

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	U.S. Food and Drug Administration (FDA) The FDA does not follow the NIH Page Limitation Guidelines or the Enhanced Peer Review Scoring Criteria. Applicants are encouraged to consult with FDA Agency Contacts for additional information regarding page limits and the FDA Peer Review Process.
Components of Participating Organizations	Center for Food Safety and Applied Nutrition
Funding Opportunity Title	Cooperative Agreement to Support the Joint Institute for Food Safety and Applied Nutrition, JIFSAN (U01)
Activity Code	U01 Research Project – Cooperative Agreements
Announcement Type	New
Related Notices	None
Funding Opportunity Announcement (FOA) Number	RFA-12-016
Companion Funding Opportunity	None
Number of Applications	Only one application per institution is allowed 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) is announcing its intention to receive and consider a single source application for the award of a cooperative agreement in fiscal year 2012 (FY12) to the University of Maryland, College Park (UMCP), to support the Joint Institute for Food Safety and Applied Nutrition (JIFSAN). The purposes of this partnership are to, 1) continue promoting the integration of applied research, education, and outreach programs that have been established between UMCP-JIFSAN and FDA to advance the scientific base for the development of sound public policy;

	<p>2) enhance FDA's ability to address an increasing number of critical and complex food safety and public health issues associated with foods and other products that FDA regulates (i.e., food ingredients; dietary supplements; cosmetics; animal feed, feed additives and animal drugs);</p> <p>3) provide opportunities to leverage additional resources among US government agencies, academia, industry and consumers to address new and emerging issues associated with an increasingly diverse domestic and global food supply;</p> <p>4) continue to promote a greater awareness and understanding of the critical role of regulatory science and practice among academic scientists and the pool of future scientists; and</p> <p>5) Support the new Food Safety Modernization Act, which emphasizes the concept of preventing food safety-related problems before they occur and enhance FDA's efforts to partner with other nations to improve US and worldwide health.</p>
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Key Dates

Posted Date	Not Applicable
Letter of Intent Due Date	Not Applicable
Application Due Date(s)	June 1, 2012
AIDS Application Due Date(s)	http://grants.nih.gov/grants/guide/url_redirect.htm?id=11112 Not Applicable
Scientific Merit Review	http://grants1.nih.gov/grants/funding/submissionschedule.htm - reviewandaward June 1, 2012
Advisory Council Review	http://grants.nih.gov/grants/guide/url_redirect.htm?id=11113 http://grants1.nih.gov/grants/funding/submissionschedule.htm - reviewandaward Not Applicable
Earliest Start Date(s)	August 1, 2012
Expiration Date	June 2, 2012
Due Dates for E.O. 12372	Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the [PHS398 Application Guide](#) except where instructed to do otherwise (in this FOA or in a Notice [NIH Guide for Grants and Contracts](#)). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. While some links are provided, 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

FDA believes that the UMCP-JIFSAN collaboration is a sound investment. The last 15 years of FDA's partnership with UMCP-JIFSAN have been successful in developing multiple programs to support public health policy. The goal of JIFSAN is to advance sound strategies that improve public health, nutrition, and food/feed safety through three broad program areas: research, education, and outreach.

With an increasingly diverse domestic and global food supply, FDA continues to face complex food safety issues associated with products that it regulates (i.e., conventional foods; food ingredients; dietary supplements; cosmetics; animal feed, feed additives and animal drugs). FDA believes that some of these complex issues can be effectively addressed by further strengthening the available science-based programs established through JIFSAN. FDA also believes that innovative capacity-building partnerships with various sectors of stakeholders in conjunction with JIFSAN's research and training programs can further support the development of proactive approaches to the prevention of problems before they occur.

A proposal is being solicited for meeting this need as well as FDA's strategic goal to protect and promote the public health. This cooperative agreement will provide continued support so that UMCP-JIFSAN can meet the following objectives:

Establish multi-institutional, multidisciplinary applied research projects to address complex food/feed safety and public health issues associated with products that FDA regulates. Applied research includes not only traditional laboratory and field research, but also epidemiological, educational, social and behavioral science.

Continue the development of mechanisms for the exchange of technical information and scientific concepts between FDA and other sectors of the international and domestic community, through workshops, short courses and symposia, and on-line resources that focus on existing and emerging complex food/feed safety and public health issues.

Continue the development and refinement of programs based on the application of the principles of risk analysis to address food/feed defense and safety issues.

Continue the design and improvement of domestic and international collaborations, which foster greater implementation of effective food safety practices.

Continue developing innovative education and outreach programs that will provide opportunities to leverage resources among various sectors of stakeholders to address complex safety issues associated with an increasingly diverse global food/feed supply.]

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 staff will assist, guide, coordinate, or participate in project activities.]
Application Types Allowed	[New] The OER Glossary and the PHS398 Application Guide provide details on these application types.
Funds Available and Anticipated Number of Awards	[The Center for Food Safety and Applied Nutrition (CFSAN) at FDA intends to commit \$2.2 Million in FY 2012.]
Award Budget	The estimated amount of support in FY2012 will be up to \$ 2.2 million (direct plus indirect costs) with the possibility of four additional years of support, subject to the availability of funds. Allowable cost increases of up to 4.3% per annum is allowed with an estimated amount of support of up to \$ 2.6 million for the final year of the award. Future year amounts will depend on annual appropriations and successful performance.
Award Project Period	[Scope of the proposed project should determine the project period. The maximum period is 5 years.]

FDA 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 University of Maryland, College Park (UMCP), Joint Institute for Food Safety and Applied Nutrition, JIFSAN.]

[Competition is limited to UMCP-JIFSAN because FDA feels that UMCP-JIFSAN is uniquely qualified to fulfill the objectives of the proposed cooperative agreement. The administrative structure and policies of UMCP-JIFSAN offer the flexibility needed to create and operate strategic alliances involving multiple partners. They also allow effective utilization of resources to plan and run multidisciplinary and multi-institutional research programs and internationally-recognized food safety training and risk analysis programs.]

UMCP and FDA through their collaboration in JIFSAN developed FoodRisk.org, which is an extensive web-based information resource addressing many aspects of food safety risk analysis, as well as providing tools and resources for food-borne infectious disease epidemiology and surveillance; developed a risk analysis professional development training program taught through several different modalities (e.g., face-to-face and on-line); developed international food safety education and outreach

programs that foster implementation of effective food safety practices (i.e., Good Agricultural Practices, Good Aquaculture Practices, and Commercially Sterile Packaged Foods); and recently, established the first-of-its-kind full time international food safety laboratory training facility at College Park, MD to train domestic and foreign government officials, third party laboratory scientists and food producers on fit-for-purpose analytical procedures that would meet global food safety standards.

Since its inception JIFSAN has funded over 60 research projects as well as provided over 250 internships to undergraduate students to work with FDA scientists. JIFSAN food safety research topics are diverse and include the development of methods for detecting food pathogens; risk assessment studies on nutrients; studies on food packaging materials, dietary supplements, and microbial dose-responses, as well as risk communication. JIFSAN's unique structure permits it to reach beyond the UMCP campus and support research at other universities.

Moreover, UMCP-JIFSAN provides an environment in which scientific and regulatory experts from various sectors can pool their resources and ideas and promote more efficient development and dissemination of science-based information that can support public policy.]

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 eligible to apply.

Required Registrations

Applicant organizations must complete the following registrations as described in the PHS398 Application Guide to be eligible to apply for or receive an award. Applicants must have a valid Dun and Bradstreet Universal Numbering System (DUNS) number in order to begin each of the following registrations.

- [Central Contractor Registration \(CCR\)](#) – must maintain an active registration, to be renewed at least annually
- [eRA Commons](#)

All Program Directors/Principal Investigators (PD(s)/PI(s)) must also work with their institutional officials to register with the eRA Commons or ensure their existing eRA Commons account is affiliated with the eRA Commons account of the applicant organization.

All registrations must be completed by the application due date. Applicant organizations are strongly encouraged to start the registration process at least 4-6 weeks prior to the application due date.

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/Principal Investigator (PD/PI) 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 PHS398 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

Only one application per institution (normally identified by having a unique DUNS number) is allowed.

FDA will not accept any application in response to this FOA that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application. FDA will not accept any application that is essentially the same as one already reviewed.

Section IV. Application and Submission Information

1. Address to Request Application Package

Applicants are required to prepare applications according to the current PHS 398 application forms in accordance with the PHS 398 Application Guide.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the [PHS398 Application Guide](#), 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.

Letter of Intent

Not Applicable.

Application Submission

Applications must be prepared using the PHS 398 research grant application forms and instructions for preparing a research grant application. Submit one signed, typewritten original of the application, including the checklist, and five signed photocopies as noted below:

Submit one original to:

Gladys Melendez
Food and Drug Administration
Division of Acquisition and Grant Services
5630 Fishers Lane, Rm. 1078
Rockville, MD 20857
240-731-3905; E-mail: gladys.bohler@fda.hhs.gov

Submit the five signed photocopies to:

Kevin W. Robinson
Extramural Resource Specialist
Food and Drug Administration
Center for Food Safety and Applied Nutrition (CFSAN)
CPK1, Rm. 4C035, HFS-650
5100 Paint Branch Parkway
College Park, MD 20740
Telephone: 240-402-2118
Kevin.robinson@fda.hhs.gov

Page Limitations

All page limitations described in the PHS398 Application Guide and the [Table of Page Limits](#) must be followed, with the following exceptions or additional requirements:

- Research Strategy section is limited to 30 pages.

Research Plan

All instructions in the PHS398 Application Guide must be followed.

Resource Sharing Plan

Individuals are required to comply with the instructions for the Resource Sharing Plans (Data Sharing Plan) as provided in the PHS398 Application Guide

Appendix

Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix (please note all format requirements) as described in the PHS398 Application Guide.

3. Submission Dates and Times

[Part I. Overview Information](#) contains information about Key Dates.

4. Intergovernmental Review (E.O. 12372)

This initiative is not subject to [intergovernmental review](#).

5. 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](#).

6. Other Submission Requirements and Information

Applications must be received on or before the due dates in [Part I. Overview Information](#). If an application is received after that date, it will not be reviewed.

Upon receipt, applications will be evaluated for completeness by the Grants Office and responsiveness by [CFSAN](#), FDA. Applications that are incomplete and/or nonresponsive will not be reviewed.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as noted below:

The only post-submission grant application materials that the FDA will accept are those resulting from unforeseen administrative issues. Post-submission grant application materials are those submitted after submission of the grant application but prior to the initial peer review. This option is to be used when an unexpected event such as the departure of a participant, natural disaster, etc. has occurred, not to correct oversights/errors discovered after submission of the application.

Acceptable post-submission materials include:

Revised budget page(s) (e.g., change in budget request due to new funding or institutional acquisition of equipment)
Biographical sketches (e.g., change in senior/key personnel due to the hiring, replacement, or loss of an investigator)
Letters of support or collaboration resulting from a change in senior/key personnel due to the hiring, replacement, or loss of an investigator
Adjustments resulting from natural disasters (e.g., loss of an animal colony)
Adjustments resulting from change of institution (e.g., PI moves to another university)
News of an article accepted for publication (a copy of the article should not be sent)

Unacceptable post-submission materials (for all applications except those listed under Exceptions below) include:

Updated Specific Aims or Research Strategy pages
Late-breaking research findings
New letters of support or collaboration that do not result from a change in senior/key personnel due to the hiring, replacement, or loss of an investigator

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the FDA Mission, all applications submitted to the FDA are evaluated for scientific and technical merit through an FDA review process as established by the funding component and approved through the Grants Management Office.

[For this particular announcement, note the following:]

Overall Impact - Overall

Reviewers will provide an overall impact/priority 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 - Overall

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

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)

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

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

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 clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed? []

Environment

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 - Overall

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/priority 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 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 [Human Subjects Protection and Inclusion Guidelines](#).

Inclusion of Women, Minorities, and Children

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the [Human Subjects Protection and Inclusion Guidelines](#).

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. 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

Not Applicable.

Revisions

Not Applicable.

Additional Review Considerations - Overall

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/priority score.

Applications from Foreign Organizations

Not Applicable.

Select Agent Research

Not Applicable.

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 as described in the [HHS Grants Policy Statement](#)

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) appropriate Ad Hoc Review Group in accordance with FDA Ad Hoc Review policy and procedures, using the stated [review criteria](#).

As part of the Ad Hoc Review, all applications:

- Will receive a written critique.

[Appeals](#) of initial peer review will not be accepted for applications submitted response to this FOA.

3. Anticipated Announcement and Award Dates

After the Ad Hoc Review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) electronically via e-mail. The expected start date for this award will be August 1, 2012.

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

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, FDA will request "just-in-time" information from the applicant as described in the [HHS Grants Policy Statement](#).

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 grant award issued in response to this FOA will be subject to the DUNS, CCR Registration, and Transparency Act requirements.

2. Administrative and National Policy Requirements

All FDA grant and cooperative agreement awards include the [HHS Grants Policy Statement](#) as part of the NoA.

Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable OMS administrative guidelines, HHS grant administration regulations at 45 CFR Parts 74, 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.

2. 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 program, with the FDA staff being substantially involved as a partner with the PI.

The Principal Investigator will have primary responsibility for the financial management of program funds to adhere to the mission of the program as determined by the bilateral partnership.

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

2. A.2. FDA Responsibilities

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

The program project 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, as well as, any collaborative structure between JIFSAN and any other entities.

b. FDA will be directly involved in the guidance and development of the program and the collaborative structure for the program.

c. 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 [Non-Competing Continuation Grant Progress Report \(PHS 2590\)](#) annually and financial statements as required in the [HHS Grants Policy Statement](#).

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. See the [HHS Grants Policy Statement](#) for additional information on this reporting requirement.

Section VII. Agency Contacts

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

Application Submission Contacts

GrantsInfo (Questions regarding application instructions and process, finding FDA grant resources)
Telephone 301-827-7175
Email: gladys.bohler@fda.hhs.gov

Scientific/Research Contact(s):

Elizabeth M. Calvey
Project Officer
Food and Drug Administration
Center for Food Safety and Applied Nutrition (CFSAN)
5100 Paint Branch Parkway
CPK1, Rm. 4A007, HFS 006
College Park, MD 20740
240-402-1981
elizabeth.calvey@fda.hhs.gov

Peer Review Contact(s):

Kevin W. Robinson
Extramural Resource Specialist
Food and Drug Administration
Center for Food Safety and Applied Nutrition (CFSAN)
5100 Paint Branch Parkway
College Park, MD 20740
Telephone: 240-402-2118
Kevin.robinson@fda.hhs.gov

Financial/Grants Management Contact(s)

Gladys Melendez Bohler
Grants Management Specialist
Food and Drug Administration
Division of Acquisition Support and Grants
5630 Fishers Lane, Rm. 1078, HFA 500
Rockville, MD 20857
301-827-7175
gladys.bohler@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 and 405 of the Public Health Service Act as amended (42 USC 241) and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 74.