

# Department of Health and Human Services

## Part 1. Overview Information

<b>Participating Organization(s)</b>	U.S. Food and Drug Administration ( <a href="#">FDA</a> )
<b>Components of Participating Organizations</b>	Office of Regulatory Affairs (ORA)
<b>Funding Opportunity Title</b>	<b>To Develop a Training and Mentoring Program for the Office of Regulatory Affairs</b>
<b>Activity Code</b>	U56 Cooperative Agreements Exploratory Grants
<b>Announcement Type</b>	New
<b>Related Notices</b>	None
<b>Funding Opportunity Announcement (FOA) Number</b>	<b>RFA-FY-11-003</b>
<b>Companion FOA</b>	None
<b>Number of Applications</b>	See <a href="#">Section III. 3. Additional Information on Eligibility</a>
<b>Catalog of Federal Domestic Assistance (CFDA) Number(s)</b>	93.103
<b>FOA Purpose</b>	<p>Support for a training and mentoring program to be developed and implemented to train and mentor new FDA employees/investigators working in the United States.</p> <p>This program is intended to improve the investigators professional development, and job performance to provide and improve the FDA regulations in industry, protect consumers, respond to adverse outbreaks, strengthen the Federal and States relationship, and allow the FDA to be adequately prepare for emergencies.</p> <p>This Exploratory Cooperative Agreement (U56) requires substantial Federal programmatic staff involvement in developing the skill sets of newly hired FDA field inspectors/investigators. The required activities in the U56 grant program will also be defined in the terms and conditions of award.</p>

## Key Dates

<b>Posted Date</b>	
<b>Open Date (Earliest)</b>	February 14, 2011

<b>Submission Date)</b>	
<b>Letter of Intent Due Date</b>	
<b>Application Due Date(s)</b>	May 2, 2011, by 11:59 PM local time of applicant organization
<b>AIDS Application Due Date(s)</b>	N/A
<b>Scientific Merit Review</b>	June, 2011
<b>Advisory Council Review</b>	N/A
<b>Earliest Start Date(s)</b>	August, 2011
<b>Expiration Date</b>	
<b>Due Dates for E.O. 12372</b>	Not Applicable

## Required Application Instructions

It is critical that applicants follow the instructions in the [PHS398 Application Guide](http://grants.nih.gov/grants/funding/phs398/phs398.html) (<http://grants.nih.gov/grants/funding/phs398/phs398.html> 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. 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

#### Purpose

The purpose of this funding opportunity is to assist the Office of Regulatory Affairs (ORA) in the Food and Drug Administration (FDA) by developing and implementing training and mentoring programs for FDA employees. The training and mentoring program should be designed to assist in improvements to professional development and better prepare participants to support the overall public health mission of FDA and provide important technical, managerial, and leadership experiences that will improve job performance in support of FDA's mission. Overall, these activities will improve FDA's ability to regulate industry, protect consumers, respond to outbreaks, strengthen Federal/State relationships, and allow FDA to be better prepared for emergencies. The ORA protects consumers and enhances public health by maximizing compliance of FDA regulated products and minimizing risks associated with those products.

## Research Objective

The proposed application should provide a detailed plan for initiating, improving and/or leveraging collaborative partnerships to address training and mentoring on topics that may include but are not limited to those listed below:

- Develop and maintain one-on-one mentoring relationships with current FDA employees by professionals experienced in FDA processes, activities and culture.
- Develop and implement classroom training in FDA processes, activities and culture within a broad range of technical, operational, administrative managerial, and leadership courses delivered by FDA.
- Develop specific curriculum for FDA training courses by participating in course advisory groups (CAGs).

Organizations would only be provided funding to cover travel and other operating expenses for the professionals participating in the mentoring and training activities. Organizations would not be provided funding to cover the professionals time and effort spent on these activities.

## Section II. Award Information

<b>Funding Instrument</b>	The Exploratory Cooperative Agreement (U56) supports planning for new programs etc., and includes substantial Federal programmatic staff involvement to assist, guide, coordinate, or participate in project activities.
<b>Application Types Allowed</b>	New
<b>Funds Available and Anticipated Number of Awards</b>	Approximately \$150,000 will fund up to three awards.in FY 2011.
<b>Award Budget</b>	Grants will be awarded up to \$50,000 in total costs (direct costs plus

	indirect costs) per year.
<b>Award Project Period</b>	Grant applications will be awarded with up to a five-year project period.

The FDA grants policies as described in the HHS Grants Policy Statement (HHS/GPS) will apply to the applications submitted and awards made in response to this FOA. HHS/GPS available at: <http://www.hhs.gov/grantsnet/adminis/gpd/index/htm>

## Section III. Eligibility Information

### 1. Eligible Applicants

#### Eligible Organizations

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

#### 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 \(CCR\)](https://www.bpn.gov/ccrsearch/Search.aspx) – must be renewed at least annually

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

#### Eligible Individuals (Project Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed training and mentoring as the Project 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 also 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 <http://grants.nih.gov/grants/funding/phs398/phs398.html>

### 2. Cost Sharing

This FOA does not require cost sharing.

### 3. Additional Information on Eligibility

#### Number of Applications

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

## 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

<http://grants.nih.gov/grants/funding/phs398/phs398.html>

### 2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the [PHS398 Application Guide](http://grants.nih.gov/grants/funding/phs398/phs398.html), <http://grants.nih.gov/grants/funding/phs398/phs398.html> 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 <http://grants.nih.gov/grants/funding/phs398/phs398.html>

Submit a signed, typewritten original of the application, including the checklist, and three signed photocopies in one package to:

Kimberly Pendleton  
Division of Acquisition Support and Grants  
Office of Acquisitions & Grants Service  
Food and Drug Administration  
FHSL Rm 2104, HFA-500  
5630 Fishers Lane  
Rockville MD 20857  
Telephone: (301) 827-9363  
Fax: 301-827-7101  
Email: [Kimberly.Pendleton@fda.hhs.gov](mailto:Kimberly.Pendleton@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.

<http://grants.nih.gov/grants/funding/phs398/phs398.html>

#### 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.

Information on the process of receipt and determining if your application is considered “on-time” is described in detail in the PHS398 Application Guide.

## 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 [DHHS Grants Policy Statement](#) <http://www.hhs.gov/grantsnet/adminis/gpd/index.htm>.

Pre-award costs are allowable only as described in the [DHHS Grants Policy Statement](#) <http://www.hhs.gov/grantsnet/adminis/gpd/index.htm>.

## 6. Other Submission Requirements and Information

Applications must be postmarked and 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 Office of Acquisitions and Grant Services (OAGS), and scientific and programmatic responsiveness by the FDA Program area Project Officers. Applications that are incomplete and/or nonresponsive will not be reviewed.

# Section V. Application Review Information

## 1. Criteria

Only the review criteria described below will be considered in the review process. Applications that are complete and responsive to this FOA will be evaluated for scientific and technical merit by an appropriate review group convened by the Office of Regulatory Affairs (ORA), Office of Resource Management using the criteria stated below.

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 ORA program staff and all questions of an administrative or financial nature to the grants management staff.

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 training and mentoring 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 planned project address an important problem or a critical barrier to progress in training and mentoring? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or public health be improved regarding the FDA regulations in industry to protect

consumers, response to adverse outbreaks, strengthen the Federal and States relationship, and allow the FDA to be adequately prepared for emergencies?

### **Investigator(s)**

Are the PD/PIs, collaborators, and other researchers well suited to the project? 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?

### **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? In the early stages of development, will the strategy establish feasibility and manageability?

### **Environment**

Will the working environment contribute to the probability of success? Are the institutional support physical resources available to the investigators adequate for the project proposed?

## **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.

### **Budget and Period of Support**

Reviewers will consider whether the proposed budget and the requested project period of support are fully justified and reasonable in relation to the proposed training and mentoring program.

## **2. Review and Selection Process**

- Applications submitted in response to the FOA 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 merit of the proposed project as determined by peer review.
  - Availability of Funds.
  - Relevance of the proposed project to program priorities.

## **3. Anticipated Announcement and Award Dates**

After the peer review of the application is completed, the PD/PI will receive a copy of a Summary Statement (written critique) via e-mail.

# **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 [DHHS Grants Policy Statement](#)

<http://www.hhs.gov/grantsnet/adminis/gpd/index.htm>.

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 business official.

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 (see Section IV - funding restrictions)

## **2. Administrative and National Policy Requirements**

All FDA grant and cooperative agreement awards include the DHHS Grants Policy Statement as part of the Notice of Award (NoA). For these terms of award, see the DHHS Grants Policy Statement

<http://www.hhs.gov/grantsnet/adminis/gpd/index.htm>

The following Terms and Conditions will be incorporated into the award statement and will be provided to the Principal Investigator as well as to the appropriate institutional official, at the time 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 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 in the 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 FDA as defined below.

#### **2. A.1. Principal Investigator Rights and Responsibilities**

The PD(s)/PI(s) will have the primary responsibility for the scientific, technical, and programmatic aspects of the grant and for day-to-day management of the project or program. The PD/PI(s) will maintain general oversight for ensuring compliance with the financial and administrative aspects of the award, as well as ensuring that all staff has sufficient clearance and/or background checks to work on this project or program. This individual will work closely with designated officials within the recipient organization to create and maintain necessary documentation, including both technical and administrative reports; prepare justifications; appropriately acknowledge Federal support in publications, announcements, news programs, and other media; and ensure compliance with other Federal and organizational requirements.

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 DHHS, 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, FDA will have prior approval of the appointment of all key administrative and scientific personnel proposed by the grantee.

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

#### 2.A.3. Collaborative Responsibilities

Collaboration will include data analysis, interpretation of findings and, where appropriate, co-authorship of publications.

#### 2.A.4. Dispute Resolution Process

The awardee maintains the 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 Requirements

All new and continuing grants must comply with all regulatory requirements.

When multiple years are involved, awardees are required to submit the [Non-Competing Continuation Grant Progress Report \(PHS 2590\)](http://grants.nih.gov/grants/funding/2590/2590.htm) at <http://grants.nih.gov/grants/funding/2590/2590.htm> annually, and financial statements as required in the HHS Grants Policy Statement <http://www.hhs.gov/grantsnet/adminis/gpd/index.htm>

Also, a listing, and a justification for any study changes that occurred in the past year must be included in the Non-Competing Continuation Grant Progress Activity Report (PHS 2590) see above.

At the end of a grant's project period, the grantee must submit the following three requirements: 1) A final progress activity report; 2) a final Financial Report, and 3) an invention statement within 90 days after the end date of the project period as noted on the notice of grant award.

These requirements are also applicable when an award is relinquished prior to the grant's end of project period, when a recipient changes institutions, or when an award is terminated for cause.

## Section VII. Agency Contacts

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

#### 1. Scientific/Project Officer Contact(s):

Richard Garwood

Food and Drug Administration

Office of Regulatory Affairs, Office of Resource Management

5600 Fishers Lane, Room 13-45

Rockville, MD 20857

Phone: 301-796-4363

Fax: 301-443-7270

Email: [Richard.Garwood@fda.hhs.gov](mailto:Richard.Garwood@fda.hhs.gov)

#### 2. Financial/Grants Management Contact(s):

Kimberly Pendleton  
Division of Acquisition Support and Grants  
Office of Acquisitions & Grants Service  
Food and Drug Administration  
FHSL Rm 2104, HFA-500  
5630 Fishers Lane  
Rockville MD 20857  
Telephone: (301) 827-9363  
Fax: 301-827-7101  
Email: [Kimberly.Pendleton@fda.hhs.gov](mailto:Kimberly.Pendleton@fda.hhs.gov)

## Section VIII. Other Information

### 1. 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. Healthy People 2010

PHS is committed to achieving the health promotion and disease prevention objectives of Healthy People 2010, 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 2010 at <http://www.health.gov/healthypeople>.

#### 1.C. Smoke-Free Workplace

The PHS strongly encourages all grant 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.D. Authority and Regulation

This program is described in the Catalog of Federal Domestic Assistance at <http://www.cfda.gov/> and is not subject to the intergovernmental review requirements of Executive Order 12372. 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 74. All awards are subject to the terms and conditions, cost principles, and other considerations described in the [DHHS Grants Policy Statement](#) <http://www.hhs.gov/grantsnet/adminis/gpd/index.htm>.