainings, outreach meetings, joint exercises, increased information sharing, and communication/collaboration structures and processes for inclusion in RRT SOPs. This goal can be accomplished via RRT participation in national food/feed workgroups (e.g., RRT, PFP, etc.), so long as the product produced meets the purpose/intent of this goal. Note that 1.A, 4.B, 4.C, 5.B and 5.C are voluntary goals. However, grantees must elect to address at least two of these voluntary goals each grant year.

Sustainability: 6.A. All RRTs: RRTs shall submit an annual update of the sustainability plan for the RRT (use the template in Phase 2 of the RRT Capacity Building Process and Mentorship Framework) and undertake efforts to establish contingency plans for or increase the sustainability of current resources solely funded under this grant (especially data management systems and personnel). High priority efforts include: transitioning solely grant funded personnel to partial state funds; transitioning O&M costs for IT systems and other technologies to state funds. Ideally, by the end of the project period, the RRT budget should demonstrate that support for RRT operations/maintenance is diversified (split across state and grant funds) and reflective/proportional to the typical volume of response work encountered by the RRT, and that RRT grant funds are being used to support collaborative, high-impact, national level efforts for improving or increasing national capacity to respond to all hazards food/feed emergencies. To that end, RRTs shall also provide an estimate of in-kind contributions by the RRT grantee and other RRT member agencies/partners towards accomplishing the aims of this cooperative agreement (inclusive of both RRT operations [actual responses/activations], RRT continuous process improvement/program infrastructure [routine meetings, trainings, exercises, document revision/development], and contributions to national or mentorship activities undertaken as a part of the grant). In-kind contributions include personnel, equipment and supplies used to accomplish RRT activities not obtained through grant funds.

Expected Goals **(RRT Additional Optional Elective Funding):**

Applicants may propose additional projects consistent with the aims of Goal 1.B. (Innovation and National Capacity/Capability Development), above, as an Optional Elective. The activities proposed under the Optional Elective must be distinct and separate from the activities/projects proposed under the RRT base award (i.e. for applicants selecting the RRT Optional Elective, there must be activities associated with accomplishment of Goal 1.B. in the RRT Base Award, and separate activities associated with the RRT Optional Elective; the same activity shall not count for both).

The following types of projects are suggested (applicants may propose any optional elective project consistent with the aims of Goal 1.B. [Innovation and National Capacity/Capability Development]; below is a list of high-interest projects to consider):

Developing and delivering (e.g., classroom, online/on demand, recorded for future access) training courses for high risk product investigations or to address other national/regional gaps/needs, based on lessons learned from past outbreaks/contamination events and in collaboration with academic institutions and other experts. For classroom-based training courses, providing travel scholarships is encouraged (especially for non-funded RRTs, non-funded member agencies/partners of RRTs, or locals).

Develop SME resources that could be accessed remotely and in real-time by other RRTs (grant funded and non-grant funded); for example, expertise that could be shared upon request for specific types of investigations (e.g., commodity specific; especially high risk commodities) or investigation activities (e.g., tracebacks and data analysis). These SME resources could also serve as a surge capacity resource for others and conduct training/outreach activities.

On-site evaluation of a “high risk” (as identified under MFRPS Standard #3) food, commodity, or specific type of producer, manufacturer or processor (such as LACF/Acidified Foods, and including high-risk animal feed and produce/farms as well), or participation in a special study and assessment to provide additional insights into how food may become contaminated within the farm to fork continuum (non-retail point of service focus). The evaluation/exercise/study should be done in collaboration with the FDA District Office and other relevant RRT member agencies/partners, and RRTs are encouraged to use a HACCP and/or CARVER + Shock approach. Results should be documented in the form of a final report, programmatic paper, and/or technical document to identify specific hazards and critical control points, strengths of the response team efforts, recommendations and

needed improvements.

Coordinated District-State surveillance (sampling) efforts for products and contaminants of concern: Assignments should involve coordination of District-State sampling and laboratory testing capacity, and incorporate appropriate measures so as to ensure District and/or State regulatory or compliance action throughout all components of the assignment. Assignments should be targeted (e.g., risk-based; aimed at identifying points of contamination for a product within the farm to fork continuum or to address other strategic needs; and innovative approaches are encouraged). These projects may complement or augment, but shall not be duplicative of, other cooperative agreement requirements held by the laboratory (e.g., ISO, FERN).

Innovative approaches to response, such as: use of emerging/new technology or use of existing technology in a new way, piloting a new process or innovative elements to an existing activity/process, or other innovative projects identified/designed by the grantee. At its conclusion, innovative projects should undergo a cost/benefit analysis, which should include an assessment of its impact on the period of time between agency notification of an incident and implementation of effective control measures.

IV) Background

Over the past several years, the food safety system has encountered risks and emergencies of significant national concern. Multiple efforts have been undertaken at all levels, including consumers, industry, regulators, and even international organizations, to identify and implement improvements to the food safety system.

These cooperative agreements are intended to follow the constructs and directives of the following items while supporting the infrastructure of grantee State programs to implement integrated rapid response capabilities and sustain them into the future.

IV.A) National Incident Management System (NIMS) and the National Response Framework (NRF)

Issued in 2003 by President Bush, Homeland Security Presidential Directive (HSPD) 5 requires all federal departments and agencies to adopt NIMS and to use it in their individual incident management programs and activities, as well as in support of all actions taken to assist state, tribal and local governments. The directive requires federal departments and agencies to make adoption of NIMS by state, tribal and local organizations a condition for federal preparedness assistance (through grants, contracts and other activities). For more information on this, visit: https://www.fema.gov/national-incident-management-system/implementation-guidance-and-reporting.

The NRF is built on the NIMS and establishes a comprehensive, national, all-hazards approach to domestic incident response. The full NRF is available at: http://www.fema.gov/pdf/emergency/nrf/nrf-core.pdf.

These cooperative agreements require RRTs use Incident Command System (ICS)/National Incident Management System (NIMS) principles and operate under a Unified Command structure.

IV.B) National Integrated Food Safety System

FDA is continuing to work with its state partners to create a national, fully integrated food safety system that is characterized by effective communication and efficient processes among federal, state, and local partners in the food safety system.

The Partnership for Food Protection (http://www.fda.gov/ForFederalStateandLocalOfficials/FoodSafetySystem/PartnershipforFoodProtectionPFP/default.htm) is a major driving force in the establishment of a national integrated food safety system.

In alignment with this concept, these cooperative agreements work to engage partners across multiple sectors of the food safety system to collaborate to identify means of improving and optimizing the nation's food safety system.

IV.C) FDA Food Safety Modernization Act

The FDA Food Safety Modernization Act (FSMA), signed into law on January 4, 2011, provides FDA with tools to better protect public health by strengthening the food safety system. It enables FDA to focus on preventing food safety problems rather than reacting to problems after they occur. It also provides FDA with new enforcement authorities designed to achieve higher rates of compliance with prevention- and risk-based food safety standards and to better respond to and contain problems when they do occur. These include authorities such as mandatory recall, expanded administrative detention, suspension of facility registration, enhanced product tracing abilities, and additional recordkeeping requirements for high-risk foods. FSMA also gives FDA important new tools to hold imported foods to the same standards as domestic foods.

FSMA directs FDA to build an integrated national food safety system in partnership with State and local authorities, explicitly

recognizing that all food safety agencies need to work together in an integrated way to achieve national public health goals. FSMA identifies some key priorities in working with partners in areas, such as: reliance on Federal, State, and local agencies for inspections; improving foodborne illness surveillance; and leveraging and enhancing State and local food safety and defense capacities.

Full text of the law: http://www.fda.gov/food/guidanceregulation/fsma/ucm247548.htm.

IV.D) Bioterrorism Act

Alongside the increased national focus on food safety has been the increased focus on emergency preparedness and response since 2001. The events of September 11, 2001, reinforced the need to enhance the safety and defense of the U.S. food supply. Congress responded by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("Bioterrorism Act"), which President Bush signed into law on June 12, 2002. The Bioterrorism Act is divided into five titles, detailed here: http://www.fda.gov/regulatoryinformation/legislation/ucm148797.htm.

Subtitle A of Title III—Protection of Food Supply, Section 311—Grants to States for Inspections, amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding section 909, which authorizes the Secretary of Health and Human Services to award grants to States, territories, and Indian tribes that undertake examinations, inspections, and investigations, and related activities under section 702 of the FD&C Act. The grant funds are only available for the costs of conducting these examinations, inspections, investigations, and related activities. Full text: http://www.fda.gov/RegulatoryInformation/Legislation/ucm155769.htm.

Subtitle A of Title III—Protection of Food Supply, Section 312, "Surveillance and Information Grants and Authorities," amends part B of Title 111 of the Public Health Service Act to authorize the Secretary of Health and Human Services to award grants to States and Indian tribes to expand participation in networks to enhance Federal, State, and local food safety efforts. This may include meeting the costs of establishing and maintaining the food safety surveillance, technical, and laboratory capacity needed for such participation.

IV.E) Food and Drug Administration Amendments Act of 2007 (FDAAA)

FDAAA amended the FD&C Act to require FDA to work with the States to undertake activities to assist in improving food safety.

This requirement is contained within Title X (Food Safety) Section 1004 of the FDAAA (Full text: http://www.gpo.gov/fdsys/pkg/PLAW-110publ85/html/PLAW-110publ85.htm).

IV.F) Import Safety Action Plan (ISAP)

The Import Safety Action Plan acknowledges the value of mutual leveraging of State and Federal resources and recommends consideration of cooperative agreements to increase information sharing.

Specifically, the ISAP contains Recommendation 12 to maximize federal-state collaboration for federal-state rapid response (http://archive.hhs.gov/importsafety/report/actionplan.pdf; pages 37-38).

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/ORA intends to commit approximately $2,700,000, for fiscal year 2015 in support of this grant program. FDA/ORA

intends to commit an additional $2,700,000 for fiscal year 2016 in support of this grant program.

It is anticipated that up to 9 awards in fiscal year 2015 will be made not to exceed $375,000 in total costs (direct plus indirect) per award and up to 9 awards in fiscal year 2016 may be made not to exceed $375,000 in total costs (direct plus indirect) per award (for a total of up to 18 awards to be made under this grant program).

RRT Base Award: Applicants who submit for a base award may receive funds up to $300,000 in total costs (direct plus indirect) per award.

Additional optional elective funding: Applicants who submit for and propose an additional optional elective, may receive additional funds up to $75,000 in total costs (direct plus indirect) per award.

Applicants may propose additional projects consistent with the aims of Goal 1.B. (Innovation and National Capacity/Capability Development), as an Optional Elective. The activities proposed under the Optional Elective must be distinct and separate from the activities/projects proposed under the RRT base award (i.e. for applicants selecting the RRT Optional Elective, there must be activities associated with accomplishment of Goal 1.B. in the RRT Base Award, and separate activities associated with the RRT Optional Elective; the same activity shall not count for both).

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):

July 1, 2015 (FY2015) application due date:

	Base Budget	Optional Elective Budget	Total Project Award Budget
Year 01	$300,000	$75,000	$375,000
Year 02	$300,000	$75,000	$375,000
Year 03	$300,000	$75,000	$375,000

March 8, 2016 (FY2016) application due date:

	Base Budget	Optional Elective Budget	Total Award Budget
Year 01	$300,000	$75,000	$375,000
Year 02	$300,000	$75,000	$375,000

Award Project Period

The scope of the proposed project should determine the project period.

July 15, 2015 (FY2015) application due date:

The maximum project period is three (3) years.

March 8, 2016 (FY2016) application due date:

The maximum project period is two (2) years.

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

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Governments

- State Governments

This opportunity is only available to State food safety agencies with current FDA food safety inspection contracts that are also enrolled in the Manufactured Food Regulatory Program Standards (MFRPS) and currently receiving funding under the Food Protection Rapid Response Team cooperative agreements awarded under RFA-FD-12-013 or RFA-FD-13-006. State food safety agencies who are currently receiving funding under RFA-FD-12-013 are eligible to apply in FY15 and FY16, and State food safety agencies who are currently receiving funding under RFA-FD-13-006 are eligible to apply only in FY16.

Competition is limited to these organizations because they have established Rapid Response Teams and have demonstrated significant achievements in accordance with the goal of developing and implementing rapid response concepts. The foundational work conducted under the current FDA food safety inspection contracts and the MFRPS is both necessary and promising for the completion of significant improvements in food emergency response among federal, state, and local partners through the program described in this funding opportunity. Additionally, this cooperative agreement will require a significant mentorship component which necessitates the participation of only established, experienced Food Protection Rapid Response Teams.

Applicants must also maintain MFRPS enrollment and remain under a FDA food safety inspection contract for the duration of the award.

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

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.

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

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
- Intent to apply for additional optional elective funding

The letter of intent should be emailed to:

Dan Lukash
Telephone: 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 20 pages.

Instructions for Application Submission

The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this FOA.

SF424(R&R) Cover

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

SF424(R&R) Project/Performance Site Locations

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

SF424(R&R) Other Project Information

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

SF424(R&R) Senior/Key Person Profile

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

R&R Budget

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

- Applications proposing an additional optional elective, must clearly describe all the costs associated with the optional elective separately from the base award budget in the narrative budget justification.
- Applications requesting multiple years of support must complete and submit a separate detailed budget breakdown and narrative justification for each year of financial support requested.
- If an applicant is requesting indirect costs as part of their budget, a copy of the most recent Federal indirect cost rate or F&A agreement must be provided as part of the application submission. This agreement should be attached to the RESEARCH & RELATED Other Project Information Component as line #12 'Other Attachments'.
- If the applicant organization has never established an indirect cost rate and/or does not have a negotiated Federal indirect cost rate agreement, a de minimis indirect cost rate of 10 percent (10%) of modified total direct costs (MTDC) will be allowed. MTDC means all direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel, and subaward and subcontracts up to the first $25,000 of each subaward or subcontract. MTDC excludes equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs and the portion of each subaward and subcontract in excess of $25,000.
- Applicants may also apply for personnel, training, and surveillance sample analysis if they have the necessary equipment and it shall be available for these projects.
- Where personnel costs are requested, documentation must be provided to associate these costs with the specific goals.
- A portion of budgeted travel funds must be set aside to attend an annual face-to-face meeting of the RRT States and FDA Headquarters and District Offices, as well as the biennial Integrated Foodborne Outbreak Response Management Conference, which is held in odd number years (a minimum of 2 key personnel for the RRT Annual Meeting and at least 1 person representing the RRT to InFORM).

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:

The applicant must specifically address, and will be judged on the following in the cooperative agreement application. If the applicant is proposing an additional optional elective, the Research Strategy must clearly describe the base award plan separately from the optional elective plan.

Applications must include the following information in the Research Strategy attachment not to exceed 20 pages in length:

a. Demonstrate the applicant agency's commitment to and support for this project, including the implementation and maintenance of the RRT concept and associated activities. Also demonstrate commitment from other RRT member agencies external to the applicant agency (at a minimum, entities representing feed, epidemiology and laboratory as described above in I.C.1) in the form of a letter(s) of support.
b. Demonstrate the availability of adequately trained staff (grant funded and in-kind contributions) and if applicable, the criteria and ability to hire and/or train personnel to meet the goals and aims of cooperative agreement. Provide justification for hiring new staff, including qualifications, training needs, and equipment needs.
c. Demonstrate adequate need within the state for advanced capacity and capabilities to respond to all hazards food/feed emergencies (description of: active state firm inventory [and proportion of high risk firms] for manufactured foods, animal feed, and farms; average number of natural disasters affecting food/feed firm operations; average number of recalls of food/feed commodities resulting from firms in the state; average number of recalls of food/feed commodities with distribution in the state (by class); average number of food/feed outbreaks (especially those involving FDA regulated commodities) where there were illnesses or distribution/processing/production of the contaminated product in the state)
d. In the "Appendix" provide the following documentation to allow for baseline characterization of your RRT (procedures and past accomplishments): the most recent RRT Capability Assessment Tool (including the RRT Activity Table) (completed within the last 12 months).
   In this section describe other instances (not captured within the CAT/Activity Table; e.g., surveillance, post response/prevention) where effective implementation of RRT capacity/capabilities to address actual food/feed contamination events within the last 12 months had significant public health impact.
e. Provide a properly detailed budget that is intended to meet the goals for the RRT Base Award and accomplish the activities detailed within this RFA, including RRT operations/maintenance (process improvement and responding to incidents) and participating in collaborative, high-impact, national level activities/initiatives for improving or increasing national capacity/capabilities to respond to all hazards food/feed emergencies (see Section I, part III, above. The costs any additional funding should be included in the overall project budget for the first year. In the "Other Attachment" section please detail the costs associated with the extra activities.
f. Provide the previous year and current funding level certification for the food safety program from State funding appropriations.
g. Outline a detailed methodology to accomplish the goals, as described in this announcement (see Section I, part III, above). For applicants that choose to pursue the Optional Elective, as described in this announcement (see Section I, part III, above), outline a detailed methodology to accomplish activities proposed under the Optional Elective.
h. Demonstrate the ability to satisfy the reporting requirements outlined in section VI.3 of this announcement.
i. Demonstrate the ability to fully participate in initiatives supporting the RRT Program, such as sending at least 2 key RRT personnel to an annual face-to-face meeting (as determined by FDA/OP) and at least 1 person representing the RRT to the biennial Integrated Foodborne Outbreak Response Management Conference (held in odd number years), participating in FoodSHIELD workgroups, RRT monthly conference calls, sharing of best practices and other RRT Program activities identified by OP.

Supporting Laboratory Facilities

When funds or equipment from the cooperative agreement are provided to a State food/feed laboratory that is not the main servicing laboratory for the food program as identified in Standard 10 of the MFRPS, the following information must be provided as detailed below. It is strongly recommended that any laboratory involved in analyzing samples for the RRT be accredited or pursuing ISO 17025:2005 accreditation for pertinent food/feed analyses/technologies. Cooperative agreement funds may not be used for significant construction (e.g., to construct, renovate, or remodel laboratories or other physical facilities) but instead, for

example, for equipment, installation, supplies, or development of policy and/or procedures manuals.

If funds or equipment from the cooperative agreement are provided to a State food/feed laboratory, the applicant must provide a complete description of the laboratory facilities with the mid-year report submission (unless it is the same as was submitted in a previous year under this cooperative agreement, in which case a modified report shall be required). The description must include the following information: The name and address of the State facility conducting the food sample tests; the name of the most responsible individual for the facility conducting the tests; and the location and installation requirements of any equipment purchased with cooperative agreement funds. Other facilities information that may be required includes:

a. Operational support areas to be used for the project, including details about the availability of ancillary laboratory safety and support equipment and facilities;
b. Details describing the sample receiving and sample storage areas and a description of any existing chain-of -custody procedures;
c. A detailed description of the proposed upgrades to existing laboratory facilities to accommodate new equipment, including drawings and cost estimates.
d. A summary description of any quality management system in place or under development as it relates to quality control and quality assurance procedures and practices;
e. A summary description of staffing management, specifically including food sample testing abilities and procedures;
f. A summary description of procedures in place to monitor food sample workflow, including the tracking and monitoring of sample analyses in progress, including a description of the laboratory work product review process and how reports of sample analyses shall be provided within reasonable timeframes;
g. A description of the ability to perform and complete (or an agreement with another laboratory to do so) the food/feed sample analyses and provide reports of sample analyses within reasonable timeframes. A recipient's conformity to the laboratory testing procedures, methodology, and protocols employed and accepted by FDA in the assessment of food/feed samples is a minimum requirement for participation under this cooperative agreement.

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 ,with the following additional instructions:

- **Please provide the following:**
  The most recent RRT Capability Assessment Tool (including the RRT Activity Table) (completed within the last 12 months). In this section describe other instances (not captured within the CAT/Activity Table; e.g., surveillance, post response/prevention) where effective implementation of RRT capacity/capabilities to address actual food/feed contamination events within the last 12 months had significant public health impact.

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*.

These cooperative agreements are intended to support multi-jurisdictional, multi-disciplinary Rapid Response Teams (RRTs) that operate using Incident Command System (ICS)/National Incident Management System (NIMS) principles and a Unified Command structure to conduct integrated responses to all-hazards food/feed emergencies. RRTs conduct multi-jurisdictional, multi-disciplinary approach activities that support preparedness, surveillance, response, mitigation and recovery/prevention efforts for food/feed as part of a national integrated food safety system.

This will be accomplished through the provision of funding for program improvement and shall require extensive cooperation and coordination with FDA District Offices and other FDA program offices.

The cooperative agreements will provide funding for additional personnel, equipment, supplies, and training to support activities related to the goals/aims of this grant program. Allowable and unallowable costs are delineated below.

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.

A decrease in the amount of the non-competitive segment may occur if there is an unobligated balance from the prior budget period that will not be used in the current budget period, in which case prior year funds can be used as an offset for the current year award

Allowable costs:

1) Rental, purchasing, calibration, and maintenance of supplies and equipment relevant to the RRT, including sample collection supplies and lab equipment (with prior approval from FDA) relevant to the RRT

2) Surveillance work

3) Team development, training and exercises

4) Salaries, wages and fringe benefits for personnel relevant to the goals/aims of this award, including recruitment costs for hiring new employees

5) Funds may be requested in the budget to travel to FDA for meetings with program staff about the progress of the project and travel for training. Travel and per diem to trainings, exercises and meetings with RRT members (other state agencies, local agencies, FDA District/Regional Offices), other RRTs, FDA Headquarters, and Annual RRT meetings. Travel costs (airfare) must not exceed coach class fare. Registration fees are allowable.

6) Pass through of funds to RRT member agencies external to the recipient of this award (e.g., other state/local/county/tribal government agencies) to support their contribution to the aims of this grant program is encouraged, but is limited to 50% of each year's funding (total). FDA must be provided with a copy of the third party agreement showing involvement and transfer of funds to state/local/county/tribal governments.

7) Reimbursement of mileage for travel within a grant recipient's state is allowable provided that the work directly relates to

the RRT.

8) Indirect costs

9) Purchase or development of IT equipment, software, and support

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

11) Speaker fees

Non-allowable costs:

1) Facilities and work covered and funded under current FDA food safety inspection contracts shall not be counted towards fulfillment of the cooperative agreement and must remain distinct and separate from the cooperative agreement. The State must be able to account separately for fund expenditures under the food safety inspection contracts and these cooperative agreements.

2) These cooperative agreements are not to fund licensed medicated feed or routine feed safety good manufacturing practice (GMP) inspections, BSE inspections, or retail food or foodservice inspections, which are unrelated to the food manufacturing, processing, wholesaling, transportation, or warehousing of manufactured foods, or any activities which are currently covered by an FDA food or feed inspection contract.

3) Vehicle purchases are not permitted.

4) Subcontracting to third party (other than state/local/tribal government agencies participating in the RRT) is limited to 20% of each year's award.

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

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

6. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. **PAPER APPLICATIONS SHALL 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

Post submission materials will not be accepted for this FOA.

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.

All applicants will submit a budget and justification for RRT base award funding (up to $300,000 per year). This required section of the application will be evaluated using the criteria in the section below. Applicants' scores for the RRT base award will be used as a deciding factor in determining whether any additional funding (RRT Optional Elective) will be considered.

1) Effective use of grant funds: The relevance/impact of the proposed budget towards achieving the goals/aims of the cooperative agreement (**weight = 10%**):

2) Demonstration of an established RRT with functioning core infrastructure necessary for carrying out the objectives of this agreement (**weight = 30%**)

Adequate program resources (especially staff) are available to complete project needs (grant funded and in-kind contributions), including RRT operations/maintenance (process improvement and responding to incidents) and participating in collaborative, high-impact, national level activities/initiatives for improving or increasing national capacity/capabilities to respond to all hazards food/feed emergencies – see Goals (Section I, part III above);

Established relationships with partners in other, relevant organizations (e.g., letters of support/commitment from feed program, laboratory and epidemiology programs) to collaborate as a multi-jurisdictional, multi-disciplinary RRT to respond to all hazards food and feed emergencies;

Demonstration of an established RRT with functioning core infrastructure necessary for carrying out the objectives of this agreement, as evidenced through the most recent version of the RRT Capability Assessment Tool. Highest priority consideration should be placed on the following elements: Part II Achievement Levels; Part III Metrics, Part IV RRT Characterization Data (see below):

- Completed, Up to date, Coordinated (multi-agency, multi-disciplinary) Procedures: Communications SOP, Contact Lists, Tracebacks, Joint Inspections/Investigations, Environmental Sampling, Recalls, After Action Reviews.
- Use of ICS/Unified Command
- Current Training Plan and adequate pool of proficient trained staff with appropriate expertise needed for RRT responses/activations
- Functional, ready for use supplies and equipment
- Conducts After Action Reviews and addresses process and training gaps
- The RRT demonstrates that they have an existing structure/organization in place to engage, communicate and share data with RRT member agencies/partners, consistent with the goals/objectives/aims of this cooperative agreement.

3) Demonstration of impact/benefit/effectiveness of working with RRT member agencies/partners to develop, share and operationalize capacity/capabilities to rapidly respond to all-hazards food/feed emergencies (with the ultimate goal of shortening the time between agency notification and implementation of effective control measures), as well as supporting surveillance and post-response/prevention activities (**weight = 60%**):

Having adequate need for advanced capacity and capabilities to respond to all hazards food/feed emergencies (description of: active state firm inventory [and proportion of high risk firms] for manufactured foods, animal feed, and farms; average number of natural disasters affecting food/feed firm operations; average number of recalls of food/feed commodities resulting from firms in the state; average number of recalls of food/feed commodities with distribution in the state (by class); average number of food/feed outbreaks (especially those involving FDA regulated commodities) where there were illnesses or distribution/processing/production of the contaminated product in the state);

Demonstrated effective implementation of RRT capacity/capabilities developed under past iterations of the RRT cooperative agreement to address actual contamination events; especially use of the RRT to detect contamination, respond to incidents of national significance involving firms/distribution of regulated products in the grantee state (as evidenced in the most recent RRT Capability Assessment Tool Activity Table), and take lessons learned from responses to apply them to process

improvement and prevent recurrence of contamination.

Scored Review Criteria for the RRT Optional Elective

For applicants opting to apply for additional funding, the budget and justification submitted for the RRT Optional Elective will be subject to a separate evaluation using the criteria in the section below. The RRT Optional Elective criteria will only be used to assess the request for additional funding and will have no bearing on the base application. Applicants' scores for the RRT base award will be used as a deciding factor in determining whether any additional funding (RRT Optional Elective) will be considered. (Applicants cannot receive this additional funding without a recommendation for funding of the RRT base award.)

1) Significance: Does the project address an important problem or a critical barrier in food/feed emergency response, surveillance or post response? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or response practices/processes be improved? How will successful completion of the aims change the concepts, methods, technologies, services, or preventative interventions that drive this field? Would the outcome of this project have the potential to increase detection of food/feed contamination events, reduce the time from agency notification to implementation of effective control measures to protect public health, or develop recommendations to prevent recurrence of the contamination event? Could the outcome of this project be shared with others and used to improve their capabilities/capacity? (**weight = 45%**)

2) Innovation: Does the application challenge and seek to shift current food/feed surveillance, response and post response paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one aspect of the field or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed? (**weight = 45%**)

3) Effective use of grant funds: The relevance/impact of the proposed budget towards successful achievement of the proposed activities (**weight = 10%**)

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

For Renewals, the committee will consider the progress made in the last funding period.

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.

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 grantee must maintain a food safety inspection contract with the FDA throughout the cooperative agreement project period. The grantee must also maintain enrollment in the MFRPS throughout the cooperative agreement project period.

State manufactured food programs funded under these cooperative agreements shall be required to provide the previous, current, and subsequent years of State funding to demonstrate that these funds have not replaced State allocations. A minimum of 2 key RRT personnel shall attend an annual face-to -face RRT meeting (as determined by FDA OP) and at least one person representing the RRT shall attend the biennial Integrated Foodborne Outbreak Response Management Conference (held in odd number years) as a condition of the award. The awardee should identify funds within the cooperative agreement for travel and plan accordingly.

Facilities, work, and training reimbursed under the FDA food safety inspection contract and other funding mechanisms (including MFRPS, AFRPS, VNRFRPS, FERN, ISO or Food Protection Task Force Conference Grants) must remain distinct and separate from the cooperative agreement. The grantee must be able to account separately for fund expenditures, including employee salaries, wages, and benefits, under the food safety inspection contracts and other funding mechanisms and these cooperative agreements.

Future funding will be dependent on recommendations from the OP Programmatic Staff. The scope of the recommendation will confirm that acceptable progress has been made, continued compliance with all FDA regulatory requirements, and, if necessary, a corrective action plan has been implemented.

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.

The PD(s)/PI(s) will 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 prepare justifications; appropriately acknowledge Federal support in publications, announcements, news programs, and other media; and ensure compliance with other Federal and organizational requirements. All applicants will be required to participate in a cooperative manner with FDA.

The awardee is responsible for submitting interim progress reports, when requested, to the FDA Project Scientist (PS)/Project Officer (PO) including summary data on progress to date.

FDA staff will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as

described below:

An FDA Project Scientist (PS) will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below. However, the dominant role and prime responsibility for the activity reside with the awardees(s) for the project as a whole, but not necessarily for each task.

The responsibilities of the PS include involvement during conduct of the activity, through technical assistance, advice, coordination, and/or other assistance activities that is above and beyond normal program stewardship for grants.

As appropriate, the PS will participate in the definition of objectives and approaches, and in planning, conducting, analyzing, and publishing results, interpretations, and conclusions of their studies.

Also, the grantee organization must comply with all special terms and conditions of the cooperative agreement, including those which state that future funding of the project will depend on recommendations from the Project Officer.

In addition to the PS, there may be a separate FDA Program Official (PO) who will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice.

The PO officer will monitor the recipient periodically. The monitoring may be in the form of telephone conversations, e-mails, or written correspondence between the project officer/grants management officer and the principal investigator. The recipients shall also work with the FDA District Offices in development, training, and exercises for the developing RRT. Periodic site visits with officials of the recipient organization may also occur. The results of these monitoring activities will be recorded in the official cooperative agreement file and will be available to the grant recipient, upon request, consistent with applicable disclosure statutes and FDA disclosure regulations.

Areas of Joint Responsibility include:

During performance of the award, the PS/PO, with assistance from other scientific program staff who are designated based on their relevant expertise, may provide appropriate assistance, advice and guidance. The role of the PS/PO will be to facilitate and not to direct the activities. It is anticipated that decisions in all activities shall be reached by consensus between the PI and the

PS, PO and that the FDA staff shall be given the opportunity to offer input into this process. The PS/PO will facilitate liaison activity for partnerships, and provide assistance with access to FDA supported resources and services as deemed necessary.

The PI(s) shall be responsible for the timely submission of all abstracts, manuscripts and reviews (co)authored by members of the grant and supported in part or in total under this Cooperative Agreement. Manuscripts shall be submitted to FDA PS/PO within two weeks of acceptance for publication. Publications or oral presentations of work performed under this Cooperative

Agreement shall require appropriate acknowledgement of FDA support. Timely publication of major findings is encouraged.

The PS/PO and relevant FDA field offices will have continuous interaction with the recipient through activities such as the following: collection of progress reports; training; joint inspections; investigational and compliance activities; RRT exercises and coordination; and other activities necessary for the completion of objectives as outlined in this RFA. There may be other regular meetings with recipients to assist in fulfilling the requirements of the cooperative agreement. Specific interactions between relevant FDA field offices and the award recipients include:

a. Coordination, training, and exercises with FDA District and Regional RRT partners (including emergency response coordinators), the FDA Emergency Operations Center, CFSAN and CVM, the FDA CORE, and other federal agencies.

b. Working with other State entities in food protection such as State Departments of Health or Agriculture, emergency operations centers, environmental programs, epidemiologists, local food protection agencies, and others, in the accomplishment of objectives as outlined in this announcement.

c. Engaging other relevant initiatives within the RRT Concept, such as CDC Integrated Food Safety Centers of Excellence, CDC FoodCORE, FoodNet, and EHS-Net sites.

d. All cooperative agreement recipients must have existing food safety inspection and surveillance programs under contract to FDA for food safety inspections and be enrolled in the MFRPS, both of which require extensive District-State coordination (with the caveat that all funding streams must be kept distinct and separate, as described above under Section VI.2 Cooperative Agreement Terms and Conditions of Award).

The equipment purchased by FDA will remain the property of FDA under loan to the awardee's laboratory for a specified time

period with a review every twelve months. FDA may terminate the loan at any time. Unless approved by ORA/OP, the FDA provided equipment may not be transferred by the awardees' laboratory to a third party, and the awardees' laboratory assumes full responsibility and liability for any claims that may arise as a result of operation of this equipment for the period it is in the possession of the awardees' laboratory.

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

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. If funds or equipment from the cooperative agreement are provided to a State food/feed laboratory, the applicant must provide a complete description of the laboratory facilities with the mid-year report submission (unless it is the same as was submitted in a previous year under this cooperative agreement, in which case a modified report shall be required). The description must include the following information: The name and address of the State facility conducting the food sample tests; the name of the most responsible individual for the facility conducting the tests; and the location and installation requirements of any equipment purchased with cooperative agreement funds.

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. A report guidance will be provided to grantees by the Grants Management staff upon award. A progress report is also due with each continuation application.

All progress reports (mid-year, annual and final) must contain, but are not limited to the following:

1. General Progress on Cooperative Agreement Project

A) Progress & achievements for each yearly goal.

B) Progress & achievements for other projects, identified by the grantee in the application or subsequent to receiving funding.

2. Summary of significant RRT responses or other activities within the timeframe for the report, including status of AAR & lessons learned/recommendations for improvement

3. Point of Contact and Project Key Personnel

4. Pending Issues/Concerns and Proposed Solutions

5. Funding Expended and Remaining as of date of this report (provide detailed list of funds expended)

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)

Travis Goodman
Food and Drug Administration (FDA)
Telephone: 317-226-6500 ext 108
Email: travis.goodman@fda.hhs.gov

Lauren Yeung
Project Officer
Food and Drug Administration (FDA)
Telephone: 301-796-6623
Email: lauren.yeung@fda.hhs.gov

Objective Review Contact(s)

Daniel Lukash
Office of Acquisition & Grants Services (OAGS)
Telephone: 240-402-7596
Email: daniel.lukash@fda.hhs.gov

Financial/Grants Management Contact(s)

Daniel Lukash
Office of Acquisition & Grants Services (OAGS)
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 241and 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.

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

National Institutes of Health
Office of Extramural Research
Department of Health and Human Services (HHS)

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