

RFA (SF424 RR)

Template Date: February 2, 2010

Part I Overview Information

Department of Health and Human Services

Issuing Organization

Food and Drug Administration <http://inside.fda.gov:9003/>

Participating Organizations

Office of the Chief Scientist, Office of Critical Path Programs

Components of Participating Organizations

N/A

Title: Scientific Priorities to Improve the Diagnosis, Treatment and Prevention of Tuberculosis and other Tropical Diseases.

Announcement Type

New

Request for Applications (RFA) Number: RFA-FD-10-016

NOTICE: Applications submitted in response to this Funding Opportunity Announcement (FOA) for Federal assistance must be submitted electronically through Grants.gov (<http://www.grants.gov>) using the SF424 Research and Related (R&R) forms and the SF424 (R&R) Application Guide.

APPLICATIONS MAY NOT BE SUBMITTED IN PAPER FORMAT.

This FOA must be read in conjunction with the application guidelines included with this announcement in [Grants.gov/Apply for Grants](http://Grants.gov/Apply%20for%20Grants) (hereafter called Grants.gov/Apply).

A registration process is necessary before submission and applicants are highly encouraged to start the process at least four (4) weeks prior to the grant submission date. See [Section IV](#).

Catalog of Federal Domestic Assistance Number(s)

93.103

Key Dates Release/Posted Date:

Opening Date: July 12, 2010 (Earliest date an application may be submitted to Grants.gov)

Letters of Intent Receipt Date(s): N/A

NOTE: On-time submission requires that applications be successfully submitted to Grants.gov no later than 5:00 p.m. local time (of the applicant institution/organization).

Application Due Date(s): August 11, 2010

AIDS Application Due Date(s): N/A

Peer Review Date(s): August 2010

Council Review Date(s): September 7-9, 2010

Earliest Anticipated Start Date(s): September, 2010

Additional Information To Be Available Date (Activation Date): Not Applicable

Expiration Date: August 12, 2010

Due Dates for E.O. 12372

Not Applicable

Additional Overview Content

Executive Summary

Purpose. The Office of Critical Path Programs at FDA is soliciting grant proposals for programs to expedite the development of products used in the diagnosis, treatment and prevention of tuberculosis and other tropical diseases as defined in section 524(a)(3) of the Federal Food, Drug and Cosmetic act.

The intent is to fund proposals for the development and the running of collaborative partnerships involving a range of stakeholders for the purposes of (1) identifying, prioritizing and addressing gaps in the science infrastructure needed to improve treatments for TB and other tropical diseases, and (2) developing and implementing a sustainable model for continued collaborative funding. Parties eligible for this grant are listed in section 566 of the FD&C act which describes Critical Path public private partnerships. They include institutions of higher education (as such term is defined in section 101 of the Higher Education Act of 1965 [20 USC § 1001]) or consortia of such institutions; or organizations described in section 501(c)(3) of the Internal Revenue Code of 1986 [26 USC § 501(c)(3)] and exempt from tax under section 501(a) of such Code [26 USC § 501(a)].

- **Mechanism of Support.** This FOA will utilize the Cooperative Agreement (U18) award mechanism.
- **Funds Available and Anticipated Number of Awards.** For this funding opportunity, budgets up to \$2,000,000 per year and time periods up to 3 years may be requested. Future recommended support for this project will be dependent on the research project progress, FDA Project Officer, and the Chief, Grants Management Officer recommendations, as well as the availability of funding.
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- **Budget and Project Period.** For this funding opportunity, budgets up to \$ \$2,000,000 per year and time periods up to 3 years may be requested, starting no later than September 2010 for the first year.
- **Application Research Strategy Length:** The U18 Research Strategy section may not exceed 12 pages, including tables, graphs, figures, diagrams, and charts. See http://grants1.nih.gov/grants/funding/funding_program.htm.

- **Eligible Institutions/Organizations.** Institutions/organizations listed in [Section III, 1.A.](#) are eligible to apply.
- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/ 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 NIH support.
- **Number of PDs/PIs.** More than one PD/PI (i.e., multiple PDs/PIs) may be designated on the application.
- **Number of Applications.** Applicants may submit more than one application, provided each application is scientifically distinct.
- **Resubmissions.** Resubmission applications are not permitted in response to this FOA.
- **Renewals.** Renewal applications are not permitted in response to this FOA.
- **Special Date(s).** This FOA uses non-standard due dates. See [Receipt, Review and Anticipated Start Dates.](#)
- **Application Materials.** See [Section IV.1](#) for application materials.
- **General Information.** For general information on SF424 (R&R) Application and Electronic Submission, see these Web sites:
 - o SF424 (R&R) Application and Electronic Submission Information: <http://grants.nih.gov/grants/funding/424/index.htm>
 - o General information on Electronic Submission of Grant Applications: <http://era.nih.gov/ElectronicReceipt/>
- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY: (301) 451-5936

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Part II - Full Text of Announcement

Section I. Funding Opportunity Description

1. Research Objectives

The Office of Critical Path Programs at FDA is soliciting grant proposals for programs to expedite the development of products used in the diagnosis, treatment and prevention of tuberculosis and other tropical diseases as defined in section 524(a)(3) of the Federal Food, Drug and Cosmetic act.

The intent is to fund proposals for the developments and the running of collaborative partnerships involving a range of stakeholders for the purposes of (1) identifying, prioritizing and addressing gaps in the science and infrastructure needed to improve the diagnosis, treatment and prevention of TB and/or other tropical diseases as defined in section 524(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360n(a)(3)) and (2) developing and implementing a sustainable model for continued collaborative funding. Parties eligible for this grant are listed in section 566 of the FD&C act which describes Critical Path public private partnerships. They include institutions of higher education (as such term is defined in section 101 of the Higher Education Act of 1965 [20 USC § 1001]) or consortia of such institutions; or organizations

described in section 501(c)(3) of the Internal Revenue Code of 1986 [26 USC § 501(c)(3)] and exempt from tax under section 501(a) of such Code [26 USC § 501(a)].

Proposals should provide a detailed plan for a collaborative partnership to address topics that may include but are not limited to those listed below. Proposals should include a list of collaborators and their roles, as well as a proposed plan for developing additional funding mechanisms, such as consortia, to provide financial or in-kind support for the implementation of work streams identified in the proposal. Letters from collaborators describing their roles should be included. Projects may support the development of single product or products used in combination regimens.

1. Bridging the gap between discovery of new compounds and the testing of those compounds in man

In many cases promising compounds for tuberculosis or tropical diseases are not viewed as profitable by industry, and clinical development has not occurred. There is currently a need for organizations to support the generation of *in vitro* and animal data, as well as other scientific approaches to facilitate entry of candidate products into human clinical trials.

This effort involves planning, facilitation, and summary services for a program to address the “gap” between the discovery of compounds that are active *in vitro* against *M tuberculosis* or tropical diseases, and the testing of these compounds in man for the treatment of tuberculosis or tropical diseases. Proposals are requested to develop and/or facilitate programs for nonclinical evaluation of toxicologic, pharmacologic, microbiologic (and immunologic in cases of vaccines) properties of newly discovered compounds and/or vaccines with potential activity in the treatment and prevention of tuberculosis or tropical diseases. Applicants should consider addressing the funding of such a program, the collaboration of stakeholders in the drug discovery and drug development industries and practical strategies for initial exploration of the metabolic, toxicologic and microbiologic potential of newly discovered compounds.

2. Alternative uses of existing products

Several products approved for diseases other than TB or tropical diseases have potential value in the treatment of TB or tropical diseases and in some instances are already used off label for these indications. However, there is no financial incentive for sponsors to pursue FDA approval for these indications. Proposals should address the development, funding and implementation of strategies to license existing products with potential activity against *Mycobacterium tuberculosis* or other tropical diseases for these indications. Steps in this program might include a review of candidate products, an assessment of the current state of knowledge and a “gap” analysis, development of collaboration with appropriate stakeholders to fund needed clinical studies and sponsorship of a marketing application.

3. Biomarkers for global vaccine programs

A significant challenge to the development of new TB or tropical disease vaccines is the absence of reliable immunological biomarkers for protective efficacy. This program

would involve 1) a review and evaluation of promising biomarkers for vaccine efficacy that already exist or are in development, 2) an assessment of the needs for such biomarkers, and 3) the formation of collaboration with stakeholders to fund and manage the discovery, standardization and validation of such biomarkers. The program would address clinical trials and clinical specimens needed to validate new biomarkers.

4. Capacity building for clinical studies of TB and tropical diseases

These diseases are typically most prevalent in the developing world where infrastructure for the conduct of clinical research is lacking. Programs to build capacity in such sites may include:

- *The development of an open source electronic case report form (eCRF) for investigators involved in studies in resource poor settings.* The case report form should use newly published CDISC/HL7 tuberculosis domain data standards and associated terminology. The CRF should address inter-operability with open source clinical trial electronic Case Report Forms that are being developed and utilized in resource poor locations. Applicants may consider addressing novel technologies for data transfer, e.g. satellite communications and/or cell phones.
- *Training in laboratory skills needed to support the conduct of high quality clinical trials.* Lack of laboratory infrastructure is an important limitation to the conduct of clinical trials at sites in resource poor settings. A training program would be developed to assist such sites in developing the needed laboratory services to support a clinical trial in tuberculosis/ or other tropical diseases according to standards acceptable to the US Food and Drug Administration. The program would consider optimal delivery of such training either at a central facility, web based training or on site training. An appropriate collaboration of stakeholders would address the needs of such a program, the practical implementation, funding and sustainability.

5. Development of diagnostics

A public workshop on TB diagnostics hosted by FDA, CDC and NIH will be held in June 2010. Proposals are requested to extend the results of that workshop for the development and evaluation of

- diagnostic biomarkers that will be reliable surrogates for determination of relapse-free cures and prediction of relapse in TB clinical trials
- new rapid and reliable diagnostic tests for tuberculosis and for drug resistance which are practical for use in resource poor settings.

6. Combination therapy for tuberculosis

This program will address *in vitro* and *in vivo* approaches to the selection of the most effective combination drug regimens for the treatment of drug-susceptible and/or drug-resistant TB. The program will explore technologies and models to determine the most appropriate combinations of drugs and the required durations of therapy.

Timelines should be provided for milestones in each project. Intermediate and final goals should be clearly identified in the program description. Applicants should be able to describe specific

short, medium and long term outcomes of public health relevance that will be reported as the program progresses.

It is expected that FDA will participate in the design of programs involving collaborative partnerships that may be formed as a result of this funding, and will provide oversight of the funded programs.

See [Section VIII, Other Information - Required Federal Citations](#), for policies related to this announcement.

Section II. Award Information

1. Mechanism of Support

This FOA will use the Cooperative Agreement (U18) award mechanism. The Project Director/Principal Investigator (PD/PI) will be solely responsible for planning, directing, and executing the proposed project.

This FOA uses “Just-in-Time” information concepts (see [SF424 \(R&R\) Application Guide](#)). It also uses the modular as well as the non-modular budget formats (see <http://grants.nih.gov/grants/funding/modular/modular.htm>).

U.S. applicants requesting more than \$250,000 in annual direct costs and all foreign applicants must complete and submit budget requests using the Research & Related Budget component.

This funding opportunity will use an FDA cooperative agreement award mechanism. In the cooperative agreement mechanism, the PD(s)/PI(s) retain(s) the primary responsibility and dominant role for planning, directing, and executing the proposed project, with FDA staff being substantially involved as a partner with the PD(s)/PI(s), as described under the [Section VI. 2. Administrative Requirements](#), "Cooperative Agreement Terms and Conditions of Award".

2. Funds Available

For this funding opportunity budgets up to \$2,000,000 per year can be requested for a time period up to 3 years. More than one application will be considered depending on the availability of funds.

Applications will be evaluated based on factors such as public health impact, track record, expertise, practicality of real results, engagement of appropriate collaborators, scientific soundness, originality, and lack of duplication.

Facilities and Administrative (F&A) costs requested by consortium participants are included in the direct cost limitation.

FDA grants policies as described in the [DHHS Policy Statement](#) <http://www.hhs.gov/grantsnet/adminis/gpd/index.htm> will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

1.A. Eligible Institutions

The following organizations/institutions are eligible to apply:

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education
- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- 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)
- Small Businesses
- For-Profit Organizations (Other than Small Businesses)
- State Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribally Designated Organizations
- County Governments
- City or Township Governments
- Special District Governments
- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- U.S. Territory or Possession
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- Regional Organizations
- Non-domestic (non-U.S.) Entities (Foreign Organizations)
- Other(s): (Specify as appropriate from the list below)
- Eligible Agencies of the Federal Government
- Faith-based or Community-based Organizations

1.B. Eligible Individuals

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the 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.

More than one PD/PI (i.e., multiple PDs/Pis), may be designated on the application for projects that require a “team science” approach and therefore clearly do not fit the single-PD/PI model. Additional information on the implementation plans and policies and procedures to formally allow more than one PD/PI on individual research projects is available at http://grants.nih.gov/grants/multi_pi. All PDs/Pis must

be registered in the NIH electronic Research Administration (eRA) Commons prior to the submission of the application (see <http://era.nih.gov/ElectronicReceipt/preparing.htm> for instructions).

The decision of whether to apply for a grant with a single PD/PI or multiple PDs/PIs is the responsibility of the investigators and applicant organizations and should be determined by the scientific goals of the project. Applications for grants with multiple PDs/PIs will require additional information, as outlined in the instructions below. When considering the multiple PD/PI option, please be aware that the structure and governance of the PD/PI leadership team as well as the knowledge, skills and experience of the individual PDs/PIs will be factored into the assessment of the overall scientific merit of the application. Multiple PDs/PIs on a project share the authority and responsibility for leading and directing the project, intellectually and logistically. Each PD/PI is responsible and accountable to the grantee organization, or, as appropriate, to a collaborating organization, for the proper conduct of the project or program, including the submission of required reports. For further information on multiple PDs/PIs, please see http://grants.nih.gov/grants/multi_pi.

2. Cost Sharing or Matching

This program does not require cost sharing as defined in the current [DHHS Grants Policy Statement](http://www.hhs.gov/grantsnet/adminis/gpd/index.htm) <http://www.hhs.gov/grantsnet/adminis/gpd/index.htm>.

3. Other-Special Eligibility Criteria

Number of Applications. Applicants may submit more than one application, provided each application is scientifically distinct.

Resubmissions. Resubmission applications are not permitted in response to this FOA.

Renewals. Renewal applications are not permitted in response to this FOA.

Section IV. Application and Submission Information

To download a SF424 (R&R) Application Package and SF424 (R&R) Application Guide for completing the SF424 (R&R) forms for this FOA, use the "Apply for Grant Electronically" button in this FOA or link to <http://www.grants.gov/Apply/> and follow the directions provided on that Web site.

Registration:

Appropriate registrations with Grants.gov and eRA Commons must be completed on or before the due date in order to successfully submit an application. **Several of the steps of the registration process could take four weeks or more.** Therefore, applicants should immediately check with their business official to determine whether their organization/institution is already registered with both [Grants.gov](http://www.grants.gov) and the [Commons](http://era.nih.gov). All registrations must be complete by the submission deadline for the application to be considered "on-time" (see 3.C.1 for more information about on-time submission).

A one-time registration is required for institutions/organizations at both:

- Grants.gov (http://www.grants.gov/applicants/get_registered.jsp) and
- eRA Commons (<http://era.nih.gov/ElectronicReceipt/preparing.htm>)

PDs/PIs should work with their institutions/organizations to make sure they are registered in the NIH eRA Commons.

Several additional separate actions are required before an applicant can submit an electronic application, as follows:

1) [Organizational/Institutional Registration in Grants.gov/Get Registered](#)

- Your organization will need to obtain a [Data Universal Number System \(DUNS\) number](#) and register with the [Central Contractor Registration \(CCR\)](#) as part of the Grants.gov registration process.
- If your organization does not have a Taxpayer Identification Number (TIN) or Employer Identification Number (EIN), allow for extra time. A valid TIN or EIN is necessary for CCR registration.
- The CCR also validates the EIN against Internal Revenue Service records, a step that will take an additional one to two business days.
- Direct questions regarding Grants.gov registration to:
[Grants.gov Customer Support](#)
Contact Center Phone: 800-518-4726
Business Hours: M-F 7:00 a.m. - 9:00 p.m. Eastern Time
Email support@grants.gov

2) [Organizational/Institutional Registration in the eRA Commons](#)

- To find out if an organization is already Commons-registered, see the "[List of Grantee Organizations Registered in NIH eRA Commons.](#)"
- Direct questions regarding the Commons registration to:
eRA Commons Help Desk
Phone: 301-402-7469 or 866-504-9552 (Toll Free)
TTY: 301-451-5939
Business hours M-F 7:00 a.m. – 8:00 p.m. Eastern Time
Email commons@od.nih.gov

3) Project Director/Principal Investigator (PD/PI) Registration in the NIH eRA Commons: Refer to the [NIH eRA Commons System \(COM\) Users Guide](#).

- The individual(s) designated as PDs/PIs on the application must be registered also in the NIH eRA Commons. In the case of multiple PDs/PIs, all PDs/PIs must be registered **and be assigned the PI role** in the eRA Commons prior to the submission of the application.
- Each PD/PI must hold a PD/PI account in the Commons. Applicants should not share a Commons account for both an Authorized Organization Representative/Signing Official (AOR/SO) role and a PD/PI role; however, if they have both a PD/PI role and an NIH Internet Assisted Review (IAR) role, both roles should exist under one Commons account.
- When multiple PDs/PIs are proposed, all PDs/PIs at the applicant organization must be affiliated with that organization. PDs/PIs located at another institution need not be affiliated with the applicant organization, but must be affiliated with their own organization to be able to access the Commons.
- This registration/affiliation must be done by the AOR/SO or his/her designee who is already registered in the Commons.

Both the PDs/PI(s) and AOR/SO need separate accounts in the NIH eRA Commons since both are authorized to view the application image.

Note: The registration process is not sequential. Applicants should begin the registration processes for both Grants.gov and eRA Commons as soon as their organization has obtained a DUNS number. Only one DUNS number is required and the same DUNS number must be referenced when completing Grants.gov registration, eRA Commons registration and the SF424 (R&R) forms.

1. Request Application Information

Applicants must download the SF424 (R&R) application forms and the SF424 (R&R) Application Guide for this FOA through [Grants.gov/Apply](https://grants.gov/apply).

- Note: Only the forms package directly attached to a specific FOA can be used. You will not be able to use any other SF424 (R&R) forms (e.g., sample forms, forms from another FOA), although some of the "Attachment" files may be useable for more than one FOA.

For further assistance, contact GrantsInfo -- Telephone 301-435-0714; Email: GrantsInfo@nih.gov.

Telecommunications for the hearing impaired: TTY: (301) 451-5936

2. Content and Form of Application Submission

Prepare all applications using the SF424 (R&R) application forms for this FOA through [Grants.gov/Apply](https://grants.gov/apply) and in accordance with the SF424 (R&R) Application Guide (<http://grants.nih.gov/grants/funding/424/index.htm>).

The SF424 (R&R) Application Guide is critical to submitting a complete and accurate application to FDA. Some fields within the SF424 (R&R) application components, although not marked as mandatory, are required by NIH (e.g., the "Credential" log-in field of the "Research & Related Senior/Key Person Profile" component must contain the PD/PI's assigned eRA Commons User ID). Agency-specific instructions for such fields are clearly identified in the Application Guide. For additional information, see "Frequently Asked Questions – Application Guide, [Electronic Submission of Grant Applications](#)."

The SF424 (R&R) application has several components. Some components are required, others are optional. The forms package associated with this FOA in [Grants.gov/APPLY](https://grants.gov/apply) includes all applicable components, required and optional. A completed application in response to this FOA includes the data in the following components:

Required Components:

SF424 (R&R) (Cover component)
Research & Related Project/Performance Site Locations
Research & Related Other Project Information
Research & Related Senior/Key Person
PHS398 Cover Page Supplement
PHS398 Research Plan
PHS398 Checklist
PHS398 Non-Modular Budget or Research & Related Budget, as appropriate
(See Section IV.6 regarding appropriate required budget component.)
Research & Related Subaward Budget Attachment(s) Form

Optional Components:

PHS398 Cover Letter File

Foreign Organizations (Non-Domestic [non-U.S.] Entities)

FDA policies concerning grants to Foreign (non-U.S.) organizations can be found in the *DHHS Grants Policy Statement* at: DHHS Grants Policy Statement <http://www.hhs.gov/grantsnet/adminis/gpd/index.htm>

Applications from Foreign organizations must:

- Request budgets in U.S. dollars;
- Prepare detailed budgets for all applications (that is, complete the Research & Related Budget component of the SF424 (R&R) application forms – not the PHS398 Modular Budget component)(see [NOT-OD-06-096](#));
- Not include any charge-back of customs and import fees;
- Comply with the format specifications, which are based upon a standard U.S. paper size of 8.5” x 11” within each PDF;
- If appropriate, request funds for up to 8% administrative costs (excluding equipment) (see [NOT-OD-01-028](#), March 29, 2001);
- Comply with Federal/NIH policies on human subjects, animals, and biohazards; and
- Comply with Federal/NIH biosafety and biosecurity regulations (see [Section VI.2.](#), “Administrative and National Policy Requirements”).

Proposed research should provide special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions in other countries that are not readily available in the United States (U.S.) or that augment existing U.S. resources.

SPECIAL INSTRUCTIONS

Applications with Multiple PDs/PIs

When multiple PDs/PIs are proposed, FDA requires one PD/PI to be designated as the "Contact" PI, who will be responsible for all communication between the PDs/PIs and the FDA, for assembling the application materials outlined below, and for coordinating progress reports for the project. The contact PD/PI must meet all eligibility requirements for PD/PI status in the same way as other PDs/PIs, but has no other special roles or responsibilities within the project team beyond those mentioned above.

Information for the Contact PD/PI should be entered on the SF424 (R&R) Cover component. All other PDs/PIs should be listed in the Research & Related Senior/Key Person component and assigned the project role of "PD/PI." Please remember that all PDs/PIs must be registered in the eRA Commons prior to application submission. **The Commons ID of each PD/PI must be included in the "Credential" field of the Research & Related Senior/Key Person component. Failure to include this data field will cause the application to be rejected.**

Multiple PD/PI Leadership Plan: For applications designating multiple PDs/PIs, the Research Plan section and the "Multiple PD/PI Leadership Plan", must be included. A rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure of the leadership team and the research project should be described, and should include communication plans, process for making decisions on scientific direction, and procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PDs/PIs and other collaborators.

If budget allocation is planned, the distribution of resources to specific components of the project or the individual PDs/PIs should be delineated in the Leadership Plan. In the event of an award, the requested allocations may be reflected in a footnote on the Notice of Award (NoA).

Applications Involving a Single Institution

When all PDs/PIs are within a single institution, follow the instructions contained in the SF424 (R&R) Application Guide.

Applications Involving Multiple Institutions

When multiple institutions are involved, one institution must be designated as the prime institution and funding for the other institution(s) must be requested via a subcontract to be administered by the prime institution. When submitting a detailed budget, the prime institution should submit its budget using the Research & Related Budget component. All other institutions should have their individual budgets attached separately to the Research & Related Subaward Budget Attachment(s) Form. See Section 4.8 of the SF424 (R&R) Application Guide for further instruction regarding the use of the subaward budget form.

When submitting a modular budget, the prime institution completes the PHS398 Modular Budget component only. Information concerning the consortium/subcontract budget is provided in the budget justification. Separate budgets for each consortium/subcontract grantee are not required when using the Modular budget format. See Section 5.4 of the Application Guide for further instruction regarding the use of the PHS398 Modular Budget component.

3. Submission Dates and Times

See [Section IV.3.A.](#) for details.

3.A. Submission, Review, and Anticipated Start Dates

Opening Date: July 12, 2010 (Earliest date an application may be submitted to Grants.gov)

Letters of Intent Receipt Date(s): N/A.

Application Due Date(s): August 11, 2010

Peer Review Date(s): August, 2010

Council Review Date(s): September 7-9, 2010

Earliest Anticipated Start Date(s): September, 2010

3.A.1. Letter of Intent

A letter of intent is not required for the funding opportunity.

3.B. Submitting an Application Electronically to the FDA

To submit an application in response to this FOA, applicants should access this FOA via http://www.grants.gov/applicants/apply_for_grants.jsp and follow Steps 1-4. Note: Applications must only be submitted electronically. **PAPER APPLICATIONS WILL NOT BE ACCEPTED.** All attachments must be provided to NIH in PDF format, filenames must be included with no spaces or special characters, and a .pdf extension must be used.

In order to expedite the review, applicants are requested to notify the (FDA) Office of Critical Path Programs by email Carrie.Bryant@fda.hhs.gov when the application has been submitted. Please include the FOA number and title, PD/PI name, and title of the application.

3.C. Application Processing

3.C.1 Submitting On-Time

Applications **may** be submitted on or after the opening date and **must** be successfully received by Grants.gov no later than **5:00 p.m. local time** (of the applicant institution/organization) on the application due date(s). (See [Section IV.3.A.](#) for all dates.) If an application is not submitted by the due date(s) and time, the application may be delayed in the review process or not reviewed. All applications must meet the following criteria to be considered “on-time”:

- All registrations must be complete prior to the submission deadline
- The application must receive a Grants.gov tracking number and timestamp (or eRA help desk ticket confirming a system issue preventing submission) by 5:00 p.m. local time on the submission deadline date.
- Any system identified errors/warnings must be corrected and the submission process completed within the “error correction window.”

Please visit http://era.nih.gov/electronicReceipt/app_help.htm for detailed information on what to do if Grants.gov or eRA system issues threaten your ability to submit on time.

Submission to Grants.gov is not the last step – applicants must follow their application through to the eRA Commons to check for errors and warnings and view their assembled application!

3.C.2 Two Day Window to Correct eRA Identified Errors/Warnings

Once an application package has been successfully submitted through Grants.gov, NIH provides applicants a two day *error correction window* to correct any eRA identified errors or warnings before a final assembled application is created in the eRA Commons. The standard error correction window is two (2) business days, beginning the day after the submission deadline and excluding weekends and standard federal holidays. All errors must be corrected to successfully complete the submission process. Warnings will not prevent the application from completing the submission process.

Please note that the following caveats apply:

- Initial application submission must be “on-time.”
- The AOR/institutions is expected to enforce that application changes made within the error correction window are restricted to those necessary to address system-identified errors/warnings. NIH may reject any application that includes additional changes.
- Proof of “on-time” submission (e.g., Grants.gov timestamp and tracking number) and description of all changes made within the window must be documented in the PHS 398 Cover Letter component of the application.

3.C.3 Viewing an Application in the eRA Commons

Once any eRA identified errors have been addressed and the assembled application has been created in the eRA Commons, the PD/PI and the Authorized Organization Representative/Signing Official (AOR/SO) have two weekdays (Monday – Friday, excluding Federal holidays) to view the assembled application before it automatically moves forward to [FDA](#) for further processing.

- If everything is acceptable, no further action is necessary. The application will automatically move forward to the Division of Receipt and Referral in the Center for Scientific Review for processing after two weekdays, excluding Federal holidays.
- Prior to the submission deadline, the AOR/SO can “Reject” the assembled application and submit a changed/corrected application within the two-day viewing window. This option should be used if it is determined that some part of the application was lost or did not transfer correctly during the submission process, the AOR/SO will have the option to “Reject” the application and submit a Changed/Corrected application. In these cases, please contact the eRA Help Desk to ensure that the issues are addressed and corrected. Once rejected, applicants should follow the instructions for correcting errors in Section 2.12 of the SF 424 (R&R) application guide,

including the requirement for cover letters on late applications. The “Reject” feature should also be used if you determine that warnings are applicable to your application and need to be addressed now. Remember, warnings do not stop further application processing. If an application submission results in warnings (but no errors), it will automatically move forward after two weekdays if no action is taken. Some warnings may need to be addressed later in the process.

- If the two-day window falls after the submission deadline, the AOR/SO will have the option to “Reject” the application if, **due to an eRA Commons or Grants.gov system issue**, the application does not correctly reflect the submitted application package (e.g., some part of the application was lost or didn’t transfer correctly during the submission process). The AOR/SO should first contact the [eRA Commons Helpdesk](#) to confirm the system error, document the issue, and determine the best course of action. NIH will not penalize the applicant for an eRA Commons or Grants.gov system issue.
- If the AOR/SO chooses to “Reject” the image after the submission deadline for a reason other than an eRA Commons or Grants.gov system failure, a changed/corrected application still can be submitted, but it will be subject to the [NIH late policy](#) guidelines and may not be accepted. The reason for this delay should be explained in the cover letter attachment.
- Both the AOR/SO and PD/PI will receive e-mail notifications when the application is rejected or the application automatically moves forward in the process after two weekdays.

Upon receipt, applications will be evaluated for completeness by the Project Officer and responsiveness by the Grants Management Contact. Incomplete and/or non-responsive applications will not be reviewed.

There will be an acknowledgement of receipt of applications from Grants.gov and the [Commons](#). The submitting AOR/SO receives the Grants.gov acknowledgments. The AOR/SO and the PI receive Commons acknowledgments. Information related to the assignment of an application to a Scientific Review Group is also in the Commons.

Note: Since email can be unreliable, it is the responsibility of the applicant to check periodically on the application status in the Commons.

The FDA will not accept any application in response to this funding opportunity that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. However, when a previously unfunded application, originally submitted as an investigator-initiated application, is to be submitted in response to a funding opportunity, it is to be prepared as a NEW application. That is, the application for the funding opportunity must not include an “Introduction” describing the changes and improvements made, and the text must not be marked to indicate the changes from the previous unfunded version of the application.

4. Intergovernmental Review

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 DHHS Grants Policy Statement <http://www.hhs.gov/grantsnet/adminis/gpd/index.htm>.

Pre-award costs are allowable. A grantee may, at its own risk and without FDA prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new or renewal award if such costs: 1) are necessary to conduct the project, and 2) would be allowable under the grant, if awarded, without FDA prior approval. If specific expenditures would

otherwise require prior approval, the grantee must obtain FDA approval before incurring the cost. FDA prior approval is required for any costs to be incurred more than 90 days before the beginning date of the initial budget period of a new or renewal award.

The incurrence of pre-award costs in anticipation of a competing or non-competing award imposes no obligation on FDA either to make the award or to increase the amount of the approved budget if an award is made for less than the amount anticipated and is inadequate to cover the pre-award costs incurred. FDA expects the grantee to be fully aware that pre-award costs result in borrowing against future support and that such borrowing must not impair the grantee's ability to accomplish the project objectives in the approved time frame or in any way adversely affect the conduct of the project (see the [DHHS Grants Policy Statement](http://www.hhs.gov/grantsnet/adminis/gpd/index.htm) <http://www.hhs.gov/grantsnet/adminis/gpd/index.htm>).

6. Other Submission Requirements

Warning: Please be sure that you observe the direct cost, project period, and page number limitations specified above for this FOA. Application processing may be delayed or the application may be rejected if it does not comply with these requirements.

PD/PI Credential (e.g., Agency Login)

The FDA requires the PD(s)/PI(s) to fill in his/her Commons User ID in the "PROFILE – Project Director/Principal Investigator" section, "Credential" log-in field of the "Research & Related Senior/Key Person Profile" component.

Organizational DUNS

The applicant organization must include its DUNS number in its Organization Profile in the eRA Commons. This DUNS number must match the DUNS number provided at CCR registration with Grants.gov. For additional information, see "Frequently Asked Questions – Application Guide, [Electronic Submission of Grant Applications](#)."

PHS398 Research Plan Component Sections

All application instructions outlined in the SF424 (R&R) Application Guide are to be followed, incorporating "Just-in-Time" information concepts, and with the following additional requirements:

- Introduction (required for a resubmission or revision application) is limited to 1 page.
- Specific Aims is limited to 1 page.
- Research Strategy, including tables, graphs, figures, diagrams, and charts, is limited to 12 pages. See [Table of Page Limits](#).

Budget Component

U.S. applicants and all foreign applicants must complete and submit budget requests using the Research & Related Budget Non-Modular component.

Appendix Materials

Applicants **must** follow the specific instructions on Appendix materials as described in the SF424 (R&R) Application Guide (As reference only, NIH has provided guidance on this topic See <http://grants.nih.gov/grants/funding/424/index.htm>).

Do not use the Appendix to circumvent the page limitations.. An application that does not comply with the required page limitations may be delayed in the review process.

Resource Sharing Plan(s)

FDA considers the sharing of unique research resources developed through FDA-sponsored research an important means to enhance the value and further the advancement of the 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 the Resource Sharing section of the application (NIH has provided guidance on this topic, for reference only see http://grants.nih.gov/grants/policy/data_sharing/data_sharing_faqs.htm.)

(a) *Data Sharing Plan*: Regardless of the amount requested, investigators are expected to include a brief 1-paragraph description of how final research data will be shared, or explain why data-sharing is not possible. Applicants are encouraged to discuss data-sharing plans with their FDA program contact (NIH has provided guidance on this topic, for reference only see [Data-Sharing Policy](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html) or <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>.)

(b) *Sharing Model Organisms*: Regardless of the amount requested, all applications where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organisms and related resources or state appropriate reasons why such sharing is restricted or not possible (NIH has provided guidance on this topic, for reference only see [Sharing Model Organisms Policy](#), and [NOT-OD-04-042](#).)

(c) *Genome-Wide Association Studies (GWAS)*: Regardless of the amount requested, applicants seeking funding for a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or provide an appropriate explanation why submission to the repository is not possible. A genome-wide association study is defined as any study of genetic variation across the entire genome that is designed to identify genetic associations with observable traits (e.g., blood pressure or weight) or the presence or absence of a disease or condition. For further information see Policy for Sharing of Data Obtained in FDA Supported or Conducted Genome-Wide Association Studies (NIH has provided guidance on this topic, for reference only go to [NOT-OD-07-088](#), and <http://grants.nih.gov/grants/gwas/>.)

Section V. Application Review Information

1. Criteria

2. Review and Selection Process

Review Process

Applications that are complete and responsive to this FOA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the Office of Critical Path Programs and in accordance with FDA peer review procedures using the review criteria stated below.

As part of the scientific peer review, all applications will:

- Undergo a selection process in which only those applications deemed to have the highest scientific and technical merit, generally the top half of applications under review, will be discussed and assigned an impact/priority score;

- Receive a written critique; and
- Receive a second level of review by the National Cancer Institute, National Advisory Board.

Mission: The Office of Critical Path Programs (OCP), in FDA's Office of the Commissioner, was created to provide central coordination for the Initiative; lead certain Agency-wide Critical Path Initiative (CPI) projects; support CPI projects in the Centers with funding, staffing, and/or project management expertise; and lead Critical Path Communications, both within and external to the Agency.

Overall Impact

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 five scored review criteria, and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the five review criteria below in the determination of scientific and technical 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/PIs, 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

As applicable for the project proposed, reviewers will consider **the following additional items in the determination of scientific and technical merit, 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.

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.

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, see <http://grants.nih.gov/grants/olaw/VASchecklist.pdf>.

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.

Resubmission Applications. N/A

Renewal Applications. N/A

Revision Applications. N/A

Additional Review Considerations

As applicable for the project proposed, reviewers will address 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. As applicable for the FOA or submitted application, 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 Agents 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: (NIH has provided guidance on this topic. For reference only see 1) Data Sharing Plan (http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm); 2) Sharing Model Organisms (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html>); and 3) Genome Wide Association Studies (GWAS) (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html>).

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.

Selection Process

Applications submitted in response to this 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 Ad Hoc Review of the application is completed, the PD/PI will receive his or her 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. For details, applicants may refer to the [DHHS Grants Policy Statement](http://www.hhs.gov/grantsnet/adminis/gpd/index.htm) <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. The NoA signed by the grants management officer is the authorizing document. Once all administrative and programmatic issues have been resolved, the NoA will be generated via email notification from the awarding component 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.5.](#), "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 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.

2.A. 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 Parts 74 and 92 (Part 92 is applicable when State and local Governments are eligible to apply), 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 the NIH 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 follows.

The PO is the official responsible for the programmatic, and scientific concerns of this project. The PO's responsibilities include, but are not limited to, post-award monitoring of project/program performance, including review of progress reports and conducting site visits; and other activities. The PO and the Grants Management Officer will work as a team in many of these activities.

Additionally, the PO will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice.

2.A.3. Collaborative Responsibilities

An Ad Hoc Review Committee will adjudicate applications and decide on awards. Membership will include:

- two representatives from each of the following Centers: CDER, CDRH and CBER as delegated by the respective Center directors
- two representatives from the Office of the Chief Scientist
- one representative from NIH
- one representative from CDC with appropriate expertise
- one representative from the Office of Critical Path Programs who will chair the committee.

Each member will have a single vote in the selection of each RFA. If the award will directly or indirectly fund activities within the office of a voting member, that member will recuse him/herself from the vote.

Each full member will have one vote. Awardee members of the Ad Hoc Review Committee will be required to accept and implement policies approved by the Ad Hoc Review Committee.

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

Awardees will be required to submit the [Non-Competing Continuation Grant Progress Report \(PHS 2590\)](#)

quarterly and annually and financial statements as required in the [HHS Grants Policy Statement](http://www.hhs.gov/grantsnet/adminis/gpd/index.htm)
<http://www.hhs.gov/grantsnet/adminis/gpd/index.htm>

A final progress report, invention statement, and Financial Status Report are required when an award is relinquished when a recipient changes institutions or when an award is terminated.

Section VII. Agency Contacts

We encourage your inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research (program), peer review, and financial or grants management issues:

1. Scientific/Research/Peer Review Contact(s):

Leonard Sacks, MD
Food and Drug Administration
Office of the Commissioner; Office of the Chief Scientist
Office of Critical Path Programs
10903 New Hampshire Avenue
Bldg 32, Room 4174
Sliver Spring, MD 20993
Phone: 301-796-8502
Fax: 301-847-8614
Email: Leonard.sacks@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

Section VIII. Other Information

Required Federal Citations

Use of Animals in Research:

Recipients of PHS support for activities involving live, vertebrate animals must comply with PHS Policy on Humane Care and Use of Laboratory Animals (<http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf>) as mandated by the Health

Research Extension Act of 1985 (<http://grants.nih.gov/grants/olaw/references/hrea1985.htm>), and the USDA Animal Welfare Regulations (<http://www.nal.usda.gov/awic/legislat/usdaleg1.htm>) as applicable.

Human Subjects Protection:

Federal regulations (45 CFR 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>).

Data and Safety Monitoring Plan:

Data and safety monitoring is required for all types of clinical trials, including physiologic toxicity and dose-finding studies (Phase I); efficacy studies (Phase II); efficacy, effectiveness and comparative trials (Phase III). Monitoring should be commensurate with risk. The establishment of data and safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risks to the participants ("NIH has provided guidance for Data and Safety Monitoring, as reference only see" *NIH Guide for Grants and Contracts*, <http://grants.nih.gov/grants/guide/notice-files/not98-084.html>).

Sharing Research Data:

Investigators submitting an FDA application in direct costs in any single year are expected to include a plan for data sharing or state why this is not possible. Investigators should seek guidance from their institutions, on issues related to institutional policies and local institutional review board (IRB) rules, as well as local, State and Federal laws and regulations, including the Privacy Rule.

Policy for Genome-Wide Association Studies (GWAS):

FDA is interested in advancing genome-wide association studies (GWAS) to identify common genetic factors that influence health and disease through a centralized GWAS data repository. For the purposes of this policy, a genome-wide association study is defined as any study of genetic variation across the entire human genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight), or the presence or absence of a disease or condition. All applications, regardless of the amount requested, proposing a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or provide an appropriate explanation why submission to the repository is not possible. Data repository management (submission and access) is governed by the Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies, NIH Guide [NOT-OD-07-088](#). For additional information, see <http://grants.nih.gov/grants/gwas/>.

Sharing of Model Organisms:

FDA is committed to support efforts that encourage sharing of important research resources including the sharing of model organisms for biomedical research (NIH has provided guidance on this topic, for reference only see http://grants.nih.gov/grants/policy/model_organism/index.htm). At the same time, the NIH recognizes the rights of grantees and contractors to elect and retain title to subject inventions developed with Federal funding pursuant to the Bayh-Dole Act (see the DHHS Policy Statement <http://www.hhs.gov/grantsnet/adminis/gpd/index.htm>). All investigators submitting an FDA application or contract proposal are expected to include in the application/proposal a description of a specific plan for sharing and distributing unique model organism research resources generated using FDA funding or state why such sharing is restricted or not possible. This will permit other researchers to benefit from the resources developed with public funding. The inclusion of a model organism sharing plan is not subject to a cost threshold in any year and is expected to be included in all applications where the development of model organisms is anticipated.

Access to Research Data through the Freedom of Information Act:

The Office of Management and Budget (OMB) Circular A-110 has been revised to provide access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are: (1) first produced in a project that is supported in whole or in part with Federal funds; and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a

regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm. Applicants may wish to place data collected under this funding opportunity in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

Inclusion of Women And Minorities in Clinical Research:

It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. NIH has provided guidance on this topic, for reference only, all investigators proposing clinical research should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research" (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>); a complete copy of the updated Guidelines is available at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm.

Inclusion of Children as Participants in Clinical Research:

The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all clinical research, conducted or supported by the FDA, unless there are scientific and ethical reasons not to include them. NIH has provided guidance on this topic, for reference only, all investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects (<http://grants.nih.gov/grants/funding/children/children.htm>).

Required Education on the Protection of Human Subject Participants:

FDA policy requires education on the protection of human subject participants for all investigators submitting FDA applications for research involving human subjects and individuals designated as key personnel. NIH has provided guidance on this topic, for reference only, see <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

Human Embryonic Stem Cells (HESC):

Criteria for Federal funding of research on hESCs can be found at <http://stemcells.nih.gov/index.asp> and at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-116.html>. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (<http://escr.nih.gov/>). It is the responsibility of the applicant to provide in the project description and elsewhere in the application as appropriate, the official NIH identifier(s) for the hESC line(s) to be used in the proposed research.

Standards for Privacy of Individually Identifiable Health Information:

The Department of Health and Human Services (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 website (<http://www.hhs.gov/ocr/>) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule. NIH has provided guidance on this topic, for reference only, see <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html>.

URLs in FDA Grant Applications or Appendices:

All applications and proposals for FDA funding must be self-contained within specified page limitations. For publications listed in the appendix and/or Progress report, Internet addresses (URLs) or PubMed Central (PMC) submission identification numbers must be used for publicly accessible on-line journal articles. Publicly accessible on-line journal articles or PMC articles/manuscripts accepted for publication that are directly relevant to the project may be included **only as URLs or PMC submission identification numbers** accompanying the full reference in either the Bibliography & References Cited section, the Progress Report Publication List section, or the Biographical Sketch section of the FDA grant application. A URL or PMC submission identification number citation may be repeated in each of these sections as appropriate. There is no limit to the number of URLs or PMC submission identification numbers that can be cited.

Healthy People 2010:

The Public Health Service (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 PA 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>.

Authority and Regulations:

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 Parts 74 and 92. 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) <http://www.hhs.gov/grantsnet/adminis/gpd/index.htm>.

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.