

# Department of Health and Human Services

## Part 1. Overview Information

|  |   |
|--|---|
| <b>Participating Organization(s)</b>             | <p>U.S. Food and Drug Administration (<a href="#">FDA</a>)</p> <p>NOTE: The policies, guidelines, terms, and conditions stated in this Notice of Funding Opportunity (NOFO) may differ from those used by the NIH. Where this NOFO provides specific written guidance that may differ from the general guidance provided in the grant application form, please follow the instructions given in this NOFO.</p> <p>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.</p> |
| <b>Components of Participating Organizations</b> | <p>Human Food Program (<a href="#">HFP</a>)</p>   |
| <b>Funding Opportunity Title</b>                 | <p>Retail Food Safety Regulatory Association Collaboration</p>  |
| <b>Activity Code</b>                             | <p>UF4</p>  |
| <b>Announcement Type</b>                         | <p>New</p>  |
| <b>Related Notices</b>                           | <p>None</p>   |
| <b>Funding Opportunity Number (FON)</b>          | <p>RFA-FD-26-003</p>  |
| <b>Companion Funding Opportunity</b>             | <p>None</p>   |

|                                     |  |
|-------------------------------------|--|
| <b>Number of Applications</b>       | See Part 2, Section III. 3. Only one application per institution is allowed.   |
| <b>Assistance Listing Number(s)</b> | 93.103   |
| <b>Funding Opportunity Purpose</b>  | The purpose of this NOFO is to collaboratively advance retail food initiatives to reduce foodborne illness. This funding opportunity aims to advance practices in retail food protection and identify opportunities for collaboration to reduce the occurrence of foodborne illness risk factors.  |
| <b>Funding Opportunity Goals</b>    | The goals of this NOFO are to assist retail food regulatory programs and industry in reducing foodborne illness by implementing effective intervention strategies designed to reduce the occurrence of foodborne illness risk factors; implementing and achieving full conformance with the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS); promoting use of risk-based inspection methods to effectively identify the occurrence of foodborne illness risk factors, conduct root cause analysis, assess gaps in industry active managerial control (AMC), and promote regulatory compliance; promoting adoption of the most recent version of the FDA Food Code; effectively responding to foodborne illness outbreaks; and responding to emerging food safety trends. The program is also intended to encourage the research, development, and implementation of industry food safety management systems and the prerequisite food safety culture necessary to achieve AMC of foodborne illness risk factors. |

**Key Dates**

|   |  |
|---|--|
| <b>Posted Date</b>                          | June 01, 2026  |
| <b>Open Date (Earliest Submission Date)</b> | June 01, 2026  |
| <b>Letter of Intent Due Date(s)</b>         | June 12, 2026<br>All letters of intent are due by 11:59 PM local time of applicant organization. |

**Application Due Date(s)**

July 14, 2026

All applications are due by 11:59 PM local time of applicant organization.

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.

No late applications will be accepted for this Notice of Funding Opportunity (NOFO).

**AIDS Application Due Date(s)**

Not Applicable

|                        |               |
|------------------------|---------------|
| <b>Expiration Date</b> | July 30, 2026 |
|------------------------|---------------|

**Advisory Council Review**

Not Applicable

|                                 |                |
|---------------------------------|----------------|
| <b>Due Dates for E.O. 12372</b> | Not Applicable |
|---------------------------------|----------------|

**Required Application Instructions**

Conformance to all requirements, both in the Application Instruction Guide and in the NOFO, is required and strictly enforced. When the program-specific instructions deviate from those in the Application Instruction Guide, follow the program-specific instructions.

**Applications that do not comply with these instructions will not be accepted for review.**

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## Part 2. Full Text of Announcement

## Section I. Notice of Funding Opportunity Description

### BACKGROUND

Foodborne illness remains a major public health concern in the United States. Foodborne diseases cause approximately 48 million illnesses, 128,000 hospitalizations, and 3,000 deaths each year (Scallan et al., 2011). The annual economic burden from health losses due to foodborne illness is estimated at 77.7 billion dollars (Scharff, 2012).

According to the Centers for Disease Control and Prevention (CDC, 2014) more than half of foodborne illness outbreaks that occur each year are associated with food from restaurants. When considering incidents in 2014 involving a single location of food preparation, for example, restaurants accounted for 485 outbreaks (65%) and 4,780 illnesses (44%) (CDC, 2014).

In a study of restaurant-associated outbreaks in the United States from 1998-2013, Angelo, Nisler, Hall, Brown, and Gould (2016) identified 9,788 restaurant-associated outbreaks, with a median of 620 outbreaks per year. Norovirus caused 46% of the 3,072 outbreaks associated with a single, confirmed etiology. Activities related to food handling and preparation practices were the most commonly reported contributing factors within restaurant-associated outbreaks.

Surveillance data from the CDC have consistently identified five major risk factors related to food safety practices within the retail food industry that contribute to foodborne illness. Most regulatory retail food inspection programs throughout the United States monitor these risk factors in their routine inspections, and each necessitates specific food safety behaviors and practices. These risk factors include:

- Poor personal hygiene
- Improper food holding/time and temperature
- Contaminated equipment/lack of protection from contamination
- Inadequate cooking
- Food obtained from unsafe sources

Recent legislative and strategic initiatives have addressed FDA's relationship with state, local, territorial, and tribal authorities in retail food protection activities. Please visit <https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/retail-food-protection> for more information

The Food and Drug Administration (FDA), Human Foods Program (HFP) is announcing the availability of funding to be awarded under limited competition to non-profit membership national retail food organizations/associations focused on retail food safety initiatives. The intended outcome of this funding opportunity is to achieve a greater outcome utilizing the skills, resources and strengths of national retail food safety organizations/associations to collaboratively advance retail food protection and reduce foodborne illness. The resulting awards will provide support to advance retail food safety by researching, identifying, and promoting strategies to encourage industry's active managerial control (AMC) of foodborne illness risk factors. AMC means the purposeful incorporation of specific actions or procedures by industry management into the operation of their business to attain control over foodborne illness risk factors. It embodies a preventive rather than reactive approach to food safety through a continuous system of monitoring and verification. This includes, but is not limited to, promoting the development and implementation of industry food safety management systems and prerequisite food safety culture necessary to achieve AMC of foodborne illness risk factors. Awards made under this announcement will also advance retail food safety by promoting implementation and full conformance of the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS) by state, local, tribal, and territorial (SLTT) jurisdictions, supporting full adoption of the most recent FDA Food Code, enhancing communication, sharing of best practices, and improving foodborne illness outbreak response.

The resulting awards will include one year of funding with up to two years of additional non-competitive support, dependent on recipient performance and continued availability of appropriations.

## Program Objectives:

The proposed research strategy may address a portion or all the objectives listed below:

- Maintain and expand the strategy to support national Food Code adoption.
  - Expand and maintain a Food Code adoption toolkit/library for retail regulatory agencies that includes adoption tools such as real-time adoption reporting and Food Code adoption maps. Retail regulatory agencies are government agencies that work on retail food safety and perform regulatory activities for retail food safety (inspections, outreach, etc). Retail regulatory agencies include State, Local, Territorial, and Tribal (SLTTs) agencies. Examples might be a State public health agency or local health department.
  - Develop, measure and assess performance metrics to evaluate success, utilization and effectiveness of tools, and identify additional tools needed to support Food Code adoption.
- Increase use of risk-based inspections and intervention strategies.
  - Develop and implement a targeted strategy to increase risk-based inspections and intervention strategies within state, local, tribal and territorial retail food regulatory jurisdictions and industry.
  - Develop and maintain a risk-based inspection toolkit/library for resource centralization and promotion.
  - Develop, measure and assess performance metrics to evaluate success, utilization and effectiveness of tools, and identify additional tools needed to support risk-based inspections and intervention strategies.
- Increase use of the national Voluntary National Retail Food Regulatory Program Standards.
  - Implement a targeted strategy to increase active engagement and conformance of state, local, tribal and territorial retail food regulatory jurisdictions with the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS).
  - Develop and maintain a VNRFRPS toolkit/library for resource centralization and promotion.
  - Develop, measure and assess performance metrics to evaluate success, utilization and effectiveness of tools, and identify additional tools needed to support the VNRFRPS toolkit/library for resource centralization and promotion.
- Improve foodborne outbreak investigation methods.
  - Develop and implement a strategic action plan to improve foodborne illness outbreak training, education, activation and response within state, local, tribal and territorial retail food regulatory agencies.
  - Expand and maintain a Foodborne Illness Outbreak toolkit/library for resource centralization and promotion.
  - Develop, measure and assess performance metrics to evaluate success, utilization and effectiveness of tools, and identify additional tools needed to support foodborne outbreak investigation strategies.
- Increase the number of restaurants and other retail food establishments with well-developed food safety management systems that use active managerial control.
  - Develop and implement a targeted strategy for implementing Food Safety Management Systems within retail regulatory agencies and retail industry.
  - Develop and maintain a Food Safety Management System toolkit/library for resource centralization and promotion.
  - Develop, measure and assess performance metrics to evaluate success, utilization and effectiveness of tools, and identify additional tools needed to support active managerial controls.

- Develop a strategy to enhance communication and better catalog and present information on the detailed efforts by FDA, Associations and the retail regulatory agencies enrolled in the Retail Program Standards.
  - Develop and maintain an external communication strategy to explain the work of the collaborative and share developed resources with retail food regulatory, industry, academic, and consumer audiences.
  - Maintain Retail Food Safety Regulatory Association Collaborative communication tools.
  - Collaborate with FDA and host an annual virtual FDA Retail Food Seminar each calendar year. While the event will be hosted by FDA, the recipients of record will assist with various aspects of the planning.

See [Section VIII. Other Information](#) for award authorities and regulations.

## Section II. Award Information

|   |   |
|---|---|
| <b>Funding Instrument</b>                               | Cooperative Agreement: A financial assistance mechanism used when there will be substantial Federal scientific or programmatic involvement. See Section VI.2 for additional information about the substantial involvement for this NOFO.  |
| <b>Application Types Allowed</b>                        | New<br>Only those application types listed here are allowed for this NOFO.  |
| <b>Clinical Trial?</b>                                  | Clinical trial not allowed.   |
| <b>Funds Available and Anticipated Number of Awards</b> | <p>FDA intends to commit \$2,250,000 for fiscal year 2026.</p> <p>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 two (two) additional year(s) contingent upon annual appropriations, availability of funding and satisfactory recipient performance.</p> <p>It is anticipated that up to three (3) awards will be made, not to exceed \$750,000 in total costs (direct plus indirect)</p> |
| <b>Award Budget</b>                                     | <p>Application budgets may not exceed the award ceilings outlined below and must reflect the actual needs of the proposed project.</p> <p>YR 01: \$750,000</p> <p>YR 02: \$750,000</p> <p>YR 03: \$750,000</p>  |

|                             |   |
|-----------------------------|---|
| <b>Award Project Period</b> | The scope of the proposed project should determine the project period. The maximum project period is 3 years. |
|-----------------------------|---|

HHS grants policies as described in the [HHS Grants Policy Statement](#) will apply to the applications submitted and awards made from this NOFO.

## Section III. Eligibility Information

### Eligible Organizations

Eligibility to apply for this funding opportunity is limited to national organizations/associations as outlined below:

1. National organizations/associations that represent SLTT retail food regulatory programs or retail food/foodservice industries as a primary purpose. National associations/organizations have the membership, resources, structure, and expertise necessary to build national consensus among state/local agencies and/or industry on key food safety issues. They are the primary means for communication and collaboration on issues of national significance for SLTT retail food regulatory agencies and/or industry. The outcomes are position statements, resolutions, and legislation that are uniformly supported by SLTT agencies and/or industry.
2. These national organizations/associations have a vested interest and share the FDA's vision to leverage the resources and strengths of national retail food safety associations to collaboratively advance retail food initiatives and activities to reduce foodborne illness.
3. A principal purpose of the organization(s)/association(s) must be to facilitate harmonization of state standards and requirements in areas congruent with the purpose and goals of this funding opportunity announcement. The association(s) should act as a leader and a resource to SLTT retail food regulatory agencies or industry in developing and implementing strategies to promote public health and consumer protection related to retail foods. Additionally, the association(s) must have knowledge on the infrastructure, capacity, strengths, and needs of SLTT retail food regulatory programs and/or industry. The association(s) must have successful experience in carrying out national efforts to build an integrated food safety system, which includes federal, SLTT agencies, and industry. The association(s) must be comprised of regular members that are officials of SLTT regulatory agencies that administer retail food inspection programs in conjunction and in collaboration with the FDA and/or comprised of regular members from the retail food/foodservice industries.
4. Applicant associations must hold an information sharing agreement with FDA under 21 CFR 20.88(e) or be able to obtain an agreement prior to the start date of the award. Information sharing is limited to pre-decisional information and only for the purpose outlined in this award.

### Foreign Organizations

Non-domestic (non-U.S.) Entities (Foreign Organizations) **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 NIH Grants Policy Statement](#), **are not** allowed.

### Required Registrations

#### Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the [How to Apply - 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, please reference the [HHS Grants Policy Statement](#) for additional information

- [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.
  - Unique Entity Identifier (UEI) - A UEI is issued as part of the SAM.gov registration process. The same UEI must be used for all registrations, as well as on the grant application.
- [eRA Commons](#) - Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their Grants.gov registrations; 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 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 their organization to develop an application for 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 [How to Apply - Application Guide](#).

The PD/PI should be an established investigator in the scientific area in which the application is targeted and capable of providing both administrative and scientific leadership to the development and implementation of the proposed program. The PD/PI will be expected to monitor and assess the program and submit all documents and reports as required.

## **2. Cost Sharing**

This NOFO does not require cost sharing as defined in the [HHS Grants Policy Statement](#).

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

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

## **Section IV. Application and Submission Information**

### **1. Requesting an Application Package**

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace are available in [Part 1](#) of this NOFO. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

## 2. Content and Form of Application Submission

The application package has all the forms you need to apply. You can find it online. Go to Search Grants at Grants.gov or eRA ASSIST and search for opportunity number: RFA-FD-26-003.

### Letter of Intent

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

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

- Descriptive title of proposed activity
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel
- Participating institution(s)
- Number and title of this funding opportunity

The letter of intent should be sent to:

Danielle Head, Grants Management Specialist  
 Email: [danielle.head@fda.hhs.gov](mailto:danielle.head@fda.hhs.gov)

### Page Limitations

| Component         | Form to use                       | Page limit |
|-------------------|-----------------------------------|------------|
| Project abstract  | Project Abstract Summary form     | 1 page     |
| Project narrative | Project Narrative Attachment form | 30 pages   |
| Budget narrative  | Budget Narrative Attachment form  | No         |

### Instructions for Application Submission

Download the application guide from grants.gov. The following section supplements the instructions found in the Application Guide and should be used for preparing an application to this NOFO.

#### Application for Federal Financial Assistance (SF-424)

#### SF-424 A Budget Information - Non-Construction Programs Form

#### Project/Performance Site Location(s)

#### Project Abstract Summary

#### Project Narrative Attachment

The Project Narrative should address the following:

1. Demonstrate ability to develop tool kits, and other educational materials and resources.

2. Demonstrate technical knowledge of the VNRFRPS, FDA Food Code, foodborne illness risk factor studies, and other aspects of retail food regulatory programs and/or industry. Include efforts to design, develop, document, deliver, manage, and implement programs and initiatives supporting SLTT regulatory retail food programs and/or industry commensurate with the objectives of this NOFO.
3. Demonstrate ability to conduct research on the use of effective intervention strategies, risk-based inspection methods, and emerging trends.
4. Demonstrate ability to develop and implement effective communication strategies to promote and assist with implementation of retail food safety initiatives across all stakeholders.
5. Demonstrate ability to collaborate with national initiatives.
6. Outline the plan, resources available, and qualifications of the personnel that will support this project.

### **Budget Justification and Narrative Attachment**

All applicants planning research (funded or conducted in whole or in part by the FDA) that results in the generation of scientific data are required to comply with the instructions for the Data Management and Sharing Plan. All applications, regardless of the amount of direct costs requested for any one year, must address a Data Management and Sharing Plan.

#### **Appendix:**

- No publications or other material, with the exception of blank questionnaires or blank surveys, may be included in the Appendix.

Not applicable. Clinical trails are not allowed.

Not applicable.

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

See Part 2. 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](#) 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. When a submission date falls on a weekend or [Federal holiday](#), the application deadline is automatically extended to the next business day.

Organizations must submit applications to [Grants.gov](#) (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the [eRA Commons](#), FDA's electronic system for grants administration. FDA 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. Applications that miss the due date and time are subjected to the FDA Policy on Late Application Submission.

**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 [How to Apply - 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](#).

- Recipients must comply with all applicable federal anti-discrimination laws material to the government's payment decisions for purposes of 31 U.S.C. § 3729(b)(4).
- Discretionary awards shall not be used to fund, promote, encourage, subsidize, or facilitate:
- racial preferences or other forms of racial discrimination by the recipient, including activities where race or intentional proxies for race will be used as a selection criterion for employment or program participation.
- denial by the recipient of the sex binary in humans or the notion that sex is a chosen or mutable characteristic.
- harm reduction
- illegal immigration; or
- any other initiatives that compromise public safety or promote anti-American values.

All activities proposed in your application and budget narrative must align with applicable law, including but not limited to statutes, executive orders, federal regulations, and applicable judicial holdings. Accordingly, discretionary awards shall not be used to fund, promote, encourage, subsidize, or facilitate: racial preferences or other forms of racial discrimination by the recipient, including activities where race or intentional proxies for race will be used as a selection criterion for employment or program participation; denial by the recipient of the sex binary in humans, or the belief that sex is a chosen or mutable characteristic; illegal immigration; or any other initiatives that compromise public safety. If an application does not align, the application will not receive funding to the extent permitted by law and applicable court orders.

Non-allowable costs under this funding opportunity announcement are listed below:

1. Facilities, work, and training reimbursed under other cooperative agreements, grants, contracts, and other funding mechanisms shall 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 or remodeling of existing facilities.
4. Cooperative agreement funds may not be utilized for uniforms or clothing except Personal Protective Equipment (PPE).

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 [How to Apply - Application Guide](#). Paper applications will not be accepted.

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

For assistance with your electronic application or for more information on the electronic submission process, visit [How to Apply - Application Guide](#). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the [Dealing with System Issues](#) guidance. For assistance with application submission, contact the Application Submission Contacts in Section VII.

**Important reminders:**

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile form. 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 the FDA. See Section III of this NOFO for information on registration requirements.

The applicant organization must ensure that the unique entity identifier provided on the application is the same identifier used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the [How to Apply - 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 FDA Grants Management Specialist and responsiveness by components of participating organizations. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

### Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in [the policy](#).

Not allowed.

## Section V. Application Review Information

### 1. Criteria

Only the review criteria described below will be considered in the review process. Applications submitted to the FDA in support of the FDA mission are evaluated for technical merit through the FDA objective review system.

For this particular NOFO, note the following: Reviewers will consider each of the review criteria below in the determination of scientific merit and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

### Overall Impact

Reviewers will provide a score to reflect their assessment of the likelihood for project success, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

### Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

| Significance   | Maximum Points: 30 |
|--|--------------------|
| <p>Does the project address an important problem or a critical barrier to progress in the field? Is the prior research that serves as the key support for the proposed project rigorous? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?</p> |                    |
| <p>Are the proposed system, strategies, and approach to meet the intended outcome of the cooperative agreement well-reasoned, appropriate, and complete? Does the proposed project(s) address an important problem or critical barrier related to reducing foodborne illness risk factors at retail? Will the projects promote reduction of retail foodborne illness risk factors?</p>   |                    |

|   |                           |
|---|---------------------------|
| <b>Investigator(s)</b>  | <b>Maximum Points: 15</b> |
| <p>Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance, and organizational structure appropriate for the project?</p>  |                           |
| <b>Cooperation and Collaboration</b>  | <b>Maximum Points: 25</b> |
| <p>Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?</p> <p>Does the applicant demonstrate a history and/or an ability to be effective in working with retail food regulatory programs, industry, allied associations, the FDA, and other stakeholders to accomplish the goals of the project?</p>  |                           |
| <b>Approach</b>   | <b>Maximum Points: 30</b> |
| <p>Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?</p> <p>If the project involves human subjects and/or FDA-defined clinical research, are the plans to address the protection of human subjects from research risks justified in terms of the scientific goals and research strategy proposed?</p> <p>Is the overall strategy, methodology, and analyzes well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented?</p> |                           |

**Additional Review Criteria**

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.

None.

**Resubmissions**

Not applicable.

**Renewals**

Not applicable.

**Revisions**

Not applicable.

**Additional Review Considerations**

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items.

## **Applications from Foreign Organizations**

Not Applicable.

### **Select Agent Research**

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

### **Resource Sharing Plans**

Reviewers will comment on whether the Resource Sharing Plan(s) (i.e., [Sharing Model Organisms](#)) or the rationale for not sharing the resources, is reasonable.

### **Authentication of Key Biological and/or Chemical Resources:**

For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

### **Budget and Period of Support**

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

Applications will be evaluated for scientific and technical merit by (an) appropriate Objective Review Committee convened by the FDA, using the stated review criteria. Assignment to an Objective Review Committee will be shown in eRA Commons.

As part of the objective review, all applications will receive a written critique.

Applications may undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.

Applications will compete for available funds with all other recommended applications submitted in response to this NOFO. 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.

Information regarding the disposition of applications is available in the [HHS Grants Policy Statement](#).

## **Section VI. Award Administration Information**

### **1. Award Notices**

A Notice of Award (NoA) is the official authorizing document notifying the applicant that an award has been made and that funds may be requested from the designated HHS payment system or office. The NoA is signed by the Grants Management Officer and emailed to the recipient's business official.

In accepting the award, the recipient agrees that any activities under the award are subject to all provisions currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

Recipients must comply with any funding restrictions described in [Section IV.6. Funding Restrictions](#). Any pre-award costs incurred before receipt of the NoA are at the applicant's own risk. For more information on the Notice of Award, please refer to the [HHS Grants Policy Statement](#).

Institutional Review Board or Independent Ethics Committee Approval: Recipient institutions must ensure that protocols are reviewed by their IRB or IEC. To help ensure the safety of participants enrolled in FDA-funded studies, the recipient must provide FDA copies of documents related to all major changes in the status of ongoing protocols.

## 2. Administrative and National Policy Requirements

The following Federal wide and HHS-specific policy requirements apply to awards funded through FDA:

- The rules listed at [2 CFR Part 200](#), Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.
- All FDA grant and cooperative agreement awards include the [HHS Grants Policy Statement](#) as part of the terms and conditions in the Notice of Award (NoA). The NoA includes the requirements of this NOFO.

All federal statutes and regulations relevant to federal financial assistance, including those highlighted in the [HHS Grants Policy Statement](#).

Recipients are responsible for ensuring that their activities comply with all applicable federal regulations. FDA may terminate awards under certain circumstances. See [2 CFR Part 200.340 Termination](#) and [HHS Grants Policy Statement](#).

Successful recipients under this NOFO agree that:

Where the award funding involves implementing, acquiring, or upgrading health IT for activities by any funded entity, recipients and subrecipient(s) are required to: Use health IT that meets standards and implementation specifications adopted in 45 CFR part 170, Subpart B, if such standards and implementation specifications can support the activity. Visit <https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-B> to learn more.

Where the award funding involves implementing, acquiring, or upgrading health IT for activities by eligible clinicians in ambulatory settings, or hospitals, eligible under Sections 4101, 4102, and 4201 of the HITECH Act, use health IT certified under the ONC Health IT Certification Program if certified technology can support the activity. Visit <https://www.healthit.gov/topic/certification-ehrs/certification-health-it> to learn more.

Pursuant to the Cybersecurity Act of 2015, Div. N, § 405, Pub. Law 114-113, 6 USC § 1533(d), the HHS Secretary has established a common set of voluntary, consensus-based, and industry-led guidelines, best practices, methodologies, procedures, and processes.

Successful recipients under this NOFO agree that:

When recipients, subrecipients, or third-party entities have:

1. ongoing and consistent access to HHS owned or operated information or operational technology systems; and
2. receive, maintain, transmit, store, access, exchange, process, or utilize personal identifiable information (PII) or personal health information (PHI) obtained from the awarding HHS agency for the purposes of executing the award.

Recipients shall develop plans and procedures, modeled after the [NIST Cybersecurity framework](#), to protect HHS systems and data. Please refer to [HHS Grants Policy Statement](#) for additional information.

## Cooperative Agreement Terms and Conditions of Award

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

**The Project Director/Principal Investigator (PD/PI) retains the primary responsibility and dominant role for planning, directing, and executing the proposed project, with FDA 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 sufficient clearance and/or background checks 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/HFP Program Staff will have substantial programmatic involvement that is above and beyond the normal programmatic oversight, monitoring, and stewardship of awards, as described below:** The PO 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/ORAs includes, but is not limited to, the following:

- Evaluate the supported program, including development of program-level performance measures, consistent data collection, and reporting procedures and protocols; and
- Participate in data analysis, interpretation of findings, and where appropriate, co-authorship of publications.

### 3. Data Management and Sharing

Consistent with the FDA Policy for Data Management and Sharing, when data management and sharing is applicable to the award, recipients will be required to adhere to the Data Management and Sharing requirements as outlined in the [HHS Grants Policy Statement](#). Upon the approval of a Data Management and Sharing Plan, it is required for recipients to implement the plan as described.

### 4. Reporting

When multiple years are involved, recipients will be required to submit the [Research Performance Progress Report \(RPPR\)](#) annually and financial statements as required in the [HHS Grants Policy Statement](#).

Initial, mid-year, and annual reports are required. The Research Performance Progress Report (RPPR) will be considered the annual program progress report for the budget period.

Link to report template:

<https://www.fda.gov/media/181968/download?attachment>

The report template should be emailed to the project officer assigned and [ORAOPDataHub@fda.hhs.gov](mailto:ORAOPDataHub@fda.hhs.gov). This should occur at the initial, mid-year and annual reporting.

Mid-year reports should be emailed to the project officer. End of year reports should be placed in eRA Commons.

Mid-year progress and end of year reports shall contain the elements below as applicable to the application and award, including but not limited to, the following:

1. Detailed progress report on the grantee meeting the project milestones detailed in the cooperative agreement, proposal, strategic plan, conditions of the award, etc. Goals and objectives should be broken out and specific progress reported.
2. Status report on the hiring and training of cooperative agreement funded personnel.
3. Contributions of personnel, especially employees receiving salary and/or benefits through the cooperative agreement or identified as key personnel, towards the goals of the cooperative agreement should be reported against. Contributions should be directly related to the objectives of the funding agreement.
4. Identifying any pending issues or concerns that may affect accomplishing the objectives and goals of the cooperative agreement.
5. Summary of grant expenditures and obligations during the current budget period.
6. Summary report on surveys, field testing, assessments, and other activities conducted in support of the cooperative agreement goals, including evaluation of effectiveness, response rates, impact, analysis, and recommendations.
7. Status report on the support and identification of any pilot projects implemented.
8. Status report on networking activities, collaboration with the FDA, best practices, studies, technical assistance and outreach and reports shared with FDA and other stakeholders, including the following:
  - Efforts to support and enhance VNRFRPS technical assistance
  - Development of strategies to promote best practices, food protection success stories and joint recommendations between FDA and grantee associations.
  - Activities to promote adoption of the FDA Food Code among SLTT regulatory agencies.
  - Results of identification and assessment of industry intervention strategies.

**External Program Communications and Branding:**

When promoting the Retail Food Safety Collaboration program, recipients must adhere to the following requirements:

1. Ensure usage of Retail Collaborative branding materials
2. Posting of work funded under this cooperative agreement to the Retail Collaborative website <https://www.retailfoodsafetycollaborative.org/>
3. Submission of outputs under this cooperative agreement to the Retail Collaborative Communications Workgroup for external communication
4. A representative from each organization/association that will be actively involved in the Retail Collaborative Communications Workgroup. Additional external program communications and branding requirements may be required for this award, and if applicable, will be listed under Section IV – Special Terms and Condition of the Notice of Award.

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 [HHS Grants Policy Statement](#). FDA NOFOs outline intended research goals and objectives. Post award, the FDA will review and measure performance based on the details and outcomes that are shared within the RPPR, as described at 2 CFR Part 200.301.

The Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients of applicable FDA grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at [www.fsrs.gov](http://www.fsrs.gov) on all subawards over the threshold. See the [HHS Grants Policy Statement](#) for additional information on this reporting requirement.

In accordance with the regulatory requirements provided at 2 CFR Part 200.113 and Appendix XII to 2 CFR Part 200, 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 (Responsibility/Qualification in SAM.gov, formerly 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 2 CFR Part 200 Award Term and Condition for Recipient Integrity and Performance Matters.

## 5. Evaluation

Not applicable.

## 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, application errors and warnings, documenting system problems that threaten submission by the due date, and post-submission issues)

Finding Help Online: <https://www.era.nih.gov/need-help> (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](mailto:support@grants.gov)

### Scientific/Research Contact(s)

Maribeth Niesen

Consumer Safety Officer, Human Food Program (HFP)

Email: [Maribeth.niesen@fda.hhs.gov](mailto:Maribeth.niesen@fda.hhs.gov)

### Peer Review Contact(s)

Examine your eRA Commons account for review assignment and contact information (information appears two weeks after the submission due date).

### Financial/Grants Management Contact(s)

Danielle Head

Grants Management Specialist, Office of Acquisitions and Grants Services (OAGS)

Email: [danielle.head@fda.hhs.gov](mailto:danielle.head@fda.hhs.gov)

## Section VIII. Other Information

Recently issued [policy notices](#) may affect your application submission. A full list of policy notices is provided in the [Guide for Grants and Contracts](#). 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 21 U.S.C. 399 and under Federal Regulation 2 CFR Parts 200 and 300.