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)
Funding Opportunity Title	**Cooperative Agreement to Support Shellfish Safety Assistance Project (U01)**
Activity Code	U01 Research Project – Cooperative Agreements
Announcement Type	New
Related Notices	None
Funding Opportunity Announcement (FOA) Number	**RFA-FD-16-006**
Companion Funding Opportunity	None

Number of Applications	See Section III. 3. Additional Information on Eligibility.
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.103
Funding Opportunity Purpose	The Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN), Office of Food Safety (OFS) is announcing its intent to award a single source cooperative agreement to the Interstate Shellfish Sanitation Conference (ISSC). The purpose of this cooperative agreement is to enhance the FDA's molluscan shellfish sanitation program and provide the public greater assurance of the quality and safety of these products. Molluscan shellfish have been recognized by FDA as a significant source of seafood-borne illnesses and continue to be the subject of congressional, state, industry, and public concern. FDA has given high priority to enhance the agency's shellfish safety program and to provide the public greater assurance of the quality and safety of these products. FDA administers the National Shellfish Sanitation Program (NSSP). Under that program, the NSSP Model Ordinance serves as guidance for State shellfish sanitation programs and the promulgation of state regulations and laws concerning shellfish safety. This cooperative agreement will enhance FDA efforts to help ensure that shellfish are free of harmful pathogens.

Key Dates

Posted Date	
Open Date (Earliest Submission Date)	February 16, 2016
Letter of Intent Due Date(s)	Not Applicable
Application Due Date(s)	April 8, 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 1, 2016
Expiration Date	April 9, 2016
Due Dates for E.O. 12372	Not Applicable

Required Application Instructions

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

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

This proposed cooperative agreement with the Interstate Shellfish Sanitation Conference (ISSC) will continue to: (1) address the need to improve information exchange and transfer among States, Federal Agencies, industry, and consumers; (2) strengthen state activities by providing them with procedural and policy guidance, technical training, research, consumer education, and support for States to participate in ISSC biennial meetings and ISSC committee meetings; and (3) promote efforts and projects, including research, that will contribute significantly to the ability of FDA and states to identify and implement scientifically defensible food safety controls to reduce the risk of illness associated with molluscan shellfish consumption, including Vibrio vulnificus and Vibrio parahaemolyticus. Research efforts will provide information and data that can be used to reduce assumptions and tighten modeling outputs of the Vibrio vulnificus and Vibrio parahaemolyticus risk assessments developed by the Food and Agriculture Organization of the World Health Organization and FDA respectively. Additionally, these efforts will further the development of Vibrio forcasting tools being developed by FDA in conjunction with NOAA for use by federal, state and industry shellfish partners for managing risk.

The ISSC was formed in 1982 as a partnership of Federal, State, Local, and Foreign shellfish control officials representing public health and environmental agencies to provide a formal structure wherein State regulatory authorities could establish and maintain science based guidelines and procedures for uniform application to ensure the sanitary control of the molluscan shellfish industry and help ensure that safe shellfish reach consumers. Thirty-nine States, the Washington District of Columbia and four foreign countries are members of the ISSC, including all twenty-three coastal shellfish-producing States. The ISSC is a voluntary organization open to all persons interested in fostering controls that help to ensure sources of safe and sanitary shellfish. In 1984, FDA formally recognized the ISSC through a Memorandum of Understanding (MOU). Today, FDA continues to recognize the ISSC as the primary voluntary national organization of State shellfish regulatory officials that provides guidance and counsel to the States on matters of sanitary control of molluscan shellfish. In 1993, 1996, 2001, 2006, and 2011 FDA awarded a non-competitive grant to the ISSC for one year, with an additional four years during each intended award period, based on satisfactory performance and availability of funding. Each year FDA receives $60,000 from the Department of Commerce, National Oceanic and Atmospheric Administration, National Marine Fisheries Services (NMFS) as additional support for this project. Since 1993, the annual allocation to the ISSC under this cooperative agreement, including NMFS funding and supplemental funding, has been $325,000.00.

Beginning in September 1996, in accordance with Congressional earmarks, FDA awarded supplemental funding to the ISSC cooperative agreement to provide for implementation and enhancement of activities associated with the control of Vibrio vulnificus and Vibrio parahaemolyticus, two naturally occurring pathogens that account for numerous, but preventable, foodborne illness from consuming raw molluscan shellfish. Although no longer an earmark, FDA continues to support ISSC Vibrio control efforts through supplemental funding as deemed appropriate and as funds are available.

Substantive accomplishments of the ISSC under previous cooperative agreements include:

1. Coordination of annual shellfish safety meetings of federal regulators, state regulators, and industry members for the purpose of developing improved science based shellfish safety controls in the NSSP Model Ordinance for implementation by state shellfish control agencies and the shellfish industry;

2. Facilitation of the incorporation and implementation of HACCP into the NSSP Model Ordinance;

3. Facilitation of an ISSC Unresolved Issues Process to resolve shellfish safety program discrepancies between FDA and states, ensuring continued compliance with NSSP shellfish safety controls;

4. Coordination of NSSP Model Ordinance revisions and electronic online availability;

5. Coordination with FDA on the development and oversight of a Vibrio parahaemolyticus control plan;

6. Development of an educational training video concerning the risks and control of illegal shellfish harvesting

7. Development of an education training video concerning the public health implications associated with overboard waste discharges from harvest vessels;

8. Development of accredited on-line training courses for medical professionals concerning Vibrio illness and shellfish consumption.

9. Development and maintenance of a World Wide Web site for continuous accessibility to molluscan shellfish safety information, including up-to-date information regarding outbreaks and recalls;

10. Coordination with FDA on the development and oversight of a Vibrio vulnificus control plan;

11. In conjunction with FDA, conduct of retail and processing plant product sampling studies to examine Vibrios in molluscan shellfish that have undergone a post harvest process to reduce levels of Vibrios; and,

12. In conjunction with FDA, conduct of a retail shellfish study to look at the occurrence of pathogens in molluscan shellfish, including norovirus, Hepatitis A virus, salmonella, and Vibrios.

13. In conjunction with FDA, development of a risk-based approach to evaluating state compliance with NSSP Model Ordinance requirements for controlling the safety of molluscan shellfish.

14. Hosted a Male Specific Coliphage (MSC) summit meeting to bring together experts in the field of pollution source indicators and assessment as part of an ISSC effort to bring MSC into the NSSP as a recognized tool for assessing the risk of viral contaminationn of mulloscan shellfish associated with fecal waste discharges.

Other substantive accomplishments of the ISSC include: facilitating and coordinating development of shellstock time-temperature controls for Vibrio vulnificus and Vibrio parahaemolyticus; funding support for Vibrio vulnificus virulent strain identification research; funding support to research the effects of ice chilling on Vibrio vulnificus; funding support to research the influence of water and air temperature, dissolved oxygen, and nutrients on Vibrio parahaemolyticus concentrations in Pacific oysters; funding support to conduct an economic assessment of mandating post-harvest treatment of oysters; funding support to conduct a consumer acceptance study of oysters that have been post-harvest treated to reduce Vibrio levels to non-detect; development of a Vibrio vulnificus laboratory methodology training video; and development and broadcast of a public service announcement to alert at risk consumers of the dangers associated raw shellfish consumption.

This project will (1) enhance both the effectiveness and uniformity of the national molluscan shellfish safety program by improving the flow of information between Federal and State regulatory agencies, industry, and consumers; (2) strengthen State activities by providing assistance in such areas as procedural and policy guidance, technical training, research, consumer education, and conformity with requirements of the NSSP Model Ordinance; (3) provide for research opportunities related to shellfish safety; and (4) bring to final resolution the development and implementation of effective Vibrio risk control plans for implementation by states and industry that are consistent with current science, epidemiology, and HACCP-based food safety measures.

Substantive Involvement by the FDA will include: (1) FDA will monitor the ISSC's overall conduct under this cooperative agreement; (2) FDA will have representation on the ISSC Executive Board, Committees and Task Forces; (3) FDA will collaborate and work closely with the ISSC on Vibrio

vulnificus and Vibrio parahaemolyticus risk reduction efforts. FDA will continue to monitor state activities to ensure illness/risk reduction goals of the ISSC Vibrio vulnificus control plan are met and continue to monitor state activities to ensure that the ISSC Vibrio parahaemolyticus control plan is fully implemented; (4) FDA will continue to work with ISSC to develop State program evaluation criteria; (5) FDA will analyze state shellfish program data and information and work through the ISSC to resolve any State shellfish program problems that may impact public health; (6) FDA will conduct training courses in growing area classification, plant sanitation, and HACCP and plant standardization for participants of the ISSC, including online training modules; (7) FDA will work with ISSC to develop new microbiological and marine biotoxin techniques and to develop and implement early warning systems for toxic algal blooms and new strategies for managing areas affected by toxic algal blooms; (8) FDA will continue to work with ISSC to establish improved mechanisms for incorporating new lab methods into the NSSP; (9) FDA will work with ISSC to develop NSSP Model Ordinance interpretations; and (10) FDA will take any action that may be necessary to ensure compliance with this cooperative agreement including, but not limited to, the pursuit of science-based HACCP controls for managing the risk of Vibrios, and developing patrol, growing area classification, and plant inspection criteria.

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	 FDA/CFSAN intends to fund up to $500,000, for fiscal year 2016 in support of this grant program. It is anticipated that up to one award will be made, not to exceed $500,000 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: $500,000 YR 02: $500,000 YR 03: $500,000 YR 04: $500,000 YR 05: $500,000

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

Eligible Organizations

The following organization is eligible to apply:

- **Interstate Shellfish Sanitation Conference**

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply.
Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.
Foreign components, as *defined in the HHS Grants Policy Statement*, **are not** allowed.

Required Registrations

Applicant Organizations

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

- Dun and Bradstreet Universal Numbering System (DUNS) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- System for Award Management (SAM) (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:

- 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.

Planned Enrollment Report

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

PHS 398 Cumulative Inclusion Enrollment Report

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

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? 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) (25 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 (10 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? 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 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

Not Applicable.

Select Agent Research

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

Resource Sharing Plans

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

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

Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Part 75, and other HHS, PHS, and FDA grant administration policies.

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

A.1. Principal Investigator Rights and Responsibilities

The Principal Investigator will have the primary responsibility for and dominant role in planning, directing, and executing the proposed project, with the FDA staff being substantially involved as a partner with the PI.

Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current HHS, PHS, and FDA policies.

A.2. FDA Responsibilities

An FDA Program Officer will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

The program officer will monitor the grantee periodically. The monitoring may be in the form of telephone conversations, emails, or written correspondence between the project officer/grants management officer and the Principal Investigator. Periodic site visits with officials of the grantee organization may also occur. The results of these monitoring activities will be recorded in the official grant file and will be available to the grantee upon request, consistent with applicable disclosure statutes and with FDA disclosure regulations. Also, the grantee organization must comply with all special terms and conditions of the grant, including those that state that future funding will depend on recommendations from the project officer. In addition,

a. FDA will have prior approval of the appointment of all key administrative and scientific personnel proposed by the grantee.
b. FDA will be directly involved in the guidance and development of the program.
FDA scientists will participate, with the grantee, in determining and carrying out scientific and technical activities. Collaboration will also include data analysis, interpretation of findings and, where appropriate, co-authorship of publications

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

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

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 Center Telephone: 800-518-4726
Web ticketing system: https://grants-portal.psc.gov/ContactUs.aspx
Email: support@grants.gov

Scientific/Research Contact(s)

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Objective Review Contact(s)

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Rockville, MD 20857
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Financial/Grants Management Contact(s)

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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.