Exercise 1

Assessing Opportunities

Once you’ve identified some possible funding opportunities, you need to assess them to determine whether they are really suitable. A grant program that sounds like a good potential match when you read the description may have to be crossed off the list as you get more information. The objective is to apply for those opportunities that you are likely to win. The best place to start this determination is with the Program Announcement or Request for Application.

There are three key areas you should address as you assess funding opportunities:

1. Are you eligible to apply for the grant program(s) you have selected?
2. If applicable, does your proposed project actually fit the program as described in the announcement?
3. If your organization applies, is it likely to receive an award?

Instructions: Review the Request for Proposal. Identify what parts of the announcement help you assess the likelihood of receiving an award. Discuss what additional information you may seek and how you would access this information.

Assessment Questions

1. Do we meet the eligibility requirements?

2. Is there a good potential funding opportunity for the project?

3. Will the organization structure support the regulations and guidelines?
4. Are there too many restrictions to performing the project or to the organization?

5. Can we support our need for the project as a priority to the goals of the funding agency?

6. Does the level of funding available sufficient to cover the project anticipated cost?

7. How many awards will be issued?

8. Are staffing levels or sufficient talent available to allow the organization to be competitive?

9. Are there sufficient facilities and equipment available to support resources needed?

10. Are there cost restrictions (direct or indirect) that would make the project ineffective?

11. Can we meet the deadline effectively?

12. Are there any organizational administrative restrictions that need to be taken into consideration?

13. Are computer systems and required registrations, and on-line submission sites already established for the organization?

14. Is this project one that would make a substantial difference to the research agenda of the organization?
Exercise 1

Part I Overview Information

Department of Health and Human Services

Participating Organizations
National Institutes of Health (NIH), (http://www.nih.gov)

Components of Participating Organizations
National Institute on Drug Abuse (NIDA), (http://www.nida.nih.gov)

Title: Medications Development for Cannabis-Related Disorders (R01)

Announcement Type
This Funding Opportunity Announcement (FOA) is a reissue of RFA-DA-09-001.

Update: The following update relating to this announcement has been issued:

- November 25, 2009 - This FOA has been updated to reflect the new requirements from NIH's Enhancing Peer Review Initiative. The new requirements are effective for submissions intended for due dates January 25, 2010 and beyond. If submitting an application intended for a due date of January 25, 2010 and beyond, follow the guidance below and be sure to use the Adobe-Forms-B version of the application forms and instructions. If applying for a due date before January 25, 2010, follow the guidance in the archived version of this FOA and be sure to use the Adobe-Forms-A version of the application forms and instructions.

Request for Applications (RFA) Number: RFA-DA-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 (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)
93.279

Key Dates
Release/Posted Date: September 24, 2009
Opening Date: March 30, 2010 (Earliest date an application may be submitted to Grants.gov)
Letters of Intent Receipt Date(s): March 30, 2010

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): April 30, 2010
Peer Review Date(s): June/July 2010
Council Review Date(s): August 2010
Earliest Anticipated Start Date(s): September 2010
Additional Information To Be Available Date (Activation Date): Not Applicable
Expiration Date: May 1, 2010

Due Dates for E.O. 12372
Not applicable

Additional Overview Content

Executive Summary

- **Purpose.** The purpose of this Funding Opportunity Announcement (FOA) is to issue a Request for Applications (RFA) to support research studies that focus on the identification, and preclinical and clinical evaluation, of medications that can be safe and effective for the treatment of cannabis-use and -induced disorders, as well as their medical and psychiatric consequences. The studies can be preclinical or FDA-defined Phase I, Phase II or Phase III clinical trials.

- **Mechanism of Support.** This FOA will utilize the R01 grant mechanism and runs in parallel with two FOAs of identical scientific scope, PA-07-365 and PA-07-366, that solicit applications under the R01 and R21 mechanisms, respectively.

- **Funds Available and Anticipated Number of Awards.** It is anticipated that a total of 6 awards will be funded for a total of $3,000,000.

- **Budget and Project Period.** The requested direct cost amount for individual awards must be less than $500,000 per year, with project periods for up to five years.

- **Application Research Plan Component Length:** The R01 application Research Strategy may not exceed 12 pages, including tables, graphs, figures, diagrams, and charts.

- **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 will be 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:
  - 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

Cannabis-related disorders (CRDs) including cannabis abuse or dependence and cannabis induced disorders (e.g., intoxication, delirium, psychotic disorder, and anxiety disorder) are a major public health issue. Cannabis use includes marijuana, hashish, and other tetrahydrocannabinol (THC) containing substances.
Nearly one million people are seeking treatment for marijuana dependence every year and sufficient research has been carried out to confirm that the use of cannabis can produce serious physical and psychological consequences. Currently, there are no medications approved by the Food and Drug Administration for the treatment of CRDs. Only recently have clinical trials been conducted testing medications to treat these disorders.

Given the extent of the use of cannabis in the general population, and the medical and psychological consequences of its use, particularly the clinically significant psychosocial impairment, there is a great public health need to develop safe and effective therapeutic interventions. The need to develop treatments targeting adolescents and young adults is particularly relevant in view of their disproportionate use patterns.

Scientific advances are making possible the development of medications to treat CRDs. They include the discovery of an endogenous cannabinoid system with specific receptors and endogenous ligands, advances in the preclinical and human laboratory methods to study the effects of medications on CRD, and the availability of new compounds that target the cannabinoid system and marketed medications whose mechanisms of actions may have potential therapeutic effects for these disorders.

In 2008, NIDA issued the RFA DA-09-001 (a reissue of RFA-DA-04-014 issued in 2004) which greatly increased the evaluation of new medications for these disorders. The present FOA will serve to maintain the momentum achieved in 2008 and further the evaluation of new and promising medications. Under this FOA, the applicants may submit preclinical as well as FDA defined Phase I, Phase II or Phase III clinical trials of new compounds or marketed medications that have theoretical or empirical evidence of efficacy to treat CRDs.

Applications may focus on the pharmacotherapy of one or various CRDs or clinical manifestations of the disorders. For example, research may focus on marijuana dependence or specifically on marijuana withdrawal. Clinical applications may include human laboratory studies to develop models for testing medications targeting single or multiple manifestations of the CRDs, and the interaction of cannabinoids with other medications, pharmacokinetic and/or pharmacodynamic studies of potentially therapeutic compounds. Applications may also focus on the specific symptoms of the disorder such as withdrawal, craving or relapse, complications such as cognitive impairment, sleep disorders/distruption of normal rhythms or the clinical surrogates of their use such as depression and other mood disorders. Preclinical applications may include pharmacological studies on new chemical entities (NCEs) leading to the identification of candidates for advanced preclinical or phase I/II IND covered clinical evaluation as potential pharmacotherapies for CRDs.

The rationale for choosing the medication(s) to be investigated can be based on a top-down approach, a bottom-up approach, or both approaches combined. The top-down approach would be the testing of marketed medications that are available for other indications and which may be promising candidates for the treatment of CRDs. For example, an FDA approved antidepressant may be chosen as a target medication. The bottom-up approach involves the identification and testing of new chemical entities that, because of their chemical characteristics and mechanism of action, could be candidates to be developed specifically for CRDs.
The testing of combinations of medications is within the scope of this FOA. Medications may target one or more neurochemical mechanisms implicated in the physiopathology of CRDs by direct or indirect modulation of the systems, or by producing synergistic or antagonist effects.

Research topics of interest include but are not limited to:

- Preclinical and clinical studies of medications for the treatment of cannabis-related disorders, alone or comorbid with other medical/psychiatric conditions.
- Human laboratory evaluation of medications that may affect the pathophysiological correlates of cannabis-use disorders such as self-administration, reward, tolerance, withdrawal, craving, and physiological dependence.
- Design and implementation of FDA defined Phase I clinical trials to assess the medical safety and tolerability of medications when treating patients with CRDs.
- Interaction studies focused on the effects of medications to treat CRDs and the concurrent use of cannabis derivatives, including pharmacokinetic and/or pharmacodynamic studies.
- Testing medications that may affect the interaction between cannabinoid, opioid and dopamine systems, and which may have therapeutic effect not only for CRDs but also for other medical conditions such as pain and other drug dependencies.
- Randomized clinical trials, defined by FDA as Phase II, to evaluate the efficacy of a new or already marketed medication for the treatment of single or multiple CRDs, or any of their clinical manifestations. For example, studies may focus on the treatment of marijuana dependence or marijuana withdrawal.
- Development of medications to block withdrawal symptoms.
- Pharmacotherapies focusing on the treatment of comorbid psychiatric conditions that may negatively affect the outcome of the disorders or their treatment. For example, pharmacotherapies may focus on treating the clinical depression associated with the use of cannabis.
- Studies focusing on interactions of medications developed for CRDs with other medications or illicit drugs.
- Pharmacotherapy studies aimed at preventing or reducing the medical consequences of cannabis use, including HIV and other infections.
- Identification and testing of potential medications which would produce one or more of the following effects in pharmacological studies: a relatively long duration of action; mild reinforcement when compared to cannabinoids; and/or blockade of cannabinoids effects in behavioral assays and on cognitive, spatial/motor and/or learning/memory functions.

Special Considerations

**HIV/AIDS Counseling and Testing Policy for the National Institute on Drug Abuse:** In light of recent significant advances in rapid testing for HIV and in effective treatments for HIV, NIDA has revised its 2001 policy on HIV counseling and testing. NIDA-funded researchers are strongly encouraged to provide and/or refer research subjects to HIV risk reduction education and education about the benefits of HIV treatment, counseling and testing, referral to treatment, and other appropriate interventions to prevent acquisition and transmission of HIV. This policy applies to all NIDA funded research conducted domestically or internationally. For more information see [http://grants.nih.gov/grants/guide/notice-files/NOT-DA-07-013.html](http://grants.nih.gov/grants/guide/notice-files/NOT-DA-07-013.html).
National Advisory Council on Drug Abuse Recommended Guidelines for the Administration of Drugs to Human Subjects: The National Advisory Council on Drug Abuse (NACDA) recognizes the importance of research involving the administration of drugs with abuse potential, and dependence or addiction liability, to human subjects. Potential applicants are encouraged to obtain and review these recommendations of Council before submitting an application that will administer compounds to human subjects. The guidelines are available on NIDA's Web site at http://www.nida.nih.gov/about/organization/nacda/CouncilStatement.html

Networking Website for Consultation and Collaboration

NIDA has established a web-based Networking Project (NNP) to encourage investigators to collaborate with other scientists to gain access to specialized expertise, unique research resources, diverse populations, or geographic locations not otherwise available. For applicants interested in identifying potential collaborators, the NNP website is available at http://nnp.drugabuse.gov, as a source of information on the mission, focus, and leadership of NIDAs research networks. The website features an interactive map with more than 300 local network sites, a directory of close to 400 addiction researchers and practitioners, and the extensive resources of 14 NIDA-supported research networks located across the country. If appropriate for the proposed research, NIDA encourages grant applicants to use the resources of the NNP and make reference in the grant application when they are utilized.

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 R01 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). Specifically, a U.S. organization submitting an application with direct costs in each year of $250,000 or less (excluding consortium Facilities and Administrative [F&A] costs) must use the PHS398 Modular Budget component.

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.

2. Funds Available

- NIDA has set aside $3,000,000 to fund eligible grant proposals.
• It is anticipated that 6 grant applications will be awarded.
• The expected direct cost amount for individual awards must be less than $500,000 per year.

Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. Although the financial plans of the IC(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds.

Facilities and Administrative (F&A) costs requested by consortium participants are not included in the direct cost limitation. See NOT-OD-05-004.

NIH grants policies as described in the NIH Grants Policy Statement 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):
  - 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 NIH 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 grant 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 NIH Grants Policy Statement.

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 will be permitted for 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 and the Commons. 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.

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 in both Grants.gov and the Commons. The NIH will accept electronic applications only from organizations that have completed all necessary registrations.

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.

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 and in accordance with the SF424 (R&R) Application Guide for this FOA through Grants.gov/Apply.

The SF424 (R&R) Application Guide is critical to submitting a complete and accurate application to NIH. 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/PIs 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 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 Research & Related Budget, as appropriate (See Section IV.6., Special Instructions, regarding appropriate required budget component.)

**Optional Components:**
PHS398 Cover Letter File
Research & Related Subaward Budget Attachment(s) Form

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


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, NIH requires one PD/PI to be designated as the "Contact PI, who will be responsible for all communication between the PDs/PIs and the NIH, 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 in Item 13 of 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.

All projects proposing Multiple PDs/PIs will be required to include a new section describing the leadership plan approach for the proposed project.

Multiple PD/PI Leadership Plan: For applications designating multiple PDs/PIs, a new section of the Research Plan, entitled 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 3.4 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: March 30, 2010 (Earliest date an application may be submitted to Grants.gov)
Letters of Intent Receipt Date(s): March 30, 2010
Application Due Date(s): April 30, 2010
Peer Review Date(s): June/July 2010
Council Review Date(s): August 2010
Earliest Anticipated Start Date(s): September 2010

3.A.1. Letter of Intent

Prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed research.
- Name, address, and telephone number of the PD(s)/PI(s).
- Names of other key personnel.
- Participating institutions.
• Number and title of this funding opportunity.

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

The letter of intent is to be sent by the date listed in Section IV.3.A.

NIDALetterofIntent@mail.nih.gov

Applicants are encouraged to send the letter of intent by email to the email address above but as an alternative the letter may also be sent to:

Director - DA-10-016
Office of Extramural Affairs
National Institute on Drug Abuse/NIH/DHHS
6101 Executive Boulevard, Suite 220, MSC 8401
Bethesda, MD 20892-8401
Rockville, MD 20852 (for express/courier service)
Telephone: (301) 443-2755
FAX: (301) 443-0538
Email: tlevitin@mail.nih.gov

3.B. Submitting an Application Electronically to the NIH

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.

In order to expedite the review, applicants are requested to notify the NIDA Referral Office by email tlevitin@mail.nih.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

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 NIH 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, 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 CSR and responsiveness by the IC. Incomplete and 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 NIH 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.
Applications submitted for January 25, 2010 due dates and beyond, will require shortened Research Strategy plan page limits. Research Strategy may not exceed 12 pages in length and must be submitted utilizing the most current forms and instructions.

Alignment of the Research Plan with Scored Peer Review Criteria

Applications submitted for January 25, 2010 due dates and beyond will require a restructured Research Plan format. This Research Strategy format is outlined in the most current application instructions. See NOT-OD-09-149.

All application instructions outlined in the SF424 (R&R) Application Guide are to be followed, incorporating "Just-in-Time" information concepts.

Appendix Materials

Applicants must follow the specific instructions on Appendix materials as described in the SF424 (R&R) Application Guide (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)

NIH considers the sharing of unique research resources developed through NIH-sponsored research an important means to enhance the value and further the advancement of the research. When resources have been developed with NIH funds and the associated research findings published or provided to NIH, 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 (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 NIH program contact (see Data-Sharing Policy 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 (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 NIH Supported or Conducted Genome-Wide Association Studies (go to NOT-OD-07-088, and http://grants.nih.gov/grants/gwas/)

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

Indicate how the proposed project has specific relevance to the mission and objectives of the NIH/IC and has the potential for significantly advancing the health sciences in the United States.

Section V. Application Review Information

1. Criteria

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

2. Review and Selection 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 NIDA and in accordance with NIH peer review procedures (http://grants1.nih.gov/grants/peer/), 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 National Advisory Council on Drug Abuse.

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.
- Compliance with resource sharing, as well as data and safety monitoring policies.

The mission of the NIH is to support science in pursuit of knowledge about the biology and behavior of living systems and to apply that knowledge to extend healthy life and reduce the
burdens of illness and disability. As part of this mission, applications submitted to the NIH for grants or cooperative agreements to support biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

**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 core review criteria, and additional review criteria (as applicable for the project proposed).

**Core 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, 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) Protections for Human Subjects, 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 tranquillizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia.

*Resubmission Applications.* When reviewing a Resubmission application (formerly called an amended application), the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

*Renewal Applications.* When reviewing a Renewal application (formerly called a competing continuation application), the committee will consider the progress made in the last funding period.
Revision Applications. When reviewing a Revision application (formerly called a competing supplement application), the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

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.

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.

Renewal Applications. When reviewing a Renewal application (formerly called a competing continuation application), the committee will consider the progress made in the last funding period.
**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.

**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.

**Budget and Period Support.** Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

**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).

**Applications from Foreign Organizations.** Reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

**Resource Sharing Plans.** Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) Data Sharing Plan (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).

3. Anticipated Announcement and Award Dates

Not Applicable.

Section VI. Award Administration Information

1. Award Notices

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the NIH eRA Commons.

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant. For details, applicants may refer to the NIH Grants Policy Statement Part II:
Terms and Conditions of NIH Grant Awards, Subpart A: General.

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 NIH grant and cooperative agreement awards include the NIH Grants Policy Statement as part of the NoA. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities.

3. Reporting

Awardees will be required to submit the Non-Competing Continuation Grant Progress Report (PHS 2590) annually and financial statements as required in the NIH Grants Policy Statement.

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 Contact(s):

Ivan Montoya, M.D., M.P.H.
Acting Deputy Director,
Division of Pharmacotherapies and Medical Consequences of Drug Abuse
National Institute on Drug Abuse/NIH/DHHS
6001 Executive Blvd., Room 4131
Bethesda, MD 20892
Telephone: (301) 443-8639
Fax: (301) 443-2599
Email: imontoya@mail.nih.gov
2. Peer Review Contact(s):

Teri Levitin, Ph.D.
Director Office of Extramural Affairs
National Institute on Drug Abuse/NIH/DHHS
6101 Executive Boulevard
Suite 220, MSC 8401
Bethesda, MD 20892-8401
Rockville, MD 20852 (for express/courier service)
Telephone: (301) 443-2755
Fax: (301) 443-0538
Email: tlevitin@mail.nih.gov

3. Financial/Grants Management Contact(s):

Deborah Wertz
Grants Management Branch
National Institute on Drug Abuse/NIH/DHHS
6101 Executive Boulevard
Suite 270 MSC 8403
Bethesda MD 20892-8403
Telephone: (301) 443-6710
FAX: (301) 594-6847
E-mail: dwertz@nida.nih.gov

Section VIII. Other Information

Required Federal Citations

Vertebrate Animals:
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/hrera1985.htm), and the USDA Animal Welfare
Regulations (http://www.nal.usda.gov/awic/legislat/usdalegl.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 Policy for Data and Safety Monitoring, NIH Guide for Grants and Contracts, http://grants.nih.gov/grants/guide/notice-files/not98-084.html).

Sharing Research Data:
Investigators submitting an NIH application seeking $500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why this is not possible (http://grants.nih.gov/grants/policy/data_sharing). 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. Reviewers will consider the data sharing plan but will not factor the plan into the determination of the scientific merit or the impact/priority score.

Policy for Genome-Wide Association Studies (GWAS):
NIH 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:
NIH is committed to support efforts that encourage sharing of important research resources including the sharing of model organisms for biomedical research (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 NIH Grants Policy Statement. Beginning October 1, 2004, all investigators submitting an NIH 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 NIH 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, Minorities, and Children:
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. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43). 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. The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the SF424 (R&R) application; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

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 NIH, unless there are scientific and ethical reasons not to include them. 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:
NIH policy requires education on the protection of human subject participants for all investigators submitting NIH applications for research involving human subjects and individuals
designated as key personnel. The policy is available at 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://esrc.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.

**NIH Public Access Policy Requirement:**
In accordance with the NIH Public Access Policy, *investigators funded by the NIH must submit or have submitted for them to the National Library of Medicine's PubMed Central (see http://www.ncbi.nlm.nih.gov/), an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication.* The NIH Public Access Policy is available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html. For more information, see the Public Access webpage at http://publicaccess.nih.gov/.

**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 on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html.

**URLs in NIH Grant Applications or Appendices:**
All applications and proposals for NIH 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 NIH grant application. A URL or PMC submission identification number citation may be repeated in each of these sections as
5. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement.

Pre-award costs are allowable. A grantee may, at its own risk and without NIH 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 NIH prior approval. If specific expenditures would otherwise require prior approval, the grantee must obtain NIH approval before incurring the cost. NIH 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 NIH 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. NIH 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 NIH Grants Policy Statement).

6. Other Submission Requirements

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

The NIH 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

Page limitations of the PHS398 Research Plan component must be followed as outlined in the SF424 (R&R) Application Guide. The R01 application Research Strategy may not exceed 12 pages, including tables, graphs, figures, diagrams, and charts.

Research Strategy Page Limitations
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 FOA 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 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement.

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.

**Loan Repayment Programs:**
NIH encourages applications for educational loan repayment from qualified health professionals who have made a commitment to pursue a research career involving clinical, pediatric, contraception, infertility, and health disparities related areas. The LRP is an important component of NIH's efforts to recruit and retain the next generation of researchers by providing the means for developing a research career unfettered by the burden of student loan debt. Note that an NIH grant is not required for eligibility and concurrent career award and LRP applications are encouraged. The periods of career award and LRP award may overlap providing the LRP recipient with the required commitment of time and effort, as LRP awardees must commit at least 50% of their time (at least 20 hours per week based on a 40 hour week) for two years to the research. For further information, please see: http://www.lrp.nih.gov/.