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 Drug Evaluation and Research (CDER)
Funding Opportunity Title	**Cooperative Agreement to Support Regulatory Research Related to FDA Commitments under The 2012 Prescription Drug User Fee Act (U19)**
Activity Code	U19 Research Program – Cooperative Agreements
Announcement Type	New
Related Notices	None
Funding Opportunity Announcement (FOA) Number	**RFA-FD-13-005**
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) announces its intention to accept and consider a single source application for award to the Engelberg Center for Health Care Reform at Brookings (ECHCR). The primary objective of this effort is to provide supporting research, identify key issues, and convene appropriate subject matter experts to

	help inform major initiatives for process improvement and regulatory science related to FDA commitments under the 2012 reauthorization of the Prescription Drug User Fee Act (PDUFA V)..

Key Dates

Posted Date	
Letter of Intent Due Date(s)	Not Applicable
Application Due Date(s)	April 15, 2013
AIDS Application Due Date(s)	Not Applicable)
Scientific Merit Review	May 2013
Advisory Council Review	Not Applicable
Earliest Start Date	June 1, 2013
Expiration Date	April 16, 2013
Due Dates for E.O. 12372	Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the PHS 398 Application Guide except where instructed to do otherwise (in this FOA or in a Notice from the HHS Grants Policy Statement). 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.**

Looking ahead: FDA is committed to transitioning all grant programs to electronic submission using the SF424 Research and Related (R&R) format and is currently investigating solutions that will accommodate FDA's multi-project programs. FDA will announce plans to transition the remaining programs in the HHS Grants Policy Statement.

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

RESEARCH OBJECTIVES

The FDA Center for Drug Evaluation and Research seeks to support efforts to research, identify key issues, and convene appropriate subject matter experts to help inform major initiatives for process improvement and regulatory science related to FDA commitments under the 2012 reauthorization of the Prescription Drug User Fee Act (PDUFA V). PDUFA, first enacted in 1992, has provided FDA with the resources and process enhancements to enable a transformation of the human drug review process, increasing the quality, number and timely access to new drugs for US patients.

The 2012 reauthorization of PDUFA initiated a set of performance goals and procedures for FDA through fiscal year 2017. These performance goals represent a series of commitments which were established in consultation with drug industry representatives, patient and consumer advocates, and health care professionals. Specific PDUFA commitments include public meetings, staff training procedures, and efficiency standards on a variety of issues.

More information about FDA's commitments under PDUFA V can be found at the following website: http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf

SPECIFIC AREAS OF RESEARCH INTEREST

In the most recent reauthorization of PDUFA, FDA has committed to build on a record of continuing improvement through a wide range of new innovative initiatives related to virtually every aspect of the new drug life cycle, each of which represent specific areas of research interest. These initiatives may include, but not be limited to, the following:

- Enhancing regulatory science and expediting drug development
- Advancing meta-analysis methods
- Advancing the use of biomarkers and pharmacogenomics
- Developing and enhancing patient-eported outcomes to support patient-focused drug development
- Facilitating rare disease drug development
- Structured approaches to enhancing FDA's assessment of benefits and risks in human drugs
- Improving evaluation, standardization, and integration of REMS
- Exploring the use of Sentinel as a tool for evaluating drug safety issues
- Requiring electronic submissions and standardization of electronic application data

Several key areas of research interest are described in greater detail below:

Developing and Enhancing Patient-Reported Outcomes to support Patient-Focused Drug Development

The advancement of patient-reported outcome measures is designed to promote patient engagement throughout the drug development process. FDA has dedicated steps toward the development of these tools by expanding clinical and statistical staff capacity, providing qualification consultations, and promoting best practices for the use of outcome assessment tools. FDA seeks to identify the challenges and opportunities within the current review and qualification of PROs, to address key issues

with PRO evidentiary standards, develop new methods for communication between the multiple stakeholders involved in PROs, and identify best practices for evaluation and statistical analysis and design of PROs.

Structured Approaches to Enhancing FDA's Assessment of Benefits and Risks in Human Drugs

FDA recognizes that the agency's efforts to develop a more structured approach to benefit-risk assessment could be complemented by further engagement of stakeholders and other parties. This engagement seeks to focus on the current efforts and methods that have been applied to structure and communicate regulatory decisions, including the relevance to the work of a regulator and how well such approaches integrate with how regulators think about their decisions. FDA expects that these discussions would focus on the results of implementing frameworks at regulatory agencies both in pre-market application review as well as post-market safety review, providing an opportunity to share challenges and lessons learned in applying a more structured approach to regulatory decision-making.

Improving Evaluation, Standardization and Integration of REMS

FDA seeks stakeholder and expert feedback on approaches to standardizing of REMS and integrating them into the healthcare delivery system. Areas for research include the following:

1. A standardized methodology for selecting appropriate risk management interventions when a REMS is deemed necessary. Such a methodology should allow FDA and sponsors to proactively identify and address the underlying causes of patient harm, and evaluate and prioritize risk management interventions based on evidence of their effectiveness and burden on the healthcare delivery system.
2. Standard approaches and best practices for implementing REMS and integrating them into the existing healthcare delivery system. These approaches may include the use of improved methods for communicating with and training REMS stakeholders and the use of information technology to facilitate REMS implementation.
3. Standard methods to evaluate REMS, including methods to assess REMS effectiveness, impact on patient access, and burden on the healthcare delivery system.

APPROACH

In order to achieve these research objectives as part of its PDUFA V commitments, FDA has committed to seek input from relevant external subject matter experts and other interested public stakeholders. In addition, this input process should be conducted so as to be timely, well-informed, candid, thoughtful, thorough, and well-documented.

FDA has a limited capacity to conduct the needed research to fully inform and undertake these external expert engagements to ensure the successful accomplishment of these PDUFA V commitments. FDA is therefore seeking to establish a cooperative agreement with the Brookings Institution's Engelberg Center for Health Care Reform (ECHCR) for its unique qualifications and experience in the conduct of the needed research, workshops and other meetings, and related work.

The goal of this collaboration is to support the implementation of PDUFA V performance goals by convening stakeholders with diverse expertise. Through a series of meetings, workshops, webinars, and/or workgroups, ECHCR would provide effective opportunities for engagement of these stakeholders to inform implementation of the PDUFA V goals. In addition to gathering input from selected stakeholder groups, ECHCR may conduct background research prior to expert engagement, and to communicate updates on the progress of PDUFA implementation to broader audiences. Specific objectives of this collaboration would include:

1. Working collaboratively with FDA to identify and prioritize pressing issues related to the implementation of PDUFA reauthorization performance goals and procedures;
2. Conducting research and reviews of relevant literature to plan the focus of sessions in which experts are convened to provide critical input to FDA regulatory enhancement discussions;
3. Convening expert stakeholders in focused, substantive discussions of these issues, and identify and explore potential strategies for resolving them; and

4. Developing reports that summarize the background research and discussion at each meeting and post these reports for public access.

The timeframe of the project is five years. Implementation of PDUFA performance goals and procedures will require a multi-year effort, involving a variety of topics, stakeholder groups, and issue specific activities. We propose to establish a five-year collaboration to work concurrently with PDUFA commitment activities, in order to facilitate the successful implementation of selected performance goals.

Inherent in the cooperative agreement award is substantive involvement by the awarding agency. Accordingly, FDA will have substantive involvement in the programmatic activities funded by this Cooperative Agreement. Substantive involvement includes, but is not limited, to the following:

1. FDA will provide guidance, direction, and assistance in the identification of key research objectives.
2. Based on interactions between FDA and ECHCR, there may be changes to the proposed scope of work, including the types and frequency of meetings, research and activities to be conducted by the recipient.

See **Section VIII, Other Information - Required Federal Citations**, for policies related to this announcement

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 PHS 398 Application Guide provide details on these application types.
Funds Available and Anticipated Number of Awards	FDA CDER anticipates providing in FY2013 up to $700,000 (total costs include direct and indirect costs) for one award subject to availability of funds in support of this project. The possibility of four additional years of support up to $700,000 plus 3% of funding is contingent upon successful performance and the availability of funds.
Award Budget	The support will be one year with the possibility of an additional four years of noncompetitive support. Continuation beyond the first year will be based on satisfactory performance during the preceding year, receipt of a noncompeting continuation application and available Federal Fiscal Year appropriations. DHHS grants policies as described in the DHHS Policy Statement http://dhhs.gov/asfr/ogapa/aboutog/grantsnet.html will apply to the applications submitted and awards made in response to this FOA.

Award Project Period	Scope of the proposed project, and available funding, 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

The following organization is eligible to apply:

The Engelberg Center for Health Care Reform at Brookings (ECHCR)

Within the Brookings Institution, the mission of the Engelberg Center for Health Care Reform at Brookings (ECHCR) is to provide practical solutions to achieve high-quality, innovative, affordable health care with particular emphasis on identifying opportunities on the national, state and local levels. Leveraging its status as a neutral, non-profit, research-focused institution with deep health care policy and technical expertise, ECHCR frequently serves as a convener of discussions, workshops, and symposia on complex policy and science topics. The Center has developed a reputation as an "honest broker" with the ability to identify practical solutions that reflect the best available science and input from all stakeholders.

The performance goals and procedures outlined within PDUFA V will require a high degree of leadership, research, outreach, and involvement from a broad range of stakeholders across the health care system. ECHCR is uniquely qualified to conduct the background research and act as a convener for engaging critical stakeholders, raising awareness, and identifying practical solutions that identify and overcome potential challenges and help determine a clear path forward.

Foreign Institutions

Background policy information is available at:
http://dhhs.gov/asfr/ogapa/grantinformation/hhsgps107.pdf.

Required Registrations

Applicant organizations must complete the following registrations as described in the PHS 398 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.

- System for Award Management (SAM)– must maintain an active entity registration (formerly CCR registration), to be renewed at least annually. Use the Sam.gov "Manage Entity" function to manage your entity registrations. See the Grants Registration User Guide at SAM.gov for additional information.
- 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(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.

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 only one application, provided that each application is scientifically distinct.

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

FDA will not accept any application that is essentially the same as the 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 PHS 398 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.

Application Submission

Applications must be prepared using the PHS 398 research grant application forms and instructions for preparing a research grant application. Submit a signed, typewritten original of the application, including the checklist, and one signed photocopy in one package to:

Oluyemisi Akinneye
LT , US Public Health Service
U.S. Food and Drug Admininistration
Division of Acquisistions and Grants
5630 Fishers Lane, Room 2037, HFA 500
Rockville, MD 20857 (U.S. Postal Service Express or mail)

Page Limitations

All page limitations described in the PHS 398 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 PHS 398 Application Guide must be followed.

Resource Sharing Plan

FDA considers the sharing of unique research resources developed through FDA sponsored research an important means to enhance the value of, and advance research. When resources have been developed with FDA funds and the associated research findings published or provided to FDA, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. If the final data/resources are not amenable to sharing, this must be explained in Resource Sharing section of the application. (FDA has developed policy guidance on this subject. For information only, see Frequently Asked Questions (FAQs) on Data Sharing).

- Individuals are required to comply with the instructions for the Resource Sharing Plans (Data Sharing Plan, Sharing Model Organisms, and Genome Wide Association Studies (GWAS)) as provided in the PHS 398 Application GuideGenerally, Resource Sharing Plans (Data Sharing Plan, Sharing Model Organisms, and GWAS Sharing Plan) are expected, but they are not applicable for this FOA.

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 PHS 398 Application Guide. All paper PHS 398 applications submitted must provide appendix material on CDs only. Include two identical CDs in the same package with the application.

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 PHS 398 Application Guide.

3. Submission Dates and Times

Part I. Overview Information contains information about Key Dates.

Information on the process of receipt and determining if your application is considered “on-time” is described in detail in the PHS 398 Application Guide.

Applicants may track the status of the application in the eRA Commons, FDA’s electronic system for grants administration.

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.

6. Other Submission Requirements and Information

Applications must be postmarked on or before the due dates in Part I. Overview Information.

Upon receipt, applications will be evaluated for completeness by the FDA Grants Office and responsiveness by components of participating organizations, 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 described in NOT-OD-10-115.

Section V. Application Review Information

1. Criteria

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

For this particular announcement, note the following:

The mission of the FDA is to protect the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices, and the safety and security of our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines more effective, and medicines and foods safer and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health. As part of this mission, applications submitted to the FDA for grants or cooperative agreements to advance public health are evaluated for scientific and technical merit through the FDA review system.

Overall Impact - Overall

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

Scored Review Criteria - 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 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

For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewals

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

Revisions

For Revisions, the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific line of investigation presented in the original application that was not for recommended approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

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 score.

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) Genome Wide Association Studies (GWAS).

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 review group convened by FDA, in accordance with HHS peer review policy and procedures, using the stated review criteria.

The applicant is strongly encouraged to contact FDA to resolve any questions about criteria before submitting the application. Please direct all questions of a technical or scientific nature to the CDER Scientific/Research contact and all questions of an administrative or financial nature to the grants management staff.

As part of the review, all applications:

- Will receive a written summary statement.

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

The following will be considered in making funding decisions:

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

3. Anticipated Announcement and Award Dates

After the review of the application is completed, the PD/PI will be provided his or her Summary Statement (written critique).

Notification regarding the results of the review is anticipated within two weeks after review of the application is completed.

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. Once all administrative and programmatic issues have been resolved, the Notice of Award will be generated via email notification from the awarding component 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 the DUNS, CCR Registration, and Transparency Act requirements as noted on the Award Conditions and Information for HHS Grants website.

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 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's objective is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipient 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 awardee for the project as a whole, although specific tasks and activities may be shared between the awardee and the FDA as defined below.

The PD(s)/PI(s) will have the primary responsibility for:
The Principal Investigator/Program Director (PD/PI) 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.

Awardee 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 DHHS, PHS, and FDA policies.

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

The FDA Project Scientist will monitor the project-related activities of the grantee periodically. The monitoring may be in the form of telephone conversations, emails, or written correspondence between the Project Scientist and the PD/PI. Periodic site visits with the PD/PI and other officials of the grantee organization may also occur. The results of these monitoring activities will be recorded in the official cooperative agreement 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 FDA Project Scientist. 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.

The FDA Project Scientist 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.

In addition to the Project Scientist, an FDA Program Official will be responsible for normal stewardship of the cooperative agreement, and will be named in the Notice of Award.

Areas of Joint Responsibility include:

None

Dispute Resolution:
Any disagreements that may arise in scientific or programmatic matters (within the scope of the award) between award recipients and the FDA may be brought to Dispute Resolution. A Dispute Resolution Panel will be convened and will have three members: a designee of the Steering Committee chosen without FDA staff voting, one FDA designee, and a third designee with expertise in the relevant area who is chosen by the other two members; in the case of individual disagreement, the first member may be chosen by the individual awardee. This special dispute resolution procedure does not alter the awardee's right to appeal an adverse action that is otherwise appealable in accordance with PHS regulation 42 CFR Part 50, Subpart D and DHHS regulation 45 CFR Part 16.

3. Reporting

When multiple years are involved, awardee 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.

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 301-435-0714
TTY 301-451-5936
Email: GrantsInfo@nih.gov

eRA Commons Help Desk (Questions regarding eRA Commons registration, tracking application status, post submission issues)
Phone: 301-402-7469 or 866-504-9552 (Toll Free)
TTY: 301-451-5939

Email: commons@od.nih.gov

Scientific/Research Contact(s)

Adam Kroetsch, MSPPM
Operations Research Analyst
Office of Planning and Analysis
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
10903 New Hampshire Avenue, Building 51, Room 1192
Telephone: 301-796-3842
Email: adam.kroetsch@fda.hhs.gov

Financial/Grants Management Contact(s)

Oluyemisi Akinneye
Grants Management Specialist
U.S. Food and Drug Admininistration
Division of Acquisistions and Grants
5630 Fishers Lane, Room 2037, HFA 500
Rockville, MD 20857 (U.S. Postal Service Express or mail)

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 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Parts 74 and 92.

Required Federal Citations

1.A. Access to Research Data through the Freedom of Information Act (FOIA)
The Freedom of Information Act (FOIA), 5 U.S.C. 552, provides individuals with a right to access certain records in the possession of the Federal government, subject to certain exemptions. The government may withhold information pursuant to the exemptions and exclusions contained in the FOIA. The exact language of the exemptions can be found in the FOIA. Additional guidance on the exemptions and how they apply to certain documents can be found in the HHS regulations implementing the FOIA (45 CFR part 5) and FDA regulations implementing the FOIA (21 CFR part 20). Also, see the HHS Web site http://www.hhs.gov/foia/ and FDA Web site at http://www.fda.gov/RegulatoryInformation/FOI/default.htm
Data included in the application may be considered trade secret or confidential commercial information within the meaning of relevant statutes and implementing regulations. FDA will protect trade secret or confidential commercial information to the extent allowed under applicable law.

1.B. Standards for Privacy of Individually Identifiable Health Information
HHS issued final modification to the Standards for Privacy of Individually Identifiable Health Information, the Privacy Rule, on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information, and is administered and enforced by the HHS Office for Civil Rights (OCR).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR Web site http://www.hhs.gov/ocr/ provides information on the Privacy Rule.

1.C. Healthy People 2020

PHS is committed to achieving the health promotion and disease prevention objectives of Healthy People 2020, a PHS-led national activity for setting priority areas. This Funding Opportunity Announcement is related to one or more of the priority areas. Potential applicants may obtain a copy of Healthy People 2020 at http://www.health.gov/healthypeople.

1.D. Smoke-Free Workplace

The PHS strongly encourages all grant and cooperative agreement recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

1.E. Authority and Regulation

This program is not subject to the intergovernmental review requirements of Executive Order 12372. FDA's research program is described in the Catalog of Federal Domestic Assistance (CFDA), No. 93.103 http://www.cfda.gov/

FDA will support the clinical studies covered by this notice under the authority of section 301 of the PHS Act as amended (42 U.S.C. 241) and under applicable regulations at 42 CFR Part 52 and 45 CFR Parts 74 and 92. All grant and cooperative agreement awards are subject to applicable requirements for clinical investigations imposed by sections 505, 512, and 515 of the act (21 U.S.C. 355, or 360e) or safety, purity, and potency for licensing under section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262), section 351 of the PHS Act, including regulations issued under any of these sections.

All human subject research regulated by FDA is also subject to FDA's regulations regarding the protection of human subjects (21 CFR Parts 50 and 56). Applicants are encouraged to review the regulations, guidance, and information sheets on human subject protection and Good Clinical Practice available on the Internet at http://www.fda.gov/oc/gcp/

The applicant is referred to HHS regulations at 45 CFR 46.116 and 21 CFR 50.25 for details regarding the required elements of informed consent.

All awards will be subject to all policies and requirements that govern the research grant and cooperative agreement programs of the PHS as incorporated in the HHS Grants Policy Statement, dated January 1, 2007 http://www.hhs.gov/grantsnet/adminis/gpd/index.htm