Department of Health and Human Services
Part 1. Overview Information

Participating Organization(s)

U.S. Food and Drug Administration (FDA)

NOTE: The policies, guidelines, terms, and conditions stated in this announcement may differ from those used by the NIH. Where this Funding Opportunity Announcement (FOA) provides specific written guidance that may differ from the general guidance provided in the grant application form, please follow the instructions given in this FOA.

The FDA does not follow the NIH Page Limitation Guidelines or the NIH Review Criteria. Applicants are encouraged to consult with FDA Agency Contacts for additional information regarding page limits and the FDA Objective Review Process.

Components of Participating Organizations

Office of Regulatory Affairs (ORA)

Center for Veterinary Medicine (CVM)
Center for Food Safety and Applied Nutrition (CFSAN)

Funding Opportunity Title

Laboratory Flexible Funding Model (LFFM) (U19) Clinical Trials Not Allowed

Activity Code

U19 Research Program – Cooperative Agreements

Announcement Type

New

Related Notices

- **March 11, 2020** - Clarification of Research Strategy Structure for PAR-20-105. See Notice NOT-FD-20-011.
- **February 27, 2020** - Notice of Change to the Application Due Date for PAR-20-105. See Notice NOT-FD-20-009.

Funding Opportunity Announcement (FOA) Number

PAR-20-105

Companion Funding Opportunity

None

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Catalog of Federal Domestic Assistance (CFDA) Number(s)

93.103

Funding Opportunity Purpose

This cooperative agreement is intended to enhance the capacity and capabilities of state human and animal food testing laboratories in support of an integrated food safety system. Specifically, through sample testing in the areas of microbiology, chemistry, and radiochemistry, and the development special projects that would support and expand that testing. This project will strengthen and improve FDA's efforts to prevent foodborne illnesses and minimize foodborne exposures through building a nationally integrated laboratory science system and equip our partner laboratories with additional resources that can be employed to build and increase sample throughput capacity within their state.

Key Dates

Posted Date

February 5, 2020 **Open Date (Earliest Submission Date)**

February 5, 2020

Letter of Intent Due Date(s)

February 19, 2020

February 19, 2021

February 19, 2022

Application Due Date(s)

New Dates

May 6, 2020 by 11:59 PM Eastern Time

April 6, 2021 by 11:59 PM Eastern Time.

April 6, 2022 by 11:59 PM Eastern Time.

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

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

Late applications will not be accepted for this FOA.

AIDS Application Due Date(s)

Not Applicable

Scientific Merit Review

May 2020

May 2021

May 2022

Advisory Council Review

Not Applicable

Earliest Start Date

July 2020

July 2021

July 2022

Expiration Date

April 7, 2022

Due Dates for E.O. 12372

Not Applicable **Required Application Instructions**

It is critical that applicants follow the Multi-Project (M) Instructions in the SF424 (R&R) Application Guide, except where instructed to do otherwise (in this FOA or in a Notice from the *NIH Guide for Grants and Contracts*). Conformance to all

requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.
Applications that do not comply with these instructions may be delayed or not accepted for review.

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

1. Use the NIH ASSIST system to prepare, submit and track your application online.

   Apply Online Using ASSIST

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA Commons to track your application. Check with your institutional officials regarding availability.

Table of Contents

Part 1. Overview Information
Part 2. Full Text of the Announcement

Section I. Funding Opportunity Description
Section II. Award Information
Section III. Eligibility Information
Section IV. Application and Submission Information
Section V. Application Review Information
Section VI. Award Administration Information
Section VII. Agency Contacts
Section VIII. Other Information

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

The Food Safety Modernization Act (FSMA) outlines a new approach to food safety that is risk-informed and preventive in focus. Recognizing that sample testing can play a greater role in helping the Agency and our regulatory partners prevent contaminated product from reaching consumers, understand risks, and assess the value of strategies to control those risks, Food and Drug Administration has begun the process of rethinking how the agency deploys its resources.

In order to develop prevention-based systems, data and other information are needed to help identify and address hazards. There are different types of sample analysis that will be the focus of this project: product, whole genome sequencing of positive isolates, and emergency response/emerging issues sample analysis.

Human and animal food (livestock or pet) finished products as well as in-process and raw ingredient samples are analyzed to ensure they do not reach consumers with harmful contaminants, or to verify they contain ingredients at levels as declared on product labeling.

Emergency response and emerging issue testing can take the form of either environmental (e.g., water, soil) or product testing and could include both. Emergency response testing is routinely conducted in response to outbreaks of foodborne illness to help identify the source of the disease-causing pathogen. Emerging issues testing allows the agency to gather information about potential food safety issues based on trends or intelligence the Agency or grantee might have.

This project will be utilized to support the above-mentioned initiative by producing a large quantity of sample outputs that will drive a risk-based and prevention focused food safety system that both the FDA and our State partners can utilize for tracking and trending, early identification of emerging issues, and evaluation for future sampling initiatives and areas of focus. Participating laboratories will be equipped with additional resources that can be employed to build and increase sample throughput capacity and capability within their state.

Samples analyzed under this cooperative agreement could derive from a variety of sources including but not limited to: an approved sample plan, emergency outbreak situations, national special security exercises, or an FDA assignment.

Laboratories may be requested to participate in national special security exercises and FDA assignments. Samples may be collected by other organizations (e.g., FDA or a 3rd party) and submitted to participating laboratories for analysis.

The PD(s)/PI(s) shall retain the primary responsibility and dominant role for planning, directing, and executing the proposed project, however, the cooperative agreement award mechanism will result in substantial involvement by the FDA. Substantial involvement includes, but is not limited to:

1. Monitoring of progress through written reports, on-site visits, conference calls, and emails, as needed;

2. Review of small-scale, short-term method development, method validation, and matrix extension projects;

3. Review and approval of proposed sample collections and testing;

4. Review of laboratory data packages for violative samples;

5. Review and approval of budget modifications;

6. Annually, in conjunction with the grantee, determine changes in the overall testing needs to be applied to the recommended hazard/commodity pair table and identify opportunities for development; and

7. Review and approve annual testing proposals submitted by the laboratories.

8. In conjunction with FDA and the laboratory's regulatory program, discuss response strategies for violative samples.

Program Goals:

This cooperative agreement is intended to enhance the capacity and capabilities of state human and animal food testing laboratories in support of an integrated food safety system. Specifically, through sample testing in the areas of microbiology, chemistry, and radiochemistry, and the development of special projects that would support and expand that testing. This project will strengthen and improve the collaboration of surveillance testing activities between the FDA and our state and local laboratory partners to continue building a nationally integrated laboratory science system.

Overarching Program Structure:

Discipline	Analytical Tracks
Microbiology	• Food Defense • Human Food Product testing • Animal Food Product Testing • Whole Genome Sequencing • Microbiology Capability/ Capacity Development
Chemistry	• Food Defense • Human Food Product testing • Animal Food Product Testing • Chemistry Capability/ Capacity Development
Radiochemistry	• Food Defense • Radiochemistry Capability/ Capacity Development
Special Projects	• Sample Collection • NFSDX Integration or ORAPP Adoption • Method Development and Method Validation

Although specific work activities may vary among analytical tracks in the above chart, the following aims apply across the entire project, with the exception of the Whole Genome Sequencing, Development, and Special Project tracks:

1. Participate in, and pass, an annual proficiency test offered through a suitable proficiency testing program, for any work performed under this project. If a suitable proficiency test is unavailable, then laboratory-developed competency exercises must be performed.
2. Participate in small-scale method development, method validation research, and matrix extension research, as requested by the FDA.
3. Provide training and mentorship to other state laboratories, as requested.

4. Actively become a member of FERN and participate in conference calls, meetings, and support of FERN activities.
5. Attendance of at least two (2) key personnel, or one per discipline, whichever is greater, at an annual LFFM Face-to-Face Meeting. One (1) of these attendees must be the PI/PD of the project.
6. Maintain ISO 17025 accreditation or a quality system that ensures quality assurance and quality control of laboratory testing including but not limited to: validated methods, document control, training programs, and analyst competency requirements.
7. Maintain facilities and personnel necessary to complete the work proposed under this project.
8. Ensure methods used for analyzing samples under this project have been validated, with the exception of emergency situations, as dentified by FDA, where the rapid development and deployment of a method is needed to immediately address an outbreak event.Resources:
   Compendium of Analytical Laboratory Methods for Food and Feed Safety
9. Provide a detailed quarterly summary of all samples collected and analyzed through the FERN website, or other FDA approved system. This summary must include, at a minimum:
   a. the laboratory name;
   b. sample number;
   c. product description;
   d. the manufacturer/brand of the product;
   e. any codes listed on the product (e.g. lot codes, etc);
   f. product expiration date;
   g. country of origin, if available;
   h. collecting entity name;
   i. date collected;
   j. lab receipt date;
   k. analytical method used;
   l. screening results;
   m. confirmatory results;
   n. final results (including value and units);
   o. completion date; and
   p. comments.
10. Follow best practices recommendations for proper sampling and laboratory data documentation and use FDA Form 431, or equivalent, as necessary for analytical worksheet packages.
    Resources:
    Human and Animal Food Testing Laboratories Best Practices Manual
    FDA Form 431 - Analyst Worksheet
11. Notify the FDA project manager and the technical lead within one (1) business day of any presumptive positive or “cannot rule out” (CRO) samples. Notification via email must be sent to ORA-LFFM-CAP@fda.hhs.gov. The State regulatory program with jurisdiction overthe presumptive positive or CRO sample must also be notified.
12. Submit the full laboratory package for any confirmed positive or violative sample within three (3) business days of final determination. This would include any supplemental information, as requested. The State regulatory program and the FDA will work collaboratively to determine if regulatory action is warranted, and which organization will be the lead.
13. Maintain a valid 20.88 agreement with FDA.
    Resources:
    Information Sharing/20.88 Agreements
14. . Identify a sampling organization and develop an annual sample plan that includes the types of samples to be collected and analyzed for the upcoming year, and for which analytes they will be analyzed, with FDA approval. The preferred sampling organizations for this project are the state manufactured food regulatory program and the animal food regulatory program. Other acceptable sampling organizations include any state or local government agencies that meet the guidelines as outlined in the most recent version of the Human and Animal Food Testing Laboratories Best Practices Manual. For applicants of the Microbiology Analytical Tracks 2 and/or 3 and/or Chemistry Analytical Tracks 2 and/or 3 that reside in a state where a state regulatory agency is enrolled in the Manufactured Food Regulatory Program Standards and/or the Animal Feed Regulatory Program Standards, and the applicant laboratory is identified as the primary servicing laboratory for that program, it is required that the enrolled regulatory program collect a minimum of 15% of the samples under those tracks, if awarded. The sampling organization selected must be:
    a. State Government;
    b. County Government;
    c. City or Township Government;
    d. Special District Government;
    e. Indian/Native American Tribal Government;
    f. U.S. Territory or Possession; or
    g. have regulatory authority for human and/or animal food.

    Any personnel performing the collection on behalf of the sampling organization must be trained and have demonstrated competency in sample collection, including but not limited to:

a. Maintaining sample integrity,
b. Aseptic sampling; and
c. Proper chain of custody.

Resources:
Human and Animal Food Testing Laboratories Best Practices Manual

15. When available, and if the capability exists in the laboratory, participate in at least one(1) FDA-requested assignment annually.

Discipline A: Microbiology

Use the table below to determine the amount of funding available based on the work selected. With the exception of Development Activities, each analytical track has an associated point value. For each track, select a sample load (if applicable), and tally the number of points for all tracks combined - this will equal the base funding. Using the number of points, determine which maintenance category is applicable and add that amount to the base funding for a total amount available for this discipline.

Example 1 - Lab ABC applies for:

- Analytical Track 1: Food Defense = $125,000 (3pts)
- Analytical Track 2: Human Food Product Testing (HIGH) = $115,000 (3pts)
- Analytical Track 3: Animal Food Product Testing (LOW) = $20,000 (1pt)
- Analytical Track 4: Whole Genome Sequencing (HIGH) = $90,000 (3pt)
- Funding Available: Base Funding: $350,000
- Point Value: 10 pts
- Additional Maintenance Funding: $110,000

Total Amount Available for Microbiology: $460,000

Example 2 - Lab XYZ applies for:

- Analytical Track 1: Food Defense = $125,000 (3pts)
- Analytical Track 2: Human Food Product Testing (LOW) = $20,000 (1pt)
- Analytical Track 5: Development (Cyclospora) = $75,000 (0pts)
- Funding Available: Base Funding: $220,000
- Point Value: 4 pts
- Additional Maintenance Funding: $90,000

Total Amount Available for Microbiology: $310,000

Analytical Tracks	Sample Load	Minimum Number	Funding	Points	Maintenance
1. Food Defense	N/A	50	$125,000	3	
2. Human Food Product Testing	Low Medium High	100 250 500	$20,000 $55,000 $115,000	1 2 3	
3. Animal Food Product Testing	Low Medium High	100 250 500	$20,000 $55,000 $115,000	1 2 3	12 pts = $130,000 6-11 pts = $110,000 Less than 6 pts = $90,000
4. Whole Genome Sequencing	Low Medium High	100 250 400	$20,000 $55,000 $90,000	1 2 3	
5. Microbiology Capability/ Capacity Development 2020-2021 • Whole Genome Sequencing • Cyclospora	N/A	N/A	$135,000 $75,00	N/A	N/A

Analytical Track 1: Food Defense

The purpose of this analytical track is to ensure laboratory surge capacity for the analysis of foods and food products related to microbiological contamination, through intentional means, and to enhance the network capacity and readiness of state BSL2+ and BSL3 laboratories. These samples may consist of, but are not limited to, the following: Vegetables and fruits (fresh and packaged); juices (concentrate and diluted); grains and grain products; seafood and other fish products; milk and other dairy products; infant formula; baby foods; bottled water; condiments; and alcoholic products (beer, wine, scotch).

To be considered for this analytical track, laboratories must have:

1. The ability to analyze human or animal food for:
    a. Bacillus anthracis
    b. Yersinia pestis; and
2. A BSL2+ facility, with personal protective equipment and safeguards in place.

Additional analyses potentially needed under this track include:

1. Francisella tularensis
2. Brucella sp.
3. Burkholderia sp.
4. Clostridium botulinum toxin-Select Agent toxin (non-BSL3)
5. Staphylococcal enterotoxin- Select Agent toxin (non-BSL3)
6. Ricin- Select Agent toxin (non-BSL3)
7. FERN BSL3 High Risk Unknown Screening Procedure for Food
8. Mouse bioassays

Track Specific Aims:

1. Participate in FDA-requested exercises, and/or surveillance activities to support and maintain readiness.
2. Participate in national special security event exercises, as available.
3. Maintain preparedness to rapidly respond to a suspected or confirmed intentional contamination event involving human or animal food. This includes ensuring that BSL2+ and/or BSL3 facilities are certified, if necessary, and fully functional, analysts are trained and have passed competency exercises, equipment is in working order, and reagents and supplies are available.
4. Participate in testing associated with suspected or credible threats to the food supply where a microbiological agent is suspected, as requested by FDA.

Analytical Track 2: Human Food Product Testing

The purpose of this analytical track is to improve food testing surveillance programs through the microbiological analysis of food products and environmental samples. The test results generated by these laboratories can be used to remove adulterated food from commerce and aide regulatory inspection programs in conducting investigations.

To be considered for this analytical track, laboratories must have:

1. The ability to analyze human food and/or environmental samples for:
    a. Listeria monocytogenes;
    b. Salmonella species; and
    c. Shiga toxin-producing E. coli (STEC).

Additional analyses potentially needed under this track include:

1. Food quality testing
    a. Aerobic Plate Counts (APC)
    b. Coliform (enumeration by Most Probable Number (MPN))
    c. Generic E. coli (enumeration by MPN)
2. Food safety pathogens
    a. Salmonella Enteritidis (environmental samples only)
    b. Campylobacter
    c. Shigella
    d. Clostridium botulinum, Clostridium perfringens, Clostridium difficile
    e. Staphylococcus aureus
    f. Yersinia enterocolitica
    g. Vibrio parahaemolyticus, V. vulnificus and V. cholerae
    h. Enterobacter sakazakii

i. Bacillus cereus
3. Virology (Proposals including virology testing are not being accepted in 2019-2020)
   a. Hepatitis A virus
   b. Norovirus
4. 4. Parasitology
   a. Cyclospora
   b. Cryptosporidium
5. 5. Toxins
   a. Staphylococcal enterotoxin
   b. cereus emetic toxin
6. 6. Specialty
   a. AST (antimicrobial susceptibility testing)

Suggested Hazard to Commodity Pairs:

It is preferred that laboratories participate in a complete study which consists of at least two hundred (200) samples of a single commodity/hazard pair. A complete study of 200 samples could be accomplished by one laboratory or across multiple laboratories. Suggested hazard to commodity pair tables may change annually based on need. New tables will be provided prior to submission deadlines of annual continuation applications for this project.

The list below is a suggestion and includes items that are of current interest. The laboratories have flexibility to conduct studies on pairs that are of interest or emerging issue within their state.

Commodity	**Hazard(s)**
Fresh Produce	Salmonella, Pathogenic E. coli, and Cyclospora
Recent outbreak commodities, ex. papayas, tahini, pre-cut melons	Salmonella, Shiga toxin-producing E. coli (STEC), and Listeria
RTE products	Listeria, Pathogenic E. coli, Salmonella
RTE Cereal	Salmonella

Analytical Track 3: Animal Food Product Testing

The purpose of this analytical track is to improve animal food testing surveillance programs through the microbiological analysis of animal food products. The test results generated by these laboratories can be used to remove adulterated animal food from commerce and aide regulatory inspection programs in conducting investigations.

To be considered for this analytical track, at a minimum, laboratories must have the ability to analyze animal food and/or environmental samples for Salmonella species.

Additional analyses potentially needed under this track include:

1. Food Safety pathogens and indicator organisms
   a. Listeria monocytogenes
   b. Shiga toxin-producing E. coli (STEC)
   c. Generic E. coli (for antimicrobial resistance [AMR] monitoring)
   d. Bacillus cereus
   e. Brucella
   f. Campylobacter
   g. Clostridium botulinum, Clostridium perfringens, Clostridium difficile
   h. Staphylococcus aureus
2. Parasitology
   a. Cyclospora (Note: Matrix extension work may be needed)
   b. Toxoplasma
3. Miscellaneous
   a. Bovine Spongiform Encephalopathy (BSE)
4. Specialty
   a. AST (antimicrobial susceptibility testing) (Note: Conducted as a follow-up to pathogen (Salmonella, Listeria monocytogenes and STEC) and indicator (E. coli) positive samples upon CVM's concurrence)

Suggested Hazard to Commodity Pairs:

It is preferred that laboratories conduct a complete study which consists of at least two hundred (200) samples of a single commodity/hazard pair. A complete study of 200 samples could be accomplished by one laboratory or across multiple laboratories. Suggested hazard to commodity pair tables may change annually based on need. New tables will be provided prior to submission deadlines of annual continuation applications for this project.

The list below is a suggestion and includes items that are of current interest. The laboratories have flexibility to conduct studies on pairs that are of interest or emerging issue within their state.

Commodity	**Hazard(s)**
Animal food (pet or livestock)	BSE

Analytical Track 4: Whole Genome Sequencing

The purpose of this analytical track is to enhance the GenomeTrakr network by capturing the current and evolving genomic diversity of non-clinical pathogens across FDA-relevant areas in human or animal food, environmental, and water samples. The data generated through this analytical track, which will be housed in public databases at the National Center for Biotechnology Information (NCBI), can be accessed by researchers and public health officials for real time comparison and analysis that promises to speed foodborne illness outbreak investigations and reduce foodborne illnesses and deaths.

To be considered for this analytical track, laboratories must have:

1. The ability to sequence human or animal food, and environmental isolates for Listeria monocytogenes;
    a. Salmonella; and
    b. Shiga toxin-producing E. coli (STEC).

Track Specific Aims:

1. Sequence a variety of Salmonella, Listeria monocytogenes, Shiga toxin-producing E. coli (STEC) and other foodborne related bacterial, viral and parasite pathogen isolates, as outlined in the proposal and approved by FDA. This can include environmental samples such as agricultural water, soil and soil amendments and production facility swabs;
2. Provide training and mentorship to other state laboratories, as requested,
3. Maintain facilities and personnel necessary to complete the work proposed under this project.
4. Enter results, including the metadata, in real-time to NCBI-NIH curated national database for enteric pathogen genomes, in coordination with FDA CFSAN;
5. Participate in the GenomeTrakr network, including meetings, conference calls, proficiency tests and other activities, such as overflow assignments from neighboring network partners;
6. Participate in multi-lab validation studies, as needed;
7. Attendance of at least one (1) key personnel to the annual GenomeTrakr Meeting; and
8. Attendance of at least one (1) key personnel to the annual LFFM Face-to-Face Meeting.

Analytical Track 5: Microbiology Capability/Capacity Development

The purpose of this analytical track is to build additional capability and expand the national capacity in microbiological areas of emerging technology and/or where FDA has identified a specific need.

Unless otherwise specified, opportunities under this track are for one (1) year only. The development opportunities available under this track are pre-determined by FDA on an annual basis, and laboratories may apply for these opportunities each year. Laboratories cannot be approved for more than one development project for the same discipline in the same year.

Development Opportunities for 2020-2021:

1. 1. Whole Genome Sequencing
    a. Develop the capability to sequence a variety of Salmonella, Listeria monocytogenes, shiga toxin-producing E. coli (STEC) and other foodborne related bacterial, viral and parasite pathogen isolates. Applicants must apply for development funding for the first year but have the option of selecting Analytical Track 4: Whole Genome Sequencing for subsequentyears, at which time the specific aims of that track will apply. Subsequent funding following the development year is dependent upon the laboratory successfully completing these specific aims and implementing this capability in their program.

Specific Aims:

i. Purchase a next-generation sequencer
ii. Attend a hands-on training on whole genome sequencing
iii. Complete a bioinformatics training
iv. Complete the 4 videos in the GenomeTrakr video library
v. Complete and pass an initial competency assessment for newly trained staff
vi. Participate in the GenomeTrakr proficiency test
vii. ttend the annual GenomeTrakr meeting
viii. ttend the annual LFFM Face-to-Face Meeting.

2. 2. Cyclospora
   a. Develop the capability to test for Cyclospora in human food product and environmental samples. Only laboratories selected for Analytical Tracks 1 and/or 2 are eligible for this development option. At the completion of the development period the laboratoryis expected to have completed all specific aims and agree perform this newlydeveloped capability, as needed, in conjunction with their enrollment in Analytical Tracks 1 and/or 2.

   Specific Aims:

   i. Purchase centrifuges, bead beater or homogenizer, and peristaltic geopump, as needed
   ii. Train personnel on the FDA BAM 19b: Molecular Detection of Cyclospora cayetanensis in Fresh Produce Using Real-Time PCR method
   iii. Demonstrate competency through a proficiency test offered by a suitable proficiency testing program, or if unavailable, a laboratory developed competency exercise.
   iv. iv. Attend the annual LFFM Face-to-Face Meeting.

Discipline B: Chemistry

Use the table below to determine the amount of funding available based on the work selected. With the exception of Development activities, each analytical track has an associated point value. For each track, select a sample load (if applicable), and tally the number of points for all tracks combined - this will equal the base funding. Using the number of points, determine which maintenance category is applicable and add that amount to the base funding for a total amount available for this discipline.

Example 1 - Lab ABC applies for:

- Analytical Track 1: Food Defense = $125,000 (3pts)
- Analytical Track 2: Human Food Product Samples (HIGH) = $115,000 (3pts)
- Analytical Track 3: Animal Food Product and Environmental Samples (HIGH) = $115,000 (3pts)
- Funding Available: Base Funding: $355,000
- Point Value: 9 pts
- Additional Maintenance Funding: $200,000
- Total Amount Available for Chemistry: $555,000

Example 2 - Lab XYZ applies for:

- Analytical Track 2: Human Food Product Samples (HIGH) = $115,000 (3pts)
- Analytical Track 3: Animal Food Product and Environmental Samples (Medium) = $55,000 (2pts)
- Analytical Track 4: Development (Allergen) = $55,000 (0pts)
- Funding Available: Base Funding: $225,000
- Point Value: 5 pts
- Additional Maintenance Funding: $180,000

Total Amount Available for Chemistry: $405,000

Analytical Tracks	Sample Load	Minimum Number	Funding	Points	Maintenance
1. Food Defense	N/A	75	$125,000	3	
2. Human Food Product Testing	Low Medium High	100 250 500	$20,000 $55,000 $115,000	1 2 3	
3. Animal Food Product Testing	Low Medium	100 250	$20,000 $55,000	1 2	9 pts = $200,000 4-8 pts = $180,000

	High	500	$115,000	3	Less than 4 pts = $160,000
4. Chemistry Capability/ Capacity Development ● Allergen Testing	N/A	N/A	$55,000	N/A	N/A

Analytical Track 1: Food Defense

The purpose of this analytical track is to ensure laboratory surge capacity in the analyses of foods and food products for analyses related to chemical contamination, through intentional means. These samples may consist of, but are not limited to, the following: Vegetables and fruits (fresh and packaged); juices (concentrate and diluted); grains and grain products; seafood and other fish products; milk and other dairy products; infant formula; baby foods; bottled water; condiments; and alcoholic products (beer, wine, scotch).

To be considered for this analytical track, laboratories must have the ability to analyze human or animal food for poisons/toxins and toxic metals.

Additional analyses potentially needed under this track include:

1. Poison/toxin analysis using gas chromatography mass spectrometry (GC MS and GC MS MS)
    a. CHE.0006, or equivalent
2. Poison/toxin analysis using liquid chromatography mass spectrometry (LC MS MS)
    a. CHE.0008, or equivalent
3. Toxic metals analysis using inductively coupled plasma mass spectrometry (ICP MS)
    a. CHE.0009 (EAM 4.7), or equivalent
4. Poison/toxin analysis using special methods including ion chromatography, FTIR, XRF, Head-space gas chromatography mass spectrometry, or other FERN specific methods.

Track Specific Aims:

1. Participate in FDA-requested annual triage exercises, and/or surveillance activities to support and maintain readiness.

2. Participate in national security event exercises, as available.

3. Maintain preparedness to rapidly respond to a suspected or confirmed intentional contamination event involving human or animal food. This includes ensuring analysts are trained and have passed competency exercises, equipment is in working order, and reagents and supplies are available.

4. Participate in testing associated with suspected or credible threats to the food supply where a chemical agent is suspected, as requested by FDA.

Analytical Track 2: Human Food Product Testing

The purpose of this analytical track is to improve food testing surveillance programs through the chemical analysis of food products. The test results generated by these laboratories can be used to remove adulterated food from commerce and aide regulatory inspection programs in conducting investigations.

To be considered for this analytical track, laboratories must have the ability to analyze human food for one or more of the following: pesticides, mycotoxins, veterinary drug residues, toxic elements, nutrition, filth, decomposition, new dietary ingredients, allergens, and/or other emerging food safety issues.

Additional analyses potentially needed under this track include:

1. Nutritional analysis to verify food and/or dietary supplement label claims;
    1. Proximate analyses;
    2. Fat analysis (saturated and unsaturated);
    3. Fat soluble vitamin analyses;
    4. Water soluble vitamin analyses;

    5. Nutritional metals analyses;
    6. Amino acid analysis;
2. Pesticide residue analyses to ensure compliance with pesticide action levels;
3. Mycotoxin residue analyses to ensure compliance with mycotoxin action levels;
4. Toxic metals analyses to ensure compliance with toxic element action levels;
5. Antibiotic/veterinary drug residue analyses to ensure compliance with drug residue action levels;
6. Filth and decomposition analyses to ensure food safety and integrity;
7. Economic adulteration analyses to discover adulterated/mislabeled food (sugar adulteration, species identification, engineered foods, mislabeling, etc.);
8. Food additives and Colors analyses to ensure compliance with regulations; and
9. Seafood Toxins - PSP (saxitoxin), ASP (domoic acid), DSP (okadaic acid, dinophysistoxins and their derivatives), NSP (brevetoxins), AZP (azaspiracids), CFP (ciguatoxin), TTX (tetrodotoxin)

Suggested Hazard to Commodity Pairs:

It is preferred that laboratories conduct a complete study which consists of at least two hundred (200) samples of a single commodity/hazard pair. A complete study of 200 samples could be accomplished by one laboratory or across multiple laboratories. Suggested hazard to commodity pair tables may change annually based on need. New tables will be provided prior to submission deadlines of annual continuation applications for this project.

The list below is a suggestion and includes items that are of current interest. The laboratories have flexibility to conduct studies on pairs that are of interest or emerging issue within their state.

Commodity	**Hazard(s)**
Juices (concentrate and diluted)	Toxic elements (inorganic arsenic)
Spices	Allergens (cross contamination hazard)

Analytical Track 3: Animal Food Product Testing

The purpose of this analytical track is to improve animal food testing surveillance programs through the chemical analysis of animal food products. The test results generated by these laboratories can be used to remove adulterated animal food from commerce and aide regulatory inspection programs in conducting investigations.

To be considered for this analytical track, laboratories must have the ability to analyze animal food for one or more of the following: pesticides, mycotoxins, toxic elements, nutrition deficiency or toxicity analysis, and/or other emerging animal food safety issues.

Additional analyses potentially needed under this track include:

1. Nutritional analysis to verify nutrition deficiencies or toxicities
    a. Fat soluble vitamin analyses
    b. Water soluble vitamin analyses
2. Contaminant analysis
    a. Dioxin, PCP levels analysis
    b. Pesticide residue analyses to ensure compliance with pesticide tolerances
        1. Glyphosate and acid herbicide
    c. Mycotoxin analyses to ensure compliance with mycotoxin guidance levels
    d. Toxic metals analyses to ensure compliance with toxic element
3. Feed additives analyses to ensure compliance with regulations
    a. Urea
    b. Ethoxyquin
    c. Preservatives
4. Emergent Issues for Animal Food and Pet Food (Prior approval required)
    a. Cannabis, hemp, CPD/THC
    b. Thyroid (iodine)
    c. Engineered feed (Cell cultured meat)
    d. Pentobarbital
    e. DDSG, glycerin

Suggested Hazard to Commodity Pairs:

It is preferred that laboratories conduct a complete study which consists of at least two hundred (200) samples of a single commodity/hazard pair. A complete study of 200 samples could be accomplished by one laboratory or across multiple laboratories. Suggested hazard to commodity pair tables may change annually based on need. New tables will be provided prior to submission deadlines of annual continuation applications for this project.

The list below is a suggestion and includes items that are of current interest. The laboratories have flexibility to conduct studies on pairs that are of interest or emerging issue within their state.

Commodity	**Hazard(s)**
Fish Products (e.g. fish meal)	Heavy Metals
Rendered Products	Heavy Metals
Dog and Cat Food (dehydrated, baked, extruded or otherwise processed to be shelf stable)	Aflatoxin
Dairy Cattle Feed	Aflatoxin and Deoxynivalenol (DON, vomitoxin)
Distiller Grains, Wheat midds, and other similar types of products	Fumonisin and Zearalenone
Distiller Grains	Pesticides
Oilseed Meals (e.g. soybean meal, canola meal, cottonseed meal)	Pesticides

Analytical Track 4: Chemistry Capability /Capacity Development

The purpose of this analytical track is to build additional capability and expand the national capacity in chemical areas of emerging technology and/or where FDA has identified a specific need.

Unless otherwise specified, these projects are for one (1) year only. The development options available under this track are pre-determined by FDA on an annual basis, and applicants may apply for these opportunities each year. Applicants cannot be approved for more than one development project for the same discipline in the same year.

Development Opportunities for 2020-2021:

1. Allergens
    a. Develop the capability to analyze human and/or animal food for allergens. Only laboratories selected for Analytical Tracks 1 and/or 2 are eligible for this development option. At the completion of the development period the laboratory is expected to have completed all specific aims and agree perform this newly developed capability, as needed, in conjunction with their enrollment in Analytical Tracks 1 and/or 2.
    Specific Aims:
        i. Purchase MagPix System with XPonent 4.2, a programmable shaker, u- bottom block, flat bottom assay plate, and cover blocks, as needed.
        ii. Train personnel on the xMAP Food Allergen Detection Assay (xMAP FADA).
        iii. Demonstrate competency through a proficiency test offered by a suitable proficiency testing program, or if unavailable, a laboratory developed competency exercise.
        iv. Attend the annual LFFM Face-to-Face Meeting.

Discipline C: Radiochemistry

Use the table below to determine the amount of funding available based on the work selected. With the exception of Development activities, each analytical track has an associated point value. For each track, select a sample load (if applicable), and tally the number of points for all tracks combined - this will equal the base funding. Using the number of points, determine which maintenance category is applicable and add that amount to the base funding for a total amount available for this discipline.

Example 1 - Lab ABC applies for:

- Analytical Track 1: Food Defense = $125,000 (3pts)
- Funding Available: Base Funding: $125,000
- Point Value: 3 pts
- Additional Maintenance Funding: $125,000
- Total Amount Available for Chemistry: $250,000

Example 2 - Lab XYZ applies for:

- Analytical Track 1: Food Defense = $125,000 (3pts)
- Analytical Track 2: Development (Expansion - Alpha) = $150,000
- Funding Available: Base Funding: $275,000
- Point Value: 3 pts
- Additional Maintenance Funding: $125,000

Total Amount Available for Chemistry: $400,000

Analytical Tracks	Sample Load	Minimum Number	Funding	Points	Maintenance
1. Food Defense	N/A	25	$125,000	3	3 pts - $125,000
2. Radiochemistry Capability/ capacity Development ● Expansion- Alpha ● Expansion- Beta ● Detection of Radionuclides	N/A	N/A	$150,000 $115,000 $120,000	N/A	N/A

Analytical Track 1: Food Defense

The purpose of this analytical track is to prove presence or absence of radioactive contamination and identify the identities of radionuclides present in human or animal food samples through screening. The data generated will be used to characterize the extent of food contamination, for following trends, and for calculating intakes.

To be considered for this analytical track, laboratories must have the ability to analyze human or animal food for the detection of gamma emitters, for example: Cs-137 and I-131.

Additional analyses potentially needed under this track include:

1. Detection of alpha emitters, for example: Am/Pu

2. Detection of beta emitters, for example: Sr-90

Track Specific Aims:

1. Triage data to determine whether further analysis is needed;

2. Utilize semi-quantitative results to determine if contamination is well above or well below regulatory limits;

3. Participate in FDA-requested triage exercises, and/or surveillance activities to support and maintain readiness; and

4. Participate in national security event exercises, as available.

Analytical Track 2: Radiochemistry Capacity/Capability Development

The purpose of this analytical track is to build additional capability and expand the national capacity in radiochemical areas of emerging technology and/or where FDA has identified a specific need.

Unless otherwise specified, these projects are for one (1) year only. The development options available under this track are pre-determined by FDA on an annual basis, and applicants may apply for these opportunities each year. Applicants cannot be approved for more than one development project for the same discipline in the same year.

Development Opportunities for 2019-2020:

1. Expansion of Radionuclide Testing Capability
    a. Alpha; OR
    b. Beta
    Specific Aims:

i. Purchase equipment to analyze for alpha or beta-emitters, as needed;
ii. Train designated staff in the analysis of foods for alpha or beta-emitters;
iii. Demonstrate competency through a proficiency test offered by a suitable proficiency testing program, or if unavailable, a laboratory developed competency exercise.
iv. Attend the annual LFFM Face-to-Face Meeting.

2. Detection of Radionuclides in Human or Animal Food
   a. a. Develop the capability to analyze human or animal for at least gamma-emitters.
   Specific Aims:
      i. Obtain a license for the possession of radioactivity;
      ii. Purchase equipment to analyze for gamma-emitters, as needed;
      iii. Train designated staff in the analysis of foods for radioactivity and appoint a Radiation Safety Officer;
      iv. Demonstrate competency through a proficiency test offered by a suitable proficiency testing program, or if unavailable, a laboratory developed competency exercise.
      v. Attend the annual LFFM Face-to-Face Meeting.

Discipline D: Special Projects

Analytical Tracks	Sample Load	Minimum Number	Funding	Points	Maintenance
1. Sample Collection	Low Medium High	100 – 500 501-1000 >1000	$25,000 $35,000 $45,000	N/A N/A N/A	N/A
2. NFSDX and ORAPP Integration	N/A	N/A	$20,000	N/A	N/A
3. Method Development/Validation	N/A	N/A	$35,000	N/A	N/A

Track 1: Sample Collection

The purpose of this track is to assist laboratories in obtaining the samples needed to meet the goals of this cooperative agreement. Funds provided under this track must be utilized to: compensate the sampling organization for collecting samples, purchase supplies for the sampling organization to utilize during sample collection, pay for shipping costs, or to pay for samples purchased at the manufacturer or retail location.

Only applicants receiving the Human and/or Animal Food Testing Tracks are eligible to receive funding under this track.

Track Specific Aims:

1. Enter into an agreement with a sampling organization to collect samples to fulfill the requirements under this project, if applicable.

Track 2: National Food Safety Data Exchange (NFSDX) Integration and ORA Partner Portal (ORAPP) Adoption

The purpose of this track is to assist laboratories in enhancing their current data systems to enable them to electronically submit Sample Analysis data to FDA. This funding is only available for one (1) year. Applicants have the ability to select which year they prefer to complete this project.

Track Specific Aims:

1. In conjunction with FDA, assess the current IT capabilities of the laboratory. This must include an analysis of which fields could be mapped to FDA, and any that would need to be developed.
2. Enhance laboratory IT systems to submit data electronically by integrating laboratory IT system with NFSDX or adopting ORA Partners Portal by uploading laboratory data files. The relevant and required data fields, file formats, and data exchange mechanism shall be based on FDA guidance.
3. Participate in data exchange onboarding meeting and complete FDA questionnaire.
4. Attend collaboration meetings with the FDA NFSDX and ORAPP Teams, at frequency determined by FDA.
   a. Identify and determine laboratory access to NFSDX or ORAPP for electronic datasubmission
   b. Resolve any laboratory IT issues with data submission
   c. Provide active guidance and insights into challenges and upcoming FDA enhancements and enable additional data submission capabilities

5. Enter into a Memorandum of Understanding (MOU) and Interconnection Security Agreement (ISA) with the FDA, as required for program participation.

Track 3: Method Development and Method Validation

The purpose of this track is to conduct preliminary, short-term or exploratory investigations that focus on the feasibility of a new method and/or technology. These projects could include proof of concept for new analytical approaches, method development for representative food matrices, single laboratory validations of methods, matrix or platform extensions or multi-laboratory validation research studies. Projects will be one-year in duration but can be renewed for additional years upon demonstration of appropriate progress. Multiple-year sequential efforts may be proposed but will be approved on a year-by-year basis. Project opportunities may change annually, as requested by FDA.

Potential Project Opportunities for 2020-2021

Microbiology

1. Multi-laboratory validation of a QPCR screening method for Salmonella in foods
2. Multi-laboratory validation of a Listeria monocytogenes serogrouping method

Chemistry

1. Multi-laboratory validation of immunochemical-based histamine kits for quantitative analysis of histamine
2. Multi-laboratory validation of method for Arsenic speciation in seafood using LC-ICP-MS
3. Multi-laboratory validation of Elemental Analysis Manual method EAM 4.12: analysis of bottled water by ICP-MS
4. Multi-laboratory validation LC/MS/MS method for vet drug residues in raw milk, milk, and powdered milk
5. Single laboratory validation of extension of LC/MS/MS method for pesticide to new matrices

Track Specific Aims:

1. Follow FDA guidelines for the Validation of Analytical Methods

Validation of Analytical Methods for the Detection of Microbial Pathogens in Foods and Feeds

Validation of Chemical Methods for the FDA FVM Program

2. Complete single laboratory validation.

See Section VIII. Other Information for award authorities and regulations.

Section II. Award Information

Funding Instrument

Cooperative Agreement: A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, FDA scientific or program staff will assist, guide, coordinate, or participate in project activities. See Section VI.2 for additional information about the substantial involvement for this FOA.

Application Types Allowed

New

The OER Glossary and the SF424 (R&R) Application Guide provide details on these application types. Only those application types listed here are allowed for this FOA.

Clinical Trial?

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

Need help determining whether you are doing a clinical trial?

Funds Available and Anticipated Number of Awards

The number of awards is contingent upon FDA appropriations and the submission of a sufficient number of meritorious applications.

Award(s) will provide one (1) year of support and include future recommended support for four (4) additional year(s) contingent upon annual appropriations, availability of funding and satisfactory awardee performance.

FDA/Office of Regulatory Affairs intends to fund up to $23 million dollars, for fiscal year 2020, in support of this grant program.

It is anticipated that up to one hundred (100) awards will be made, not to exceed $1,500,000 in total costs (direct plus indirect), per award.

Award Budget

Applicants have the option to apply for multiple Projects (multiple tracks under multiple disciplines) but must follow the outlined schematic to determine their maximum budget per Project.

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

YR 01: $1,500,000

YR 02: $1,500,000

YR 03: $1,500,000

YR 04: $1,500,000

YR 05: $1,500,000

Award Project Period

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

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

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Governments

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

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for FDA support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.

Foreign components, as *defined in the HHS Grants Policy Statement*, **are not** allowed.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. Failure to complete registrations in advance of a due date is not a valid reason for a late submission.

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

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

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

Eligible Individuals (Program Director/Principal Investigator)

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

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF424 (R&R) Application Guide.

2. Cost Sharing

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

3. Additional Information on Eligibility

Number of Applications

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

The FDA will not accept duplicate or highly overlapping applications under review at the same time. This means that the FDA will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.

Section IV. Application and Submission Information

1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST or an institutional system-to-system solution. A button to apply using ASSIST is available in Part 1 of this FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the Multi-Project (M) Instructions in the SF424 (R&R) Application Guide, except where instructed in this funding opportunity announcement to do otherwise and where instructions in the Application Guide are directly related to the Grants.gov downloadable forms currently used with most FDA opportunities. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Letter of Intent

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows FDA staff to estimate the potential review workload and plan the review.

By the date listed in Part 1. Overview Information, prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed activity
- Name(s), email address(es), and telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel
- Participating institution(s)
- Number and title of this funding opportunity
- Projects (Title of each Discipline and analytical track, and sample load (if applicable)), of which there is interest

The letter of intent should be sent to:

Kiara Fowler
Email: Kiara.Fowler@fda.hhs.gov

A technical session will be held for prospective applicants in February/March of 2020-2022. The conference call information will be provided to prospective applicants that submit a letter of intent. The technical session will provide an overview of the submission requirements and allow prospective applicants an opportunity to ask questions regarding the application process. Participation in the technical session is optional, but strongly encouraged.

Page Limitations

Available Component Types	Research Strategy/Program Plan Page Limits
Overall	12
Admin Core (Use for Admin)	6
Project	12 (each Project)

Additional page limits described in the SF424 Application Guide and the Table of Page Limits must be followed.

Instructions for the Submission of Multi-Component Applications

The following section supplements the instructions found in the SF424 (R&R) Application Guide, and should be used for preparing a multi-component application.

The application should consist of the following components:

- Overall: required; maximum 1
- Admin Core: required; maximum 1
- Projects: required; minimum 1

Overall Component

When preparing your application, use Component Type 'Overall'.

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

SF424 (R&R) Cover (Overall)

Complete entire form.

PHS 398 Cover Page Supplement (Overall)

Follow standard instructions.

Research & Related Other Project Information (Overall)

Follow standard instructions.

Project/Performance Site Location(s) (Overall)

Enter primary site only.

A summary of Project/Performance Sites in the Overall section of the assembled application image in eRA Commons compiled from data collected in the other components will be generated upon submission.

Research & Related Senior/Key Person Profile (Overall)

Include only the Project Director/Principal Investigator (PD/PI) and any multi-PDs/PIs (if applicable to this FOA) for the entire application.

A summary of Senior/Key Persons followed by their Biographical Sketches in the Overall section of the assembled application image in eRA Commons will be generated upon submission.

Budget (Overall)

The only budget information included in the Overall component is the Estimated Project Funding section of the SF424 (R&R) Cover.

A budget summary in the Overall section of the assembled application image in eRA Commons compiled from detailed budget data collected in the other components will be generated upon submission.

PHS 398 Research Plan (Overall)

Introduction to Application: Not required.

Specific Aims: Describe the overall objective of the proposed multi-project application, and how the individual projects contribute to the overall objective.

Research Strategy:

Focusing on the project as a whole, describe the strategy to accomplish the overarching aims of the overall project. This should include how your personnel, resources, and organizational infrastructure are well suited to meet the goals of the project through appropriate training and experience.

Explain how the quality management system in place in the laboratory supports a strong understanding of quality control and quality assurance, and maintains critical quality elements such as management systems documentation, control of records, actions to address risks and opportunities, corrective actions, internal audits and management review.

Summarize the plan for executing the proposed sampling plan, to include designation of a sampling organization and a detailed description of how the proposed number of samples will be collected and analyzed. This should include an explanation of the regulatory authority of the sampling organization and demonstration of experience and training in sample collection.

Letters of Support: Provide any letters of support specific to the Overall component; not required.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as

provided in the SF424 (R&R) Application Guide, with the following modification:

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

Appendix:

Only limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide; any instructions provided here are in addition to the SF424 (R&R) Application Guide instructions.

PHS Human Subjects and Clinical Trials Information (Overall)

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

If you answered "Yes" to the question "Are Human Subjects Involved?" on the R&R Other Project Information form, there must be at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or a **Delayed Onset Study** record within the application. The study record(s) must be included in the component(s) where the work is being done, unless the same study spans multiple components. To avoid the creation of duplicate study records, a single study record with sufficient information for all involved components must be included in the Overall component when the same study spans multiple components.

Study Record: PHS Human Subjects and Clinical Trials Information

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

Delayed Onset Study

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

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

PHS Assignment Request Form (Overall)

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

Administration (Admin)

When preparing your application, use Component Type 'Admin Core.'

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

SF424 (R&R) Cover (Admin)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Admin)

Enter Human Embryonic Stem Cells in each relevant component. Typically, not applicable for this FOA.

Research & Related Other Project Information (Admin)

Human Subjects: Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

Vertebrate Animals: Answer only the 'Are Vertebrate Animals Used?' question.

Project Narrative: Do not complete. Note: ASSIST screens will show an asterisk for this attachment indicating it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components.

Project /Performance Site Location(s) (Admin)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Admin)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Core Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

Budget (Admin)

The appropriate budget form will be included in the application package.

- The Admin Budget should include necessary costs associated with the overall administration, management and coordination for the grant. Individual Project budgets should be submitted with each Project (see Project section below).
- 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.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Admin)

Introduction to Application: Not required.

Specific Aims: State concisely the overall strategy for the administration, management and coordination of the projects.

Research Strategy: Describe, the plans and strategy for the overall administration, management and coordination of the projects, including:

- Resources for the administration, management and coordination of the projects;
- Organizational structure and staff responsibilities,
    - Plans for Collecting and Reporting Metric.

Letters of Support: Provide any letters of support specific to the Admin component; not required.

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

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

Appendix: Only limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide; any instructions provided here are in addition to the SF424 (R&R) Application Guide instructions.

PHS Human Subjects and Clinical Trials Information (Admin)

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

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

Study Record: PHS Human Subjects and Clinical Trials Information

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

Delayed Onset Study

Note: Delayed onset does NOT apply to a study that can be described but will not start immediately (i.e., delayed start).All instructions in the SF424 (R&R) Application Guide must be followed

Project

When preparing your application, use Component Type 'Project.'

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

SF424 (R&R) Cover (Project)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project - Title must include the following:
    - Discipline Name
    - Analytical Track Name
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Project)

Enter Human Embryonic Stem Cells in each relevant component (typically not relevant to this FOA).

Research & Related Other Project Information (Project)

Human Subjects: Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

Vertebrate Animals: Answer only the 'Are Vertebrate Animals Used?' question.

Project Narrative: Do not complete. Note: ASSIST screens will show an asterisk for this attachment indicating it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components.

Project / Performance Site Location(s) (Project)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Project)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Project Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

Budget (Project)

The appropriate budget form will be included in the application package.

- A separate detailed budget must be submitted for each Project.
- 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 for each Project.
- 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.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Project)

Introduction to Application: Not required

Specific Aims: Describe the aims of the project in relation to the goals of the overall project.

Research Strategy: All applicants must complete the required assessment(s) for all projects for which they are applying. Each project must have its own separate completed assessment. The completed assessment(s) must be included in the application and be page 1 of the Research Strategy. The assessment constitutes 50% of the application score for each project. The assessment can be found at:

https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/laboratory-flexible-funding-model-cooperative-agreement/

A separate Research Strategy (aka the Project Plan) must be submitted for each proposed project. The Research Strategy for each project should be organized into the sections as outlined below:

Section I.

a. Assessment - page 1 of the Research Strategy should be the completed Assessment for the Project

Section II.

This section should address the below information as outlined for each Discipline and Analytical Track.

Maintenance Track Assessments:

1. Microbiology: Track 1 - Food Defense

2. Microbiology: Track 2 - Human Food Product Testing

3. Microbiology: Track 3 - Animal Food Product Testing

4. Microbiology: Track 4 - Whole Genome Sequencing

5. Chemistry: Tracks 1-3 (Food Defense, Human Food Product Testing, and Animal Food Product Testing)

6. Radiochemistry: Track 1 - Food Defense

Discipline A: Microbiology

All applicants applying for any analytical track under this discipline must outline the following in the Research Strategy:

1. Describe the organisms the laboratory has the ability to screen for and/or confirm.

2. Provide a facility diagram, including the location of equipment that will be utilized to support the proposed work.

3. Provide certificate(s) of ISO 17025 accreditation and accreditation scope(s). If the laboratory is not accredited to ISO 17025, describe the quality management system in place including, information regarding training, proficiency testing, document control, corrective actions, and procedures put in place to ensure that methods are properly implemented, and validated.

4. Outline the plan, and resources available, equipment and personnel included, to execute the work activities for each individual analytical track for which the laboratory is applying.

5. Demonstrate commitment to adhere to FDA guidance and use FDA methodology, as requested.

6. Detail any national laboratory response participation involving food testing over the last five (5) years, including description of incidents, testing performed, and significant outcomes.

7. Indicate whether the laboratory is regulatory for human and/or animal food, and if it is the primary servicing laboratory for the testing of manufactured human or animal food within the state.

8. Indicate laboratory's ability and willingness to participate in small-scale matrix extension, method development, and method validation, as needed.

9. Provide curriculum vitae of individuals working on the project(s).

10. Demonstrate commitment to participate in conference calls and meetings regarding cooperative agreement activities.

11. Demonstrate commitment to send a minimum of two (2) key personnel, one of which being the PD/PI, to the national laboratory face-to-face meeting per year, and the GenomeTrakr face-to-face meeting, if applicable.

12. Provide a list of proficiency tests that have been successfully completed over the last five (5) years.

Please see below for additional requirements for Analytical Tracks 1, 2 and 4.

Analytical Track 1: Food Defense

1. Describe the laboratories ability to analyze food samples in a BSL2 + environment.

2. Describe the laboratory’s ability to analyze food samples in a certified BSL3 environment, if applicable.

3. Provide a summary of select agent permits currently held.

4. Provide a summary of LRN membership and participation, if applicable.

5. Indicate the laboratory's ability and willingness to maintain competency for the BSL3 High Risk Unknown Screening Procedure for Food.

6. Indicate the laboratory's ability and willingness to maintain capability for mouse Bioassays for agents of concern.

7. Indicate the monthly sample capacity for this track, by total analyses, categorized by organism, if possible.

8. Indicate the laboratories willingness to maintain preparedness for processes and procedures outlined in your capability statements to rapidly and swiftly respond to a suspected or confirmed food defense event.

Analytical Track 2: Human Food Product Testing

1. Indicate the monthly sample capacity for this track, by total analyses, categorized by organism, if possible.

2. Indicate the commodity and hazard pairs, and projected sample numbers of each, the laboratory is proposing to analyze under this project.

Analytical Track 3: Animal Food Product Testing

1. Indicate the monthly sample capacity for this track, by total analyses.

2. Indicate the commodity and hazard pairs, and projected sample numbers of each, the laboratory is proposing to analyze under this project.

Analytical Track 4: Whole Genome Sequencing

1. Describe the organisms the laboratory has the ability to sequence.

2. If you have been a GenomeTrakr contributor, provide evidence of the number of pathogen isolate sequences submitted through GenomeTrakr over the past five (5) years.

3. Indicate ability and willingness to train and/or mentor other WGS labs.

Analytical Track 5: Microbiology Capability/Capacity Development

1. Outline the plan, and resources available, equipment and personnel included, to execute the work

activities for the development activity for which the laboratory is applying. This must include a

description of how they will accomplish this work in addition to maintenance activities under any

other analytical track.

2. Provide the qualifications of the personnel that will work on this track.

Discipline B: Chemistry

Analytical Tracks 1-3 (Food Defense, Human Food Product Testing, Animal Food Product Testing)

All applicants applying for analytical tracks 1-3 under this discipline must:

1. Provide a facility diagram, including the location of equipment that will be utilized to support the proposed work.

2. Provide certificate(s) of ISO 17025 accreditation and accreditation scope(s). If the laboratory is not accredited to ISO 17025, describe the quality management system in place including, information regarding training, document control, corrective actions, proficiency testing, and procedures put in place to ensure that methods are properly implemented and validated.

3. Outline the plan, and resources available, equipment and personnel included, to execute the work activities for each individual analytical track for which the laboratory is applying.

4. Indicate whether the laboratory is the regulatory laboratory for human and/or animal food, and if it is the primary servicing laboratory for the testing of manufactured human or animal food within the state.

5. Indicate whether the laboratory is an animal diagnostic laboratory with animal food and feed capabilities.

6. Describe the testing capabilities and all analytical platforms and technologies currently utilized in the laboratory.

7. Provide a summary of the laboratory chemists/analysts that have three (3) or more years of experience with the following, including which platforms and technologies:

a. LC/MS/MS

b. GC/MS

c. GC/MS/MS

d. GC/HRMS

e. HPLC

f. UHPLC or small bore/ultra-high liquid chromatography applications

8. Describe the proficiency tests completed in the last two (2) years and the outcome.

9. Indicate how many samples have been submitted to the FDA in last two (2) years that were:

a. Tested using or for FDA compliance programs

b. Tested using FDA methods; and

c. Documented on FDA analytical worksheets

Analytical Track 4: Chemistry Capability/Capacity Development

All applicants applying for analytical track 4 under this discipline must:

1. Outline the plan, and resources available, equipment and personnel included, to execute the work activities for the development activity for which the laboratory is applying. This must include a description of how they will accomplish this work in addition to maintenance activities under any other analytical track.

2. Provide the qualifications of the personnel that will work on this track.

Discipline C: Radiochemistry

All applicants applying for any analytical track under this discipline must:

1. Provide a facility diagram, including the location of equipment that will be utilized to support the areas of work.

2. Provide certificate(s) of ISO 17025 accreditation and accreditation scope(s). If the laboratory is not accredited to ISO 17025, describe the quality management system in place including, information regarding training, document control, corrective actions, proficiency testing, and procedures put in place to ensure that methods are properly implemented and validated.

3. Outline the plan, and resources available, equipment and personnel included, to execute the work activities for each individual analytical track for which the laboratory is applying.

4. Indicate whether the laboratory is the regulatory laboratory for human and/or animal food, an if it is the primary servicing laboratory for the testing of manufactured human or animal food within the state.

5. Indicate whether the laboratory is an animal diagnostic laboratory with animal food and feed capabilities.

6. Provide a summary of the laboratory chemists/analysts that have three (3) or more years of experience with the following, including which platforms and technologies in human or animal food:

a. Gamma analysis

b. Alpha Screening

c. Beta screening

d. Quantification of alpha and/or beta emitters ICP/MS

e. Radioanalytical separation chemistry

7. Describe the FERN proficiency tests and lab intercomparison events completed in the last two (2) years and the outcome.

8. Describe the laboratory's routine radiochemistry surveillance in human or animal food, to include any ability to:

a. Test for gamma-emitters

b. Screen for alpha and/or beta activity

c. Quantify alpha and/or beta activity

Please see below for additional requirements for Analytical Track 2.

Analytical Track 2: Radiochemistry Capability/Capacity Development

1. Outline the plan, and resources available, equipment and personnel included, to execute the work activities for the development activity for which the laboratory is applying. This must include a description of how they will accomplish this work in addition to maintenance activities under any other analytical track.

2. Provide the qualifications of the personnel that will work on this track.

Laboratories applying to develop radiochemistry capability (and not expand) must also:

1. Indicate whether the laboratory has obtained a license for the possession of radioactivity from the Nuclear Regulatory Commission or your State's Regulatory Authority. If not, has the facility been evaluated by the appropriate regulatory body for fitness to own a license for the radionuclides necessary to support the work for which the laboratory is applying.

2. Provide the qualifications of the personnel that will work on this track. Include whether a Radiation Safety Officer has been identified or if personnel have been designated to be trained to fill this role.

3. Describe how the facility has the adequate space, power, hazardous waste disposal, and environmental controls in place to support the radiation detection equipment necessary to meet the specific aims of this track.

4. Explain any training the laboratory staff has received in the analysis of foods for radioactivity. If none, explain the plan to train designated staff to serve in this capacity.

5. Outline the plan, and resources available, equipment and personnel included, to execute the work activities for each individual analytical track for which the laboratory is applying.

Discipline D: Special Projects

All applicants applying for any analytical track under this discipline must:

1. Describe how the special project will be used to support the overall goals of this cooperative agreement.

2. Outline the plan, and resources available, equipment and personnel included, to execute the work activities for each individual analytical track for which the laboratory is applying.

3. Provide the qualifications of the personnel that will work on this track.

4. Provide a facility diagram, including the location of equipment that will be utilized to support the proposed work.

5. Provide certificate(s) of ISO 17025 accreditation and accreditation scope(s). If the laboratory is not accredited to ISO 17025, describe the quality management system in place including, information regarding training, document control, corrective actions etc.

6. Outline the plan, and resources available, equipment and personnel included, to execute the work activities for each individual analytical track for which the laboratory is applying.

7. Indicate whether the laboratory is the regulatory laboratory for human and/or animal food, an if it is the primary servicing laboratory for the testing of manufactured human or animal food within the state.

8. Indicate whether the laboratory is an animal diagnostic laboratory with animal food and feed capabilities.

9. Describe the testing capabilities and all analytical platforms and technologies currently utilized in the laboratory.

10. Provide a summary of the laboratory chemists/analysts that have three (3) or more years of experience with the following, including which platforms and technologies:

a. LC/MS/MS

b. GC/MS

c. GC/MS/MS

d. GC/HRMS

e. HPLC, UHPLC or small bore/ultra-high liquid chromatography applications

11. Describe the proficiency tests completed in the last two (2) years and the outcome.

12. Indicate how many samples have been submitted to the FDA in last two (2) years that were:

a. Tested using FDA compliance programs

b. Tested using FDA methods; and

c. Documented on FDA analytical worksheets

13. Describe the organisms the laboratory has the ability to sequence.

14. Provide evidence of the number of isolates provided to GenomeTrakr over the past five (5) years.

15. Indicate ability and willingness to train and/or mentor other WGS labs.Analytical Track 4: Whole Genome Sequencing.

16. Describe the organisms the laboratory has the ability to sequence.

17. Provide evidence of the number of isolates provided to GenomeTrakr over the past five (5) years.

18. Indicate ability and willingness to train and/or mentor other WGS labs. Only include information that is different from application guide.

Letters of Support: Provide any letters of support that are specific to this project; not required

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

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

Appendix:

Only limited items are allowed in the Appendix.Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide; any instructions provided here are in addition to the SF424 (R&R) Application Guide instructions.

PHS Human Subjects and Clinical Trials Information (Project)

When involving human subjects research, clinical research, and/or FDA-defined clinical trials follow all instructions for

the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with the following additional instructions:

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

Study Record: PHS Human Subjects and Clinical Trials Information

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

Delayed Onset Study

Note: Delayed onset does NOT apply to a study that can be described but will not start immediately (i.e., delayed start).All instructions in the SF424 (R&R) Application Guide must be followed.

3. Unique Entity Identifier and System for Award Management (SAM)

See Part 1. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov.

4. Submission Dates and Times

Part I. Overview Information contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission.

Organizations must submit applications to Grants.gov (the online portal to find and apply for grants across all Federal agencies) using ASSIST or other electronic submission systems. Applicants must then complete the submission process by tracking the status of the application in the eRA Commons, FDA's electronic system for grants administration. eRA Commons and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. **Late applications will not be accepted for this FOA.**

Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review.

6. Funding Restrictions

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

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

1. Facilities and work reimbursed under the FDA human or animal food safety inspection contract or other funding mechanisms must remain distinct and separate from the cooperative agreement.

2. Vehicle purchases are not permitted.

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

4. Clothing and uniforms with the exception of personal protective equipment (PPE). PPE is defined as protective clothing or

other outerwear required to mitigate a defined workplace hazard.

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

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

For information on how your application will be automatically assembled for review and funding consideration after submission go to: http://grants.nih.gov/grants/ElectronicReceipt/files/Electronic_Multi-project_Application_Image_Assembly.pdf.

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit How to Apply – Application Guide. For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:

All PD(s)/PI(s) and component Project Leads 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.

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 (SAM). Additional information may be found in the SF424 (R&R) Application Guide.

See more tips for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the assigned Grants Management Specialist and responsiveness by components of participating organizations, FDA. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

Post Submission Materials

Post-submission materials are those submitted after submission of the grant application but prior to objective review. They are not intended to correct oversights or errors discovered after submission of the application. FDA accepts limited information between the time of initial submission of the application and the time of objective review. Applicants must contact the assigned Grants Management Specialist to receive approval, prior to submitting any post submission materials. Acceptance and/or rejection of any post submission materials is at the sole discretion of the FDA. Any inquiries regarding post submission materials should be directed to the assigned Grants Management Specialist.

Section V. Application Review Information

1. Criteria

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

Scored Review Criteria - Overall and Admin

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each.

Personnel and Resources (50 points)

Are the PD(s)/PI(s), collaborators, and other key personnel well suited to the project, including having appropriate experience and training? Does the applicant appear to have adequate staff and resources (including necessary equipment) to meet the minimum analysis activities of the analytical tracks applied for? Did the application provide

enough detail about the quality management system to provide an understanding of the quality control and assurance measures in place? Do they agree to participate in proficiency tests or competency exercises on an annual basis to maintain competency?

Approach (50 points)

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Is there adequate demonstration of effectiveness in working with other agencies and appropriate organizations to implement the goals of the cooperative agreement - for example: who will collect the required samples? Did the application provide enough detail about how the applicant will execute the activities and projects within the proposal? Are the desired technologies being utilized?

Additional Review Criteria - Overall and Admin

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Protections for Human Subjects

Generally not applicable. Reviewers should bring any concerns to the attention of assigned Grants Management Specialist.

Inclusion of Women, Minorities, and Individuals Across the Lifespan

Generally not applicable. Reviewers should bring any concerns to the attention of assigned Grants Management Specialist.

Vertebrate Animals

Generally not applicable. Reviewers should bring any concerns to the attention of assigned Grants Management Specialist.

Biohazards

Generally not applicable. Reviewers should bring any concerns to the attention of assigned Grants Management Specialist.

Resubmissions

Not Applicable

Renewals

Not Applicable

Revisions

Not Applicable

Select Agent Research

Generally not applicable. Reviewers should bring any concerns to the attention of assigned Grants Management Specialist.

Resource Sharing Plans

Generally not applicable. Reviewers should bring any concerns to the attention of assigned Grants Management Specialist.

Authentication of Key Biological and/or Chemical Resources

Generally not applicable. Reviewers should bring any concerns to the attention of assigned Grants Management Specialist.

Scored Review Criteria - Individual Projects

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each.

Effective Use of Grant Funds (10 points)

Is the proposed budget relevant and does it support the scope of activities outlined in the application?

Personnel and Resources (20 points)

Are the PD(s)/PI(s), collaborators, and other key personnel well suited to the project, including having appropriate experience and training? Does the applicant appear to have adequate staff and resources (including necessary equipment) to meet the minimum analysis activities of the analytical tracks applied for? Did the application provide enough detail about the quality management system to provide an understanding of the quality control and assurance measures in place? Do they agree to participate in proficiency tests or competency exercises on an annual basis to maintain competency?

Approach (20 points)

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Is there adequate demonstration of effectiveness in working with other agencies and appropriate organizations to implement the goals of the cooperative agreement - for example: who will collect the required samples? Did the application provide enough detail about how the applicant will execute the activities and projects within the proposal? Are the desired technologies being utilized?

Capability (50 points)

Disciplines A, B, C - Microbiology, Chemistry, and Radiochemistry - MAINTENANCE

An assessment is required for these projects. Using the submitted assessment, verify the accuracy of the assessment score through information provided in the research strategy and any supporting documentation.

a. Divide the total points earned by the total possible points.

b. Determine percentage

c. Multiply assessment percentage by 50.

-OR-

Disciplines A, B, C - Microbiology, Chemistry, and Radiochemistry - DEVELOPMENT

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have adequate resources (including staff and infrastructure) been proposed in the application budget to meet the specific aims of the cooperative agreement? Is there adequate demonstration of effectiveness in working with other agencies and appropriate organizations to implement the goals of the cooperative agreement? Did the application provide enough detail to determine how the laboratory will execute the activities and projects to be developed?

-OR-

Discipline D: Special Projects

Are the overall strategy appropriate and support the work the applicant is conducting in microbiology, chemistry, and/or radiochemistry? Does the organization have adequate resources (including staff and infrastructure) to complete the tasks outlined in the strategy in the specified timeframe? Does the applicant demonstrate the ability to develop and implement this small-scale project, in addition to any other work proposed under this cooperative agreement?

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Objective Review Committee, using the stated review criteria.

As part of the objective review, all applications:

- Will receive a written critique.

Appeals of objective review will not be accepted for applications submitted in response to this FOA.

Applications will compete for available funds with all other recommended applications submitted in response to this FOA. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by objective review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

3. Anticipated Announcement and Award Dates

Successful applicants will be notified of additional information that may be required or other actions leading to an award. The decision not to award a grant, or to award a grant at a particular funding level, is discretionary and is not subject to appeal to any FDA or HHS official or board.

Section VI. Award Administration Information

1. Award Notices

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions described in Section IV.5. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this FOA will be subject to terms and conditions found in the HHS Grants Policy Statement.

2. Administrative and National Policy Requirements

All FDA grant and cooperative agreement awards include the *HHS Grants Policy Statement* as part of the NoA.

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research.

HHS provides general guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/index.html. The HHS Office for Civil Rights also provides guidance on complying with civil rights laws enforced by HHS. Please see https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html; and https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/index.html. Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see https://www.hhs.gov/civil-rights/for-individuals/disability/index.html. Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at https://www.hhs.gov/ocr/about-us/contact-us/index.html or call 1-800-368-1019 or TDD 1-800-537-7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53.

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization

Act of Fiscal Year 2009 (Public Law 110-417), FDA awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 "Federal awarding agency review of risk posed by applicants." This provision will apply to all FDA grants and cooperative agreements.

FDA considers the sharing of research resources developed through FDA-sponsored research an important means to enhance the value and further the advancement of research. When research resources have been developed with FDA funds and the associated research findings published, those findings must be made readily available to the scientific community.

Upon acceptance for publication, scientific researchers must submit the author's final manuscript of the peer-reviewed scientific publication resulting from research supported in whole or in part with FDA funds to the NIH National Library of Medicine's (NLM) PubMed Central (PMC). FDA defines the author's final manuscript as the final version accepted for journal publication, which includes all modifications from the publishing peer review process. The PMC archive is the designated repository for these manuscripts for use by the public, health care providers, educators, scientists, and FDA. Please see the FDA Public Access Policy.

Certificates of Confidentiality – 42 U.S.C. 241(d)

Awardees are responsible for complying with all requirements to protect the confidentiality of identifiable, sensitive information that is collected or used in biomedical, behavioral, clinical, or other research (including research on mental health and research on the use and effect of alcohol and other psychoactive drugs) funded wholly or in part by the Federal Government. See 42 U.S.C. 241(d). All research funded by FDA, in whole or in part, that is within the scope of these requirements is deemed to be issued a "Certificate of Confidentiality" through these Terms and Conditions. Certificates issued in this manner will not be issued as a separate document.

Awardees are expected to ensure that any investigator or institution not funded by FDA who receives a copy of identifiable, sensitive information protected by these requirements, understand they are also subject to the requirements of 42 U.S.C. 241(d). Awardees are also responsible for ensuring that any subrecipient that receives funds to carry out part of the FDA award involving a copy of identifiable, sensitive information protected by these requirements understand they are also subject to subsection 42 U.S.C. 241(d).

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

Cooperative Agreement Terms and Conditions of Award

The administrative and funding instrument used for this program is the cooperative agreement, an assistance instrument (rather than an acquisition instrument), in which substantial FDA programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, FDA's objective is to support and stimulate the recipient's activities by involvement in and otherwise working jointly with the award recipient in a partnership role; it is not to assume direction, prime responsibility, or a dominant role of activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardee for the project although specific tasks and activities may be shared between the awardee and the FDA as defined below.

Project Director/Principal Investigator Rights and Responsibilities:

The Project Director/Principal Investigator (PD/PI) retains the primary responsibility and dominant role for planning, directing, and executing the proposed project, with FDA/ORA staff being substantially involved as a partner with the PD/PI, as described below.

The PD/PI will maintain general oversight for ensuring compliance with the financial and administrative aspects of the award, as well as ensuring that all staff have the necessary training and clearance to work on this project. This individual will work closely with designated officials within the recipient organization and with partner organizations to create and maintain necessary documentation, including both technical and administrative reports; prepare justifications; appropriately acknowledge Federal support in publications, announcements, news programs, and other media; and ensure compliance with other Federal, regulatory, and organizational requirements.

FDA Responsibilities:

The Grants Project Team may consist of a Grants Management Specialist, Program Official (PO), Project Manager (PM) and Technical Advisor. The Grants Project Team collaborates to review the progress of the grantee. The Grants Project Team may utilize the grantee's progress reports, site visits, audit reports and other supporting documentation to determine if the condition of the award was met and satisfactory progress is being made. Each team member works in consultation with each other, as needed, throughout the duration of the project. A description of each team member involved with the program are described below.

An FDA Grants Management Specialist (GMS) will be assigned and named in the Notice of Award. The GMS oversees the administrative, financial, business and other non-programmatic aspects of the program. These activities include, but are not limited to the following:

- Provides guidance on administrative, business, fiscal aspects of grants management to grantees and FDA program staff
- Monitors and manages applications and required reports on eRA Commons
- Monitors administrative and financial aspects of grantee activities
- Maintains the official grantee file

An FDA Program Official (PO) will be assigned and named in the Notice of Award. The PO is accountable for the programmatic oversight of the grant to include coordination, with the Project Manager, on the technical aspects of the grant. S/he ensures the budget of grantees are reasonable and costs are allowable and allocable. The PO reviews the progress reports to verify the budget proposed includes only allowable expenses that support the project goals and objectives. The PO also assists with post-award monitoring and establishing a corrective action plan, if necessary.

An FDA Project Manager (PM) will be assigned to the program. The FDA PM is the responsible official for the programmatic, scientific, and/or technical aspects of assigned applications and cooperative agreements. The FDA PM will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards as described below.

The PM will have substantial involvement in the design, implementation, and evaluation of program activities, and dissemination of program results and outcomes, above and beyond routine grant monitoring. Substantial involvement by FDA/ORA includes, but is not limited to, the following:

- Provide guidance, and technical assistance in project planning, implementation, and evaluation;
- Provide subject matter expertise, programmatic assistance, and evaluation services to support program studies and activities;
- Actively monitor the supported program via telephone conversations, webinars, e-mails, written correspondence, or periodic site visits;
- Evaluate the supported program, including development of program-level performance measures, consistent data collection, and reporting procedures and protocols;
- Convene trainings, meetings, conference calls, and site visits with grantee to facilitate collaboration and information sharing;
- Participate in data analysis, interpretation of findings, and where appropriate, co-authorship of publications;
- Development of programs to meet the FDA mission;
- Provision of programmatic technical assistance;
- Post-award monitoring of project/program performance, including review of progress reports and making site visits; and other activities complementary to those of the FDA.

An FDA Technical Advisor(s) will be assigned to each enrolled program. The Advisor will work cooperatively with the PO to help monitor and report grantee status/progress including sharing of information and historical backgrounds. The FDA Technical Advisor will have programmatic involvement as described below including but not limited to the following:

- Provide guidance, and technical assistance in project planning, implementation, and evaluation;
- Convene trainings, meetings, conference calls, and site visits with grantee to facilitate collaboration and information sharing;
- Provide subject matter expertise, programmatic assistance, and evaluation services to support program studies and activities;
- Provision of programmatic technical assistance;
- Post-award monitoring of project/program performance, including review of progress reports and making site visits; and other activities complementary to those of the FDA.

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

Monitoring Activities

Periodic program monitoring will be conducted by FDA on an ongoing basis which may include telephone conversations, emails, on-site visits, review of written progress reports, audit assessments, financial reports, etc.

The Project Manager and Technical Advisor conduct the monitoring of the grantee's performance, provide technical advice and assistance and, when necessary, investigate problems or deficiencies identified during review of reports.

The Grants Project Team (Grant Management Specialist, Program Official, Project Manager and Technical Advisor(s)) reviews the progress report to verify the satisfactory progress is being made toward the project objectives and goals in the project, proposed activities are allowable and within the guidelines of the FOA and budget proposed includes only allowable expenses that support project goals and objectives. When necessary, the Grants Project Team will investigate problems or deficiencies identified during review of reports and determine the corrective actions required. Performance deficiencies will be addressed by requiring a revised progress report, submission of a corrective action plan, increased reporting requirements, funding restrictions, and other methods, including up to suspension or termination of the award. The Annual Progress Report will be due as part of the Research Performance Progress Report (RPPR) and is due no later than 60 days prior to the start date of the next budget period.

Financial Reporting:

A. Cash Transaction Reports

The Federal Financial Report (FFR) has a dedicated section to report Federal cash receipts and disbursements. For recipients this information must be submitted quarterly directly to the Payment Management System (PMS) using the web-based tool. Quarterly reports are due 30 days following the end of each calendar quarter. The reporting period for this report continues to be based on the calendar quarter. Questions concerning the requirements for this quarterly financial report should be directed to the PMS.

B. Financial Expenditure Reports

A required Federal Financial Report (FFR) must be submitted annually. FDA now requires all annual financial expenditure reports to be submitted electronically using the Federal Financial Report (FFR) system located in the eRA Commons. This includes all initial FFRs being prepared for submission and any revised FSR/FFRs being submitted or re-submitted to FDA. Paper expenditure/FFR reports will not accepted.

Annual FFRs must be submitted for each budget period no later than 90 days after the end of the calendar quarter in which the budget period ended. The reporting period for an annual FFR will be that of the budget period for the grant; however, the actual submission date is based on the calendar quarter. Failure to submit timely reports may affect future funding.

C. Closeout Requirements (when applicable)

A Final Program Progress Activity Report, Final Federal Financial Report SF-425, Final Invention Statement HHS-568 (if applicable), Tangible Personal Property Report SF-428, and Statement of Disposition of Equipment (if applicable) must be submitted within 90 days after the expiration date of the project period.

D. Auditing

A non-Federal entity that expends $750,000 or more during the non-Federal entity's fiscal year in Federal awards must have a single or program-specific audit conducted for that year in accordance with the provisions of 45 CFR 75, Subpart F-Audit Requirements. Audits must be completed and submitted electronically to the Federal Audit Clearinghouse (FAC) within 30 days after receipt of the auditor's report(s), or 9 months after the end of the audit period, i.e., the end of the organization's fiscal year, whichever is earlier. If you need information on your organization's obligations, please visit the following website: http://harvester.census.gov/sac/. Valuable information is included under the "Frequently Asked Questions" section of that website.

The grantee organization must comply with all special terms and conditions of the cooperative agreement. Future funding will be dependent on recommendations from the Project Manager and Program Official. The scope of the recommendation will confirm an acceptable level of performance and continued compliance with all FDA regulatory requirements and conditions of the award. Specific project milestones, reporting requirements, and other project deliverables may be included as a condition of your award. If FDA determines that the grantee is unable to make adequate progress, FDA may place them in special condition status and may require a corrective action plan.

If a recipient of multiple FDA awards (cooperative agreements, grants, contracts), the State must be able to account

separately for fund expenditures, including employee salaries, wages, and benefits, under those funding mechanisms and this cooperative agreement.

A rebudgeting request covers reallocation of cooperative agreement funds and change of planned expenditures (compared to the existing budget on record for the grantee) either between budget categories (personnel, equipment, supplies, etc.) or within a single budget category. All rebudgeting requests that involve moving cooperative agreement funds between budget categories in excess of 10% of the total track award must be submitted and approved by FDA. A new NGA will only be issued when rebudgeting requests reach a cumulative total (during a single budget period) of 25% of the total award or more. Rebudgeting requests within a single budget category must be submitted and approved by OP/OAGS when they reach a cumulative (during a single budget period) total of $10,000 or more.

Additional Terms and Conditions:

For the purpose of this cooperative agreement, a sample is defined as one that:

- Has been taken from a lot of which federal jurisdiction can be established (e.g proof of interstate movement)
- Is representative of the lot from which collected
- Is a physical sample, large enough to permit proper laboratory examination and retain a reserve portion
- Handled, identified, and sealed in such a manner as to maintain its integrity and with a clear record of its chain of custody

Samples must consist of sufficient units, size, etc., necessary for the official laboratory methodology to be used. Samples must be collected in accordance with current food testing methodologies and techniques, as specified by the FDA.

Samples that arrive in the laboratory and are unable to be analyzed, for any reason, cannot be counted toward the sample load selected by the laboratory.

For laboratories awarded multiple tracks under this project, the same samples cannot be counted under more than one discipline.

A proposed sample plan for each upcoming year must be submitted with the Research Performance Progress Report (RPPR) and approved by FDA prior to the start of work.

Environmental swabs, products produced or environmental samples obtained in a retail setting (unless it is designated as part of a national sampling assignment assigned by the FDA, or in conjunction with a foodborne illness outbreak), municipal water (that is covered under the purview of the Environmental Protection Agency, and products regulated by the United States Department of Agriculture are not allowed under this project.

Samples analyzed under this cooperative agreement could derive from a variety of sources including but not limited to: an approved sample plan, emergency outbreak situations, national special security exercises, or an FDA assignment. Laboratories that agree to participate in national special security exercises and FDA assignments could receive samples that were not collected by their identified sampling organization.

When available, and if the capability exists in the laboratory, participate in at least one (1) FDA-requested assignment annually.

Follow best practices recommendations for proper sampling and laboratory data documentation and use FDA Form 431, or equivalent, as necessary for analytical worksheet packages.

Notify the FDA project manager and the technical lead within one (1) business day of any presumptive positive or “cannot rule out” (CRO) samples. Notification via email must be sent to ORA-LFFM-CAP@fda.hhs.gov. The State regulatory program with jurisdiction over the presumptive positive or CRO sample must also be notified.

Submit the full laboratory package for any confirmed positive or violative sample within three (3) business days of final determination. This would include any supplemental information, as requested. The State regulatory program and the FDA will work collaboratively to determine if regulatory action is warranted, and which organization will be the lead.

Key personnel (minimum of two) must attend an annual face-to-face meeting (as determined by FDA OP) as a condition of the award.

FDA reserves a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use for federal purposes any copyrighted works that are outcomes from these funding tracks, including curriculum, course content, objectives, learning outcomes, presentations, manuals, scripts, exercises, handouts, reports, documents or other tangible materials

produced by the awardee. FDA may authorize others to reproduce, publish, or otherwise use such works for Federal purposes.

Grantees participating in Food Defense work under this project are required to maintain a 20.88 agreement with the FDA.

The following are non-allowable costs under this project:

1. Facilities and work reimbursed under the FDA human or animal food safety inspection contract or other funding mechanisms must remain distinct and separate from the cooperative agreement.

2. Vehicle purchases are not permitted.

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

4. Clothing and uniforms with the exception of personal protective equipment (PPE). PPE isdefined as protective clothing or other outerwear required to mitigate a defined workplacehazard.

5. Other items listed in the HHS Grants Policy Statement or Notice of Award.

3. Reporting

When multiple years are involved, awardees will be required to submit the Research Performance Progress Report (RPPR) annually and financial statements as required in the Notice of Award. In addition to completing the RPPR in eRA Commons, awardees must also upload a completed copy of the most recent version of the LFFM Reporting Document, which will be provided by FDA, a pdf version of samples submitted in the FERN website during the reporting period, and the proposed sample plan for the upcoming year for FDA review and approval.

A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the terms and conditions of award and the *HHS Grants Policy Statement*.

A detailed quarterly summary of all samples collected and analyzed must be submitted through the FERN website, or other FDA approved system. This summary must include, at a minimum:

a. the laboratory name;

b. sample number;

c. product description;

d. the manufacturer/brand of the product;

e. any codes listed on the product (e.g. lot codes, etc);

f. product expiration date;

g. country of origin, if available;

h. collecting entity name;

i. date collected;

j. lab receipt date;

k. analytical method used

l. screening results;

m. confirmatory results;

n. final results (including value and units);

o. completion date; and

p. comments.

A Mid-Year Progress Report is required no later than fifteen (15) days after the six (6) month mark of each budget year, annually. Awardees must upload a completed copy of the most recent version of the LFFM Reporting Document, which will be provided by FDA, and a pdf version of samples submitted in the FERN website during the reporting period. A summary of the following must be included in each progress report:

1. All work completed under each analytical track, including but not limited to:

a. Samples analyzed through proposed plan, or FDA-approved

b. Status and results of any small-scale, short-term method development, method validation, and matrix extension projects

c. Status of publications, research projects, or other special projects funded under this project

2. Any hiring of new personnel, and training or existing personnel, working on this project

3. Status on the installation and operational readiness of any analytical equipment utilized for this project

4. Any regulatory actions taken by FDA or another regulatory agency, or any other significant laboratory findings

5. Participation, including attendance, in any professional meetings or conferences supporting work related to this project

6. Details of any completed proficiency testing for work done under this project

7. Changes in ISO 17025 accreditation status, or quality management system

8. Contact information for the key personnel working on each analytical track, including name, title, phone number, and email address

9. Any programmatic issues or concerns

A Budget Resolution Report is required no later than thirty (30) days after the end of each budget period, annually. This report must include the amount of the total funding spent in each of the following categories:

1. Salary/wages

2. Fringe benefits

3. Consultant services

4. Equipment

5. Supplies

6. Travel costs

7. Other costs

8. Federal facilities and administrative costs

This report must also disclose any additional resources provided to the laboratory through other FDA funding mechanisms, including but not limited to other cooperative agreements (e.g. Flexible Funding Model, AFRPS, Produce, etc.) and contracts.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable FDA grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over $25,000.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than $10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 – Award Term and Conditions for Recipient Integrity and Performance Matters.

Section VII. Agency Contacts

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

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons, submitting and tracking an application, errors and warnings, documenting system problems that threaten submission by the due date, and post-submission issues)

Finding Help Online: http://grants.nih.gov/support/ (preferred method of contact)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)
Contact Center Telephone: 800-518-4726
Email: support@grants.gov

Scientific/Research Contact(s)

Erin Woodom-Coleman
Office of Partnerships/OP
Telephone: 240-402-4617
Email: Erin.Woodom-Coleman@fda.hhs.gov

Laurie Keppley
Office of Management/OM
Telephone: 240-402-7736
Email: Laurie.Keppley@fda.hhs.gov

Objective Review Contact(s)

Kiara Fowler
Office of Acquisitions & Grants Services (OAGS)

Food and Drug Administration
Telephone: 240-402-3099
Email: Kiara.Fowler@fda.hhs.gov

Financial/Grants Management Contact(s)

Kiara Fowler
Office of Acquisitions & Grants Services (OAGS)
Food and Drug Administration
Telephone: 240-402-3099
Email: Kiara.Fowler@fda.hhs.gov

Section VIII. Other Information

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

Authority and Regulations

Awards are made under the authorization of Section 301 of the Public Health Service Act as amended (42 USC 241) and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75.

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

Department of Health
and Human Services (HHS)

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