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 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. 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	Human Foods Program (HFP)
Funding Opportunity Title	Education and Outreach to Tribal Producers through the Tribal Food Safety Alliance
Activity Code	U01 Research Project Cooperative Agreements
Announcement Type	New
Related Notices	None
Funding Opportunity Number (FON)	RFA-FD-26-009
Companion Funding Opportunity	None

Number of Applications	See Part 2, Section III. 3. Additional Information on Eligibility.
Assistance Listing Number(s)	93.103
Funding Opportunity Purpose	The primary purpose of this program is to develop and provide education and/or training, and outreach regarding FDA's Produce Safety Rule to produce farmers who are members of federally recognized Tribes. The program is expected to help Tribal farmers access appropriate technical assistance and may include Tribal farmers who are not currently required to comply with the rule but are interested in complying or see economic benefits in doing so. All activities should consider Tribal history, culture, and regional agricultural practices.
Funding Opportunity Goals	Develop, maintain, and deliver a produce safety education program for Tribal communities that aligns with the FDA Produce Safety Rule and meets Tribal needs. Strengthen partnerships and regularly evaluate the program to ensure it produces clear, measurable public health results.

Key Dates

Posted Date	July 20, 2026
Open Date (Earliest Submission Date)	July 20, 2026
Letter of Intent Due Date(s)	Not applicable.

Application Due Date(s)

August 20, 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

Expiration Date	August 21, 2026

Advisory Council Review
Not Applicable

Due Dates for E.O. 12372	Not Applicable

Required Application Instructions
Conformance to all requirements, both in the the Research (R) Instructions How to Apply - Application Guide and in the NOFO, is required and strictly enforced. Applicants must read and follow all application instructions in the How to Apply - Application Guide as well as any program-specific instructions noted in Section IV of this NOFO or an applicable related Notice posted to the Guide for Grants and Contracts. When the program-specific instructions deviate from those in the How to Apply - Application Guide, follow the program-specific instructions.

Applications that do not comply with these instructions may be delayed or not accepted for review.

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Part 2. Full Text of Announcement

Section I. Notice of Funding Opportunity Description

Background

The Food Safety Modernization Act (FSMA), signed into law in 2011, provided FDA with a legislative mandate to require comprehensive, prevention-based controls across the food supply, including standards for produce safety. FSMA also calls for enhanced partnerships with Federal, State, local, Tribal, and territorial partners to achieve public health goals and build an integrated national food safety system.

Federally recognized Tribes lack adequate access to culturally appropriate and affordable food safety education and/or training, outreach, and technical assistance needed to comply with FSMA Produce Safety requirements, creating disparities in implementation of the integrated national food safety system and potentially compromising public health outcomes in Tribal communities. Existing training materials, such as the Produce Safety Alliance's standardized curriculum, will continue to serve as a foundation for customization to meet Tribal needs, including regional and culturally specific practices.

This cooperative agreement benefits public health by driving compliance with FSMA's Produce Safety Rule (PSR), ensuring consistent implementation throughout the United States, leveraging existing Tribal expertise and authorities, and ultimately reducing food-borne illness.

Purpose and Priorities

The Food and Drug Administration's (FDA) Human Foods Program (HFP) is announcing its intent to renew a Cooperative Agreement with an estimated amount of $500,000.00 (direct and indirect costs) for fiscal year 2027. Future years of support are anticipated, depending on annual appropriations and successful performance.

This cooperative agreement will fund an entity with active working relationships with Native American tribes and/or organizations with demonstrated experience developing and providing science-based, culturally specific produce safety education and/or training, outreach, and technical assistance for Tribes, Tribal businesses, and/or tribal members, with an emphasis on agricultural production. Subcontracts to qualifying organizations are encouraged. Applicants must collaborate with national and regional Tribal stakeholder leaders, Tribal organizations, recipients of the FDA – state produce safety implementation cooperative agreement program, established FDA Food Safety Modernization Act (FSMA) Alliances, FDA HFP and other FDA program offices, the National Coordination and Regional Food Safety Centers, and FDA's FSMA partners at USDA and other federal organizations with food safety interests among Tribal stakeholders.

The primary purpose of this program is to develop and provide education and/or training, outreach and technical assistance regarding the PSR to produce farmers who are members of federally recognized Tribes. The program will help Tribal farmers access appropriate technical assistance and may include Tribal farmers who are not currently required to comply with the rule but are interested in complying or see economic benefits in doing so.

The following definitions are helpful in determining activities to comply with the objectives:

- Education and/or Training: A targeted instructional activity that facilitates two-way learning through formal or informal approaches utilizing real-time, self-paced, or a combination of formats to transfer experiences, skills, and information among participants. Examples include Produce Safety Alliance (PSA) grower training and Tribal supplemental material delivery.
- Outreach: An interactive dissemination of produce safety information and regulatory requirements that may include discussions for understanding and interactive feedback. Examples include On-Farm Readiness Reviews (OFRR) and workshops.
- Technical Assistance: A collaborative, problem-solving process to provide two-way dialogue for customized support through to address specific produce safety issues. Examples include phone calls and emails on specific issues as well as in-person discussion on specific targeted issues.

Phased Implementation Requirement

The recipient must implement the program in sequentially numbered phase. FDA will review progress at the end of each phase before recipient can begin the next phase

Limited overlap of activities may occur only with prior FDA approval and must be justified in the annual work plan.

Phase 1: Foundation and Planning of Program (Objectives 1, 2, and 3)

Objective 1: Develop an annual work plan

The recipient must develop and maintain an FDA-approved annual work plan that describes program goals, planned activities, partnerships, performance measures, timelines, expected outcomes and evaluation approaches.

Content and expectations of the annual plan will be discussed in greater detail with FDA post award

Objective 2: Develop and maintain guiding documents

The recipient will create foundational documents to guide the development and implementation of the Tribal produce safety program.

I. Conduct a Tribal covered produce landscape analysis

a. Develop and document an inventory identifying Tribal nations with production of covered produce, including the characterization of the production scale, infrastructure, location, market types, and covered produce under the PSR

II. Conduct an annual Tribal needs assessment that captures challenges, needs, barriers, and associated hazards with the framework of prioritization for the implementation of the PSR on Tribal lands, and share findings with FDA

Content and expectations of landscape analysis and needs assessment will be discussed in greater detail with FDA post award.

Objective 3: Develop a logic model

The recipient must develop a program logic model informed by the landscape analysis and needs assessment that illustrates the relationship between program inputs, activities, outputs, and intended outcomes and impacts.

Specific components and format will be finalized in collaboration with FDA post-award.

Phase 2 National Trainer Network Development (Objective 4)

Objective 4: Establish and maintain a qualified national network of Tribal produce safety trainers

A successful application will demonstrate how the program will:

a. Identify and increase the number of Produce Safety Alliance (PSA) Lead Trainers and Tribal supplemental Lead Trainers.

b. Standardize trainer qualification criteria, including required education, experience, certification, and continuing education.

c. Establish and maintain a national database of qualified Tribal produce safety trainers.

d. Provide ongoing professional development and technical assistance to current trainers, in coordination with FDA, through continuing education, mentorship, and communities of practice.

e. Deliver Train-the-Trainer (TTT) sessions for Tribal supplemental materials, offered virtually and/or in person.

f. Document all training provided to trainers and the delivery of training to Tribal nations.

Phase 3 Implementation, Integration and Continuous Improvement (Objectives 5 and 6)

Objective 5: Promote understanding and integration of produce safety and environmental considerations and co-management practices.

A successful application will demonstrate how the program will:

a. Co-develop with FDA and partnering agencies materials and resources on produce safety and environmental considerations and co-management practices tailored to farms and packinghouses within Tribal nations.

b.Establish partnerships and mechanisms with Tribal entities and relevant federal and state partners to support understanding of environmental considerations and co-management practices.

c. Capture considerations for Tribal stakeholders to implement with a focus on produce safety.

d. Create new materials and document considerations specific to Tribal produce systems.

e. Provide case examples demonstrating successful integration of produce safety and environmental co-management practices in Tribal produce systems.

Objective 6: Improve the effectiveness and reach of produce safety training and outreach

A successful application will demonstrate how the program will:

a. Apply prioritization to produce safety content education and/or training, outreach, and technical assistance for Tribal nations to ensure resources are responsive, updated, strategic, integrated, and appropriately targeted.

b. Strengthen collaboration and coordination with FDA and other produce safety partners (including Federally recognized Tribes Extension Program extension educators, 1994 Tribal land-grant colleges and universities, the Produce Safety Alliance, the FDA National Coordination Center, FSMA USDA partners, and FDA/USDA Regional Centers established under the National Food Safety Training, Education, Extension, Outreach and Technical Assistance Program) to ensure activities align with current FDA produce safety priorities and support national produce safety efforts.

c. Develop new and maintain existing trainings, workshops, field-based learning opportunities, and/or one-on-one technical assistance provided to Tribal produce growers and packers.

d. Increase the visibility of training opportunities by leveraging FDA and external partner resources to foster awareness of upcoming trainings serving Tribal populations.

e. Foster coordination of outreach activities with FDA and FDA-State Produce Safety Implementation Cooperative Agreement recipients to ensure cohesive, non-duplicative engagement with farms having Tribal affiliation.

f. Coordinate and communicate with FDA regarding Tribal engagement activities, including discussing available outreach options when Federally recognized Tribes or farms on Tribal lands initiate contact, and consulting with FDA upon receipt of requests for an On-Farm Readiness Review (OFRR) from farms with Tribal affiliation to determine the appropriate entity to conduct the OFRR.

g. Update produce safety education and/or training, outreach and technical assistance materials, tailored to Tribal contexts and producer needs, to advance understanding and capture new information from outbreaks, prevention strategies, and FDA prioritized identified areas and content for educational engagement.

h. Provide FDA materials to review for alignment to the PSR prior to utilization.

i. Develop evaluation tools and provide an annual summary of data-driven information from pre/post assessments, participant feedback surveys, and other evaluation findings, lessons learned, and data-informed improvements made to training and outreach activities to better understand training effectiveness and relevance to Tribal context.

Other Requirements

Provide a properly detailed budget (one for each of the 5 years) tied into an annual work plan intended to advance the education, training and outreach program, including identification of technical assistance resources, and estimated costs for education and outreach activities, to advance understanding of the PSR.

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

Section II. Award Information

Funding Instrument	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.
Application Types Allowed	Renewal The OER Glossary and the How to Apply - Application Guide provide details on these application types. Only those application types listed here are allowed for this NOFO.
Clinical Trial?	Not Allowed: Only accepting applications that do not propose clinical trials.
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. The award will provide one (1) year of support and include future recommended support for up to four (4) additional years contingent upon annual appropriations, availability of funding and satisfactory recipient performance. HFP intends to commit up to $500,000.00 in FY 2026 to fund one (1) award.
Award Budget	Application budgets are not limited but need to reflect the actual needs of the proposed project. YR 01: $500,000.00 YR 02: $500,000.00 YR 03: $500,000.00 YR 04: $500,000.00 YR 05: $500,000.00

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

Only the following applicant is eligible to apply for this single source funding: The University of Arkansas

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.

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may not submit more than one 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, 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

It is critical that applicants follow the instructions in the Research (R) Instructions in the How to Apply - Application Guide except where instructed in this notice of funding opportunity to do otherwise. Conformance to the requirements in the How to Apply - 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

Not applicable.

Page Limitations

All page limitations described in the How to Apply - Application Guide and the Table of Page Limits must be followed.

Instructions for Application Submission

The following section supplements the instructions found in the How to Apply - Application Guide and should be used for preparing an application to this NOFO.

SF424(R&R) Cover

All instructions in the How to Apply - Application Guide must be followed.

Descriptive Title of Applicant's Project: Applicants must include Organization Name/Abbreviation, the Project title in the applicant's title.

SF424(R&R) Project/Performance Site Locations

All instructions in the How to Apply - Application Guide must be followed.

SF424(R&R) Other Project Information

All instructions in the How to Apply - Application Guide must be followed.

The Project Summary/Abstract must include the problem statement, objectives, and intended stakeholders targeted.

SF424(R&R) Senior/Key Person Profile

All instructions in the How to Apply - Application Guide must be followed.

R&R or Modular Budget

All instructions in the How to Apply - Application Guide must be followed.

- 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. The budget and justification for the first budget year should be detailed and reflect costs that accurately and realistically portray the work that will be completed within the first budget year. A reasonable approximation of what you intend to spend in the following years must be provided making sure to include enough details to convince the reviewers that you have a good sense of the overall costs. A detailed budget justification must be submitted for each proposed subaward (see R&R Subaward Budget section).
- 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.

R&R Subaward Budget

All instructions in the How to Apply - Application Guide must be followed.

A detailed budget and justification must be submitted for each proposed subaward.

PHS 398 Cover Page Supplement

All instructions in the How to Apply - Application Guide must be followed.

PHS 398 Research Plan

All instructions in the How to Apply - Application Guide must be followed, with the following additional instructions:

Specific Aims: The Specific Aims document should list succinctly the goals for each applicable objective and summarize the expected outcome(s).

Research Strategy: As part of the research strategy, the applicant must address the following areas under each program objective for the applicable budget period.

Coversheet:

Project title

Program problem statement, objectives, and the intended tribal stakeholders for engagement during the entire funded period.

Phase 1 Foundation and Planning of Program (Objectives 1, 2, and 3)

Objective 1: Develop an annual work plan

Planned activities related toall objectives

Staffing Matrix

Subawards, including subaward name(s) and planned activities

Contract entity/entities and planned services

Objective 2: Develop and maintain guiding documents

Planned activities related to Objective 2

Objective 3: Develop a logic model

Planned activities related to Objective 3

Phase 2 National Trainer Network Development (Objective 4)

Objective 4: Promote understanding and integration of produce safety and environmental considerations and co-management practices.

Planned activities related to Objective 4

Phase 3 Implementation, Integration and Continuous Improvement (Objectives 5 and 6)

Objective 5: Establish and maintain a qualified national network of Tribal produce safety trainers

Planned activities related to Objective 5

Objective 6: Improve the effectiveness and reach of produce safety training and outreach

Planned activities related to Objective 6

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the How to Apply - Application Guide.

Other Plan(s): Note: Effective for due dates on or after January 25, 2023, the Data Management and Sharing Plan will be attached in the Other Plan(s) attachment in FORMS-H application forms packages.

All instructions in the How to Apply - Application Guide must be followed, with the following additional instructions:

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: Only limited Appendix materials are allowed as outlined below.

Applicants must attach as Appendix #1, an organizational structure to accomplish the implementation, oversight, monitoring, and reporting of program phases and corresponding objectives. Roles and responsibilities must be outlined and must directly relate to accomplishing the applicable program phases and objectives.

PHS Human Subjects and Clinical Trials Information

When involving human subjects research, clinical research, and/or FDA-defined clinical trials (and when applicable, clinical trials research experience) follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the How to Apply - 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 **Delayed Onset Study** record.

Study Record: PHS Human Subjects and Clinical Trials Information

All instructions in the How to Apply - 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 How to Apply - Application Guide must be followed.

PHS Assignment Request Form

All instructions in the How to Apply - Application Guide must be followed.

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 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.

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 applicable.

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 scientific and technical merit through the FDA programmatic review.

Overall Impact

Programmatic reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Programmatic 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: 10**

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?

Does the applicant demonstrate the ability to sustain the progress made beyond the duration of the cooperative agreement?

Investigator(s)	**Maximum Points: 10**

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?

Does the applicant demonstrate the ability to maintain program staff and partnerships necessary to implement, oversee, monitor, and report on program phases and objectives?

Does the applicant demonstrate the availability of adequately trained personnel to provide education and/or training, outreach, and technical assistance to Tribal stakeholders?

Does the applicant describe the criteria and capacity to hire and/or train personnel needed to meet the deliverables of the cooperative agreement?

Innovation	**Maximum Points: 30**

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

Approach	**Maximum Points: 25**

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?

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?

Does the applicant demonstrate the ability to develop and provide a range of educational tools for Tribal stakeholders related to FSMA regulations, specifically the Produce Safety Rule for federally recognized Tribes?

Does the applicant demonstrate the ability to develop and implement a training plan aligned with project goals that advances Tribal stakeholders' understanding of on-farm produce safety, incorporates existing materials and relevant cultural practices, and supports understanding of Produce Safety Rule requirements and other federal preventive controls standards to facilitate compliance?

Does the applicant demonstrate the ability to identify culturally appropriate methods for delivering training, outreach, and educational materials, and mechanisms to connect federally recognized Tribes with relevant technical assistance resources?

Does the applicant demonstrate the ability to meet the reporting requirements outlined in Section VI.4 of this announcement?

Environment	**Maximum Points: 25**

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

Does the applicant demonstrate the ability to engage and collaborate with national and regional Native American organization leaders, national organizations, land-grant university extension programs, the Produce Safety Alliance, the National Coordination and Regional Centers, FDA, and other federal agencies to advance understanding of the FSMA Produce Safety Rule among the target audience?

Does the applicant demonstrate the ability to cooperate and coordinate extensively with FDA's Human Foods Program (HFP), other FDA program offices, and FDA's FSMA partners at USDA to strengthen and support an integrated produce food safety system?

Does the applicant demonstrate the ability to effectively reach the target audience and collaborate with relevant partners–including Tribal academic institutions, Tribal governments, land-grant cooperative extension programs, federally recognized Tribal extension agents, Tribal NGOs and community-based organizations, and federal agencies such as USDA, CDC, and the Indian Health Service–to support work with the target audience on relevant food safety issues?

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.

Protections for Human Subjects

For research that involves human subjects but does not involve one of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Guidelines for the Review of Human Subjects.

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following three points: (1) a complete description of all proposed procedures including the species, strains, ages, and total numbers of animals to be used; (2) justifications that the species is appropriate for the proposed research and why the research goals cannot be accomplished using an alternative non-animal model; and (3) interventions including analgesia, anesthesia, sedation, palliative care, and humane endpoints that will be used to limit any unavoidable discomfort, distress, pain and injury in the conduct of scientifically valuable research. Methods of euthanasia and justification for selected methods, if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals, is also required but is found in a separate section of the application. For additional information on review of the Vertebrate Animals Section, please refer to the Worksheet for Review of the Vertebrate Animals Section.

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmissions

Not applicable.

Renewals

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

Revisions

Not applicable.

Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

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 FDA staff, using the stated review criteria.

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

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.

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

As of October 1, 2025, HHS has adopted 2 CFR Part 200, with some modifications included in 2 CFR Part 300. These regulations replace those in 45 CFR Part 75.

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:

- ongoing and consistent access to HHS owned or operated information or operational technology systems; and
- 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.

Cybersecurity plans and procedures **must** at minimum include the following:

- Develop cybersecurity plans and procedures, modeled after the NIST Cybersecurity framework, to protect HHS systems and data:
    - **Identify:**
        - Develop an inventory of all assets and accounts with access to HHS owned and operated information or operational technology systems or which obtain PII or PHI for the purposes of the award.
    - **Protect:**
        - Limit access to HHS owned and operated systems to only those in need of access to complete reward activities.
        - Require all staff to complete annual cybersecurity and privacy awareness training. Visit 405(d): Knowledge on Demand (hhs.gov) to obtain free trainings, if needed.
        - Enable multifactor authentication for all employees, subrecipients, and third-party entities to access HHS owned and operated information or operational technology systems.
        - Regularly backup sensitive data and test backups.
    - **Detect:**

        - Install anti-virus or anti-malware software on all devices, servers, and accounts used to connect to HHS owned and operated systems.
    - **Respond:**
        - Develop an incident response plan. See Incident-Response-Plan-Basics_508c.pdf (cisa.gov) to learn about developing incident response plans.
        - Have cybersecurity incident reporting procedures that ensure the relevant HHS awarding agencies are notified of a cybersecurity incident within 48 hours of discovery. A cybersecurity incident is defined as an unplanned interruption to a technology service or reduction in the quality of a technology service, or an occurrence that actually or potentially jeopardizes the confidentiality, integrity, or availability of an information system or the information the system processes, stores, or transmits.
    - **Recover:**
        - Investigate incidents and plug any security gaps identified.

Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (HHS) grant administration regulations at 2 CFR Part 200, and other HHS, PHS, and FDA grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial FDA programmatic involvement with the 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, 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 Program Officer and Subject-Matter Experts (SME) will have substantial programmatic involvement that is above and beyond the normal programmatic oversight, monitoring, and stewardship of awards, as described below:

- An FDA subject-matter expert will advise on progress of the cooperative agreement's phase-based approach, and provide approval for phase completion before the recipient may advance to subsequent phases.

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.

Additional Reporting Requirements:

This award has additional financial and performance reporting requirements as outlined below.

Performance

For the cooperative agreement, there is a lifecycle focus on the program results and recipient and sub awardee(s) performance which helps to emphasize program outcomes while successfully managing compliance.

Performance progress reports, and data reporting are required for the award.

Annual and quarterly performance progress reports are required for the award as follows:

I. Quarterly and Annual reports:

a. Submit quarterly performance progress reports documenting activities and progress toward mutually agreed-upon outcomes.

b. Reports may be submitted using a FDA-provided Excel reporting template.

c. Submit an annual Research Performance Progress Report (RPPR) at the end of each budget period.

d. Annual reports must include analysis of data trends, program needs, and implementation challenges, and these findings will be discussed with FDA.

II. Subawards

a. Performance progress reports must account for all subaward activities.

III. Required report content

a. Performance measurement data: baseline data, identified data sources, performance indicators, and target performance goals.

b. Progress on phase-based objectives and deliverables

c. Activities: description of activity (e.g., OFRR, Workshops, PSA training with Tribal supplemental material), including activity types (e.g. Education and/or Training, Outreach, Technical Assistance) and number of activities, delivery method and status.

d. Partnerships: any partnering organization involved in the work

e. Data analysis: analysis of data for trends, program needs, and challenges

f. Co-management activities: description of co-management efforts

g. Alignment: how activities align with FDA produce safety annual priorities

h. Challenges and lessons learned

i. Timelines: progress on established timelines

j. Changes in annual work plan

k. Future activities: upcoming quarterly activities, and any follow ups needed toadvance phase-based objectives.

l. Additional performance metrics: any mutually agreed upon performance measure.

IV. Defined terms

a. Recipient must use FDA provided defined terms on education, training, outreach, and technical assistance in the NOFO (see Part 1 Section I. Notice of Funding Opportunity Description) to foster distinction and accuracy in capturing performance measures.

Data reporting is an expectation for each phase and corresponding objectives. Recipients must provide data on the first phase and discuss progress with FDA, who will assess completion before recipient can move to the next phases FDA and recipient will discuss and agree post-award on timelines for each phase.

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 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.

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

Scientific/Research Contact(s)

Oscar Galagarza

Produce Safety Engagement Branch

Email:Oscar.GalagarzaAngulo@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)

Patrick Johnson

Office of Acquisitions and Grants Services

Email: patrick.johnson@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 Sections 301 of the Public Health Service Act as amended (42 USC 241) and 1009 of the Federal Food, Drug, and Cosmetic Act (21 USC 399) and subject to 2 CFR Parts 200 and 300.