Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	U.S. Food and Drug Administration (FDA) The policies, guidelines, terms, and conditions stated in this announcement may differ from those used by the NIH. Where this Funding Opportunity Announcement (FOA) provides specific written guidance that may differ from the general guidance provided in the grant application form, please follow the instructions given in this FOA. The FDA does not follow the NIH Page Limitation Guidelines or the NIH Review Criteria. Applicants are encouraged to consult with FDA Agency Contacts for additional information regarding page limits and the FDA Objective Review Process.
Components of Participating Organizations	Center for Food Safety and Applied Nutrition (CFSAN) Center for Veterinary Medicine (CVM)
Funding Opportunity Title	**Strategies that Support Global Food Safety (U01)**
Activity Code	U01 Research Project – Cooperative Agreements
Announcement Type	
Related Notices	None
Funding Opportunity Announcement (FOA) Number	**RFA-FD-16-034**
Companion Funding	None

Opportunity	
Number of Applications	See Section III. 3. Additional Information on Eligibility.
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.103
Funding Opportunity Purpose	FDA announces its intention to accept and consider a single source application for award of a cooperative agreement to the World Health Organization (WHO) Department of Food Safety and Zoonoses (FOS) to support strategies that address global food safety. This Cooperative Agreement is expected to contribute to the knowledge base of the current state of food safety globally, including challenges, risks and emerging trends, based on WHO's existing network efforts, such as the Global Foodborne Infections Network (GFN), International Food Safety Authorities Network (INFOSAN), Global Environment Monitoring System for Food (GEMS/Food); Global Early Warning Systems for Animal Diseases Including Zoonoses (GLEWS); Enable the sharing of scientific findings and data through expert meetings and technical consultations; Enhance capacity at international and national levels in such areas of laboratory analyses, surveillance, and risk assessment/risk management, including through the Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR); Contribute to the scientific, standard-setting work of the Codex Alimentarius Commission (Codex) through scientific advisory groups including the Joint Food and Agriculture Organization of the United Nations (FAO)/WHO Expert Committee on Food Additives (JECFA), the Joint FAO/WHO Meetings on Pesticide Residues (JMPR), the FAO/WHO Joint Meetings on Microbiological Risk Assessment (JEMRA), and the Joint FAO/WHO Expert Meetings on Nutrition (JEMNU) currently in development phase; and Enable participation of Member States through the Codex Trust Fund.

Key Dates

Posted Date	
Open Date (Earliest Submission Date)	March 24, 2016

Letter of Intent Due Date(s)	Not Applicable
Application Due Date(s)	May 26, 2016, by 11:59 PM Eastern Time. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. Applicants should be aware that on-time submission means that an application is submitted error free (of both Grants.gov and eRA Commons errors) by 11:59 PM Eastern Time on the application due date. **Late applications will not be accepted for this FOA.**
AIDS Application Due Date(s)	Not Applicable
Scientific Merit Review	June 2016
Advisory Council Review	Not Applicable
Earliest Start Date	September 2016
Expiration Date	May 27, 2016
Due Dates for E.O. 12372	Not Applicable

Required Application Instructions

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

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

BACKGROUND

WHO has responsibility for the provision of technical cooperation to its 194 Member States (national governments) in the area of food safety and zoonotic diseases. Among the focus areas are: surveillance for food borne disease; identification of food contamination; management of mechanisms for information sharing; and systems for emergency response, including outbreak investigations and governments' food product recalls which may potentially have a global impact or cross national boundaries, and which may fall within the requirements of the International Health Regulations. WHO's technical support complements a paradigm shift that is emerging around the globe; a shift from a focus on food safety interventions at ports-of-entry toward an approach that emphasizes preventive, risk-based efforts. This shift entails increasing accountability of entities along the supply chain that grow, harvest, manufacture, process, store, transport, distribute, and/or import foods for ensuring the safety of their products, while at the same time strengthening national authorities' capacity and systems to be able to regulate these products efficiently and effectively. Along with the Food and Agriculture Organization of the United Nations (FAO), WHO also has a responsibility in relation to harmonizing international science-based food safety standards (e.g., as one of the founding institutions and technical advisory bodies to the Codex Alimentarius Commission (Codex)). Codex was founded in 1963 to develop food standards, guidelines, and other related texts, such as codes of practice, under the Joint FAO/WHO Food Standards Programme. Currently, 185 Member States, including the United States through FDA and other U.S. Government agency technical and scientific experts, actively participate in Codex.

WHO's strategic plan for food safety provides a framework for taking action on priority issues in the area of food safety and foodborne zoonoses for the period 2013–2022, and forms the basis of the WHO Twelfth General Programme of Work (2014-2019) for the program area of food safety in Category 5. The three strategic directions are as follows:

- Provide the science base for measures along the entire food-chain to decrease foodborne health risks;

- Improve international and national cross-sectoral collaboration, enhance communication and advocacy; and

- Provide leadership and assist in the development and strengthening of risk-based, integrated national systems for food safety.

A significant outcome of the 63rd World Health Assembly, also called the continuation of sustainable preventive measures, in May 2010 was a consensus resolution on advancing food safety initiatives, which, among other items, acknowledged the continuing need for closer collaboration between the health sector and other sectors, and increased action on food safety at the international and national levels, across the full length of the food-production chain, in order to reduce significantly the incidence of food borne disease. This resolution also closed a ten year gap in WHO governance dialogue on global food safety challenges, providing all Member States with a general pathway for global collaboration and enforcing the Secretariat's role in technical cooperation.

The 63rd Health Assembly through food safety education programs, such as the FIVE KEYS TO SAFER FOOD, was developed by WHO in collaboration with FDA. The WHO FIVE KEYS TO SAFER FOOD global message and training materials for consumers in the home are now recognized as an international source for conducting national food safety education programs. In 2008, a joint Food and Agriculture Organization (FAO)/WHO Expert Meeting on the microbiological hazards in fresh leafy vegetables and herbs also acknowledged the success of the FIVE KEYS TO SAFER FOOD as it reviewed the scientific data and made recommendations for limiting the risks associated with microbial contamination of these products. An important recommendation from the meeting was the suggestion that WHO develop training and educational materials based on the FIVE KEYS TO SAFER FOOD concept. As a result, WHO, working together with FDA, developed FIVE KEYS to Growing Safer Fruits and Vegetables: Promoting Health by Decreasing Microbial Contamination, a training program designed for educating rural workers who grow fresh fruits and vegetables for themselves, their families and for sale in local markets.

For nearly 30 years, FDA, through the Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM), has participated with WHO's International Programme on Chemical Safety (IPCS) in a Cooperative Agreement that supported WHO's work in international risk assessment and its standard-setting activities for food ingredients, contaminants, and veterinary drug residues in food, including the Joint FAO/WHO Expert Committee on Food Additives (JECFA). JECFA contributes internationally-recognized science-based risk assessments of food additives, contaminants, and residues of veterinary drug reside in food. This Cooperative Agreement has also supported Joint FAO/WHO Expert Consultations on risk assessments for emerging or cross-cutting issues (e.g., the use of active chlorine species in food processing, bisphenol-A). The evaluations that are produced by JECFA and the Expert Consultations provide a sound scientific basis for Codex's standard-setting activities that contribute to improved public health and food safety worldwide.

Many of the network "building blocks" to address elements of preventive risk-based approaches to food safety reside within WHO. For example:

- The International Networks of Food Safety Authorities (INFOSAN), a joint FAO/WHO program consisting of 177 Member States, which aims to promote the rapid exchange of information during food safety related events, promote partnership and collaboration between countries, and help countries to strengthen their capacity to manage food safety risks;

- The Global Foodborne Infections Network (GFN), a network of over 1,500 individuals from 700 institutions in 177 countries, that provide human resource expertise to promote integrated, laboratory-based surveillance and intersectoral collaboration in human health, veterinary, and food-related disciplines;

- The Global Early Warning Systems for Animal Diseases Including Zoonoses (GLEWS), a joint system that coordinates alert mechanisms of the WHO, the FAO, and the World Organization for Animal Health (OIE) to assist in prediction, prevention, and control of zoonotic disease threats;

- The Global Environment Monitoring System for Food (GEMS/Food), a program, which focuses on data collection and training related to dietary exposure of chemical hazards and involves a network of WHO Collaborating Center and national institutions from around the globe;

- JECFA, the Joint FAO/WHO Meetings on Pesticide Residues (JMPR), the Joint FAO/WHO Meetings on Microbiological Risk Assessment (JEMRA), and the Joint FAO/WHO Expert Meetings on Nutrition (JEMNU) currently in development phase, that serve as technical advisory bodies to Codex; and the Threshold of Toxicological Concern Project.

- The management of the Codex Trust Fund.

- The FIVE KEYS TO SAFER FOOD training materials developed to educate food handlers in safe food handling practices.

AGISAR- Advisory Group on Integrated Surveillance for Antimicrobial Resistance (AGISAR), which works to reduce the impact of antimicrobial resistance from the use of antimicrobial drugs in food animals.

DETAILS

The cooperative agreement announced in this FOA represents the continuation of a long-standing collaboration between WHO and FDA in support of strategies and approaches that align with FDA's domestic and global food safety interests. Relevant strategies include: 1) efforts to strengthen data and information systems so they are comparable, comprehensive, and robust, thereby allowing for better decision-making for all Member States; 2) enhanced capacity around the globe to improve detection of and response to food safety threats through preventive controls, data, information, surveillance systems, and risk-based approaches; and 3) global harmonization of science-based standards and adoption or adaption of international standards by national authorities.

This Cooperative Agreement is expected to support the following types of collaboration:

- Enable the sharing of scientific findings and data through expert meetings and technical consultations;

- Enhance capacity at international and national levels in such areas of laboratory analyses, surveillance, and risk assessment/risk management, including through AGISAR;

- Contribute to the scientific, standard-setting work of Codex through scientific advisory groups including JECFA, JMPR, JEMRA, and JEMNU currently in development phase; and

- Enable participation of Member States through the Codex Trust Fund.

Inherent in the cooperative agreement award is substantive involvement by the awarding agency. Accordingly, FDA will be actively engaged in the programmatic activities of the entire project funded by this cooperative agreement, including but not limited, to the following items:

- FDA will appoint a project officer who will actively monitor the FDA-supported program under this award and work closely and collaboratively with a core group of experts. This core group of technical experts (CG/TE) from CFSAN, CVM, the Office of Global Regulatory Operations and Policy (GROP) will provide technical guidance and advice, as appropriate, to WHO in the implementation of this cooperative agreement. Support can be from various sources including in-kind participation.

- Appropriate participation of FDA in multinational advisory group(s) that are working to address food safety regulatory systems, the development and implementation of science-based standards and norms, and strengthening the existing capacity of Member States in the area of food safety and preventive controls.

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

Section II. Award Information

Funding Instrument	Cooperative Agreement: A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, FDA scientific or program staff will assist, guide, coordinate, or participate in project activities. See Section VI.2 for additional information about the substantial involvement for this FOA.
Application Types Allowed	Renewal The OER Glossary and the SF424 (R&R) Application Guide provide details on these application types.
Funds Available and Anticipated Number of Awards	The number of awards is contingent upon FDA appropriations and the submission of a sufficient number of meritorious applications. Future year amounts will depend on annual appropriations, availability of funding and awardee performance. FDA/CFSAN intends to fund up to $1,000,000, for fiscal year 2016 in support of this grant program. It is anticipated that up to one (1) award will be made, not to exceed $1,000,000 in total costs (direct plus indirect), per award.
Award Budget	Application budgets need to reflect the actual needs of the proposed project and should not exceed the following in total costs (direct and indirect): YR 01: $1,000,000 YR 02: $1,000,000 YR 03: $1,000,000 YR 04: $1,000,000 YR 05: $1,000,000
Award Project Period	The scope of the proposed project should determine the project period. The maximum project period is five (5) years. The award will provide one year support and include future recommended support for four additional years, contingent upon satisfactory performance in the achievement of project and program objectives during the preceding year and the availability of federal fiscal year appropriations.

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

Section III. Eligibility Information

1. Eligible Applicants

The following organization is eligible to apply:

The World Health Organization (WHO) Department of Food Safety and Zoonoses (FOS).

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are** eligible to apply.
Non-domestic (non-U.S.) components of U.S. Organizations **are** eligible to apply.
Foreign components, as *defined in the HHS Grants Policy Statement*, **are** allowed.

Required Registrations

Applicant Organizations

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

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

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

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

Eligible Individuals (Program Director/Principal Investigator)

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

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

the SF424 (R&R) Application Guide.

2. Cost Sharing

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

3. Additional Information on Eligibility

Number of Applications

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

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

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

Section IV. Application and Submission Information

1. Requesting an Application Package

Applicants must obtain the SF424 (R&R) application package associated with this funding opportunity using the "Apply for Grant Electronically" button in this FOA or following the directions provided at Grants.gov.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide, including Supplemental Grant Application Instructions except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

For information on Application Submission and Receipt, visit Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications.

Page Limitations

All page limitations described in the SF424 Application Guide and the Table of Page Limits must be followed, with the following exceptions or additional requirements:

- For this specific FOA, the Research Strategy section is limited to 30 pages.

Instructions for Application Submission

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

SF424(R&R) Cover

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

SF424(R&R) Project/Performance Site Locations

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

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

SF424(R&R) Senior/Key Person Profile
All instructions in the SF424 (R&R) Application Guide must be followed.

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

- Applications requesting multiple years of support must complete and submit a separate detailed budget breakdown and narrative justification for each year of financial support requested.

- If an applicant is requesting indirect costs as part of their budget, a copy of the most recent Federal indirect cost rate or F&A agreement must be provided as part of the application submission. This agreement should be attached to the RESEARCH & RELATED Other Project Information Component as line #12 'Other Attachments'.

- If the applicant organization has never established an indirect cost rate and/or does not have a negotiated Federal indirect cost rate agreement, a de minimis indirect cost rate of 10 percent (10%) of modified total direct costs (MTDC) will be allowed. MTDC means all direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel, and subaward and subcontracts up to the first $25,000 of each subaward or subcontract. MTDC excludes equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs and the portion of each subaward and subcontract in excess of $25,000.

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

PHS 398 Cover Page Supplement
All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Research Plan
All instructions in the SF424 (R&R) Application Guide must be followed.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide, with the following modification:
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- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.

Appendix: Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

PHS Inclusion Enrollment Report
When conducting clinical research, follow all instructions for completing PHS Inclusion Enrollment Report as described in the SF424 (R&R) Application Guide.

PHS Assignment Request Form
All instructions in the SF424 (R&R) Application Guide must be followed.

Foreign Institutions
Foreign (non-U.S.) institutions must follow policies described in the *HHS Grants Policy Statement*, and procedures for foreign institutions described throughout the SF424 (R&R) Application Guide.

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

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

4. Submission Dates and Times

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

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

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

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

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review.

6. Funding Restrictions

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

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

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

7. Other Submission Requirements and Information

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

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

For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically. 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 Component of the SF424(R&R) Application Package**.** Failure to register in the

Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to FDA. See Section III of this FOA for information on registration requirements.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the SF424 (R&R) Application Guide.

See more tips for avoiding common errors.

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

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in NOT-OD-13-030.

Section V. Application Review Information

1. Criteria

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

Scored Review Criteria

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

Significance (25 Points)

Does the project address an important problem or a critical barrier to progress in the field? Is there a strong scientific premise for the project? 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?

Investigator(s) (20 Points)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If 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?

Innovation (15 Points)

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 (25 Points)

Are the overall strategy, methodology, and analyses 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? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

If the project involves human subjects and/or FDA-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of children, justified in terms of the scientific goals and research strategy proposed?

Environment (15 Points)

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?

Additional Review Criteria

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

Protections for Human Subjects

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

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

Inclusion of Women, Minorities, and Children

When the proposed project involves human subjects and/or FDA-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of children to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research.

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of proposed procedures involving

animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section.

Biohazards

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

Resubmissions

Not Applicable

Renewals

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

Revisions

Not Applicable

Applications from Foreign Organizations

Reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

Select Agent Research

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

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: (1) Data Sharing Plan; (2) Sharing Model Organisms; and (3) Genomic Data Sharing Plan (GDS).

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.

2. Review and Selection Process

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

As part of the objective review, all applications:

- Will receive a written critique.

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

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

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

3. Anticipated Announcement and Award Dates

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

Section VI. Award Administration Information

1. Award Notices

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

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

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

2. Administrative and National Policy Requirements

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

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

HHS provides general guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see http://www.hhs.gov/ocr/civilrights/resources/laws/revisedlep.html. The HHS Office for Civil Rights also provides guidance on complying with civil rights laws enforced by HHS. Please see http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html; and http://www.hhs.gov/ocr/civilrights/understanding/index.html. Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html. Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at http://www.hhs.gov/ocr/office/about/rgn-hqaddresses.html or call 1-800-368-1019 or TDD 1-800-

537-7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53.

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

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

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

3. Reporting

When multiple years are involved, awardees will be required to submit the Research Performance Progress Report (RPPR) annually and financial statements as required in the Notice of Award.

A final progress report, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the *HHS Grants Policy Statement*.

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

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 registration, submitting and tracking an application, documenting system problems that threaten submission by the due date, post submission issues)
Finding Help Online: http://grants.nih.gov/support/ (preferred method of contact)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

Grants.gov Customer Support (Questions regarding Grants.gov registration and submission, downloading forms and application packages)
Contact CenterTelephone: 800-518-4726
Web ticketing system: https://grants-portal.psc.gov/ContactUs.aspx
Email: support@grants.gov

Scientific/Research Contact(s)

Julie Moss
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Center of Food Safety and Applied Nutrition (CFSAN)
5100 Paint Branch Parkway

College Park, MD 20740
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Objective Review Contact(s)

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Rockville, MD 20857
5630 Fishers Lane, Rm. 2026, HFA 500
Telephone: 240-402-2111
E-mail: bryce.jones@fda.hhs.gov

Financial/Grants Management Contact(s)

Bryce Jones
Grants Management Specialist
Food and Drug Administration
Office of Acquisitions and Grants Services
Rockville, MD 20857
5630 Fishers Lane, Rm. 2026, HFA 500
Telephone: 240-402-2111
E-mail: bryce.jones@fda.hhs.gov

Section VIII. Other Information

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

Authority and Regulations

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