# Supporting Statement for the Paperwork Reduction Act Submission Appendices

# National Institutes of Health A Process Evaluation of the NIH Director's Pioneer Award (NDPA) Program

Attachment 1: NDPA RFA 2007

**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**

This RFA is developed as an NIH roadmap initiative (<a href="http://nihroadmap.nih.gov">http://nihroadmap.nih.gov</a>). All NIH Institutes and Centers participate in roadmap initiatives. The RFA will be administered by the <a href="https://nihroadmap.nih.gov">National Institute of General Medical Sciences (NIGMS)</a> on behalf of the NIH.

Title: 2007 NIH Director's Pioneer Award Program (DP1)

#### **Announcement Type**

This is a reissue of RFA-RM-06-005, which was previously released November 18, 2005.

**NOTICE:** Applications submitted in response to this Funding Opportunity Announcement (FOA) for Federal assistance must be submitted electronically through Grants.gov (<a href="http://www.grants.gov">http://www.grants.gov</a>) 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 <u>Grants.gov/Apply for Grants</u> (hereafter called Grants.gov/Apply).

A registration process is necessary before submission, and applicants are highly encouraged to start the process at least four weeks prior to the grant submission date. See <u>Section IV</u>.

# Request For Applications (RFA) Number: RFA-RM-07-005

#### Catalog of Federal Domestic Assistance Number(s)

93.310

#### **Key Dates**

Release/Posted Date: October 11, 2006

Opening Date: December 1, 2006 (Earliest date an application may be submitted to Grants.gov)

Letters of Intent Receipt Date(s): Not applicable.

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 Receipt Date(s): January 16, 2007

Letters of Reference Submission Date(s): January 16, 2007, 5:00 p.m. (EST)

Peer Review Date(s): April, 2007

Advisory Council to the Director Date(s): August, 2007 Earliest Anticipated Start Date(s): September 30, 2007

Additional Information to be Available Date (URL Activation Date): N/A

Expiration Date: January 17, 2007

#### Due Dates for E.O. 12372

Not Applicable

# **Additional Overview Content**

#### **Executive Summary**

The NIH Director's Pioneer Award Program (NDPA) is meant to complement NIH's traditional, investigator-initiated grant programs by supporting individual scientists of exceptional creativity who propose pioneering approaches to major contemporary challenges in biomedical and behavioral research.

Purpose. The National Institutes of Health (NIH) is engaged in a series of initiatives, collectively known
as the "NIH Roadmap for Medical Research" (<a href="http://nihroadmap.nih.gov">http://nihroadmap.nih.gov</a>), which promote clinical and
translational investigation and aim to improve health and prevent disease. The NIH Director's Pioneer
Award Program, is a <a href="https://nihroadmap.nih.gov">High-Risk Research</a> initiative of Research Teams of the Future. The term

- "pioneering" is used to describe highly innovative approaches that have the potential to produce an unusually high impact, and the term "award" is used to mean a grant for conducting research, rather than a reward for past achievements.
- Mechanism of Support. This Funding Opportunity Announcement (FOA) will utilize the DP1 grant mechanism.
- Funds Available and Anticipated Number of Awards. Approximately five to ten awards of \$500,000 in direct costs are anticipated for a total of up to \$5 million per year for five years.
- Budget and Project Period. Awards will be for \$500,000 in direct costs each year for five years. Standard F&A costs will be determined at the time of award.
- Competing renewal applications are not allowed.
- Eligible Institutions/Organizations. Public/State Controlled Institution of Higher Education; Private Institution of Higher Education; Nonprofit with 501(c)(3) IRS Status (Other than Institution of Higher Education); Nonprofit without 501(c)(3) IRS Status (Other than Institution of Higher Education); Small Business; For-Profit Organization (Other than Small Business); State Government; U.S. Territory or Possession; Indian/Native American Tribal Government (Federally Recognized); Indian/Native American Tribal Government (Other than Federally Recognized); Indian/Native American Tribally Designated Organization; Non-domestic (non-U.S.) Entity (Foreign Organization); Hispanic-serving Institution; Historically Black Colleges and Universities (HBCUs); Tribally Controlled Colleges and Universities (TCCUs); Alaska Native and Native Hawaiian Serving Institutions; Regional Organization; Eligible agencies of the Federal government; Faith-based or community based organizations.)
- Eligible Project Directors/Principal Investigators (PDs/PIs): Applicant PD/PI's must be U.S. citizens, non-citizen nationals, or permanent residents at the time of application who are currently engaged in research. The research proposed need not be in a conventional biomedical or behavioral discipline; if the individual's experience is in non-biological areas, however, he/she must demonstrate a commitment to exploring topics of biomedical or behavioral relevance. Investigators at all career levels are eligible. If selected, individuals must show evidence of institutional infrastructure support. Awardees are required to commit the major portion (at least 51%) of their research effort to activities supported by the NDPA. Those at early to middle stages of their careers, women, and members of groups underrepresented in biomedical or behavioral research are especially encouraged to apply. Nominees and applicants who were not selected for an award in prior years may submit applications this year.
- Number of Applications. Applicants may submit only one application as a PD/PI in response to this
   RFA. There is no limit to the number of applications that institutions may submit.
- Application Materials. See <u>Section IV.1</u> for application materials.
- General Information. For general information on SF424 (R&R) Application and Electronic Submission, see these Web sites:
  - SF424 (R&R) Application and Electronic Submission Information: http://grants.nih.gov/grants/funding/424/index.htm

- General information on Electronic Submission of Grant Applications:
   <a href="http://era.nih.gov/ElectronicReceipt/">http://era.nih.gov/ElectronicReceipt/</a>
- **Hearing Impaired.** Telecommunications for the hearing impaired is available at: TTY 301-451-0088.

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#### Part II - Full Text of Announcement

# **Section I. Funding Opportunity Description**

#### 1. Research Objectives

A unique aspect of the NIH Roadmap for Medical Research is the NIH Director's Pioneer Award (NDPA) Program. First announced in Fiscal Year 2004, nine awards were made in September 2004 and 13 awards each were made in 2005 and 2006. The NDPA is designed to support individual scientists of exceptional creativity who propose pioneering – and possibly transformative - approaches to major challenges in biomedical and behavioral research. The term "pioneering" is used to describe highly innovative approaches that have the potential to produce an unusually high impact, and the term "award" is used to mean a grant for conducting research, rather

than a reward for past achievements. Biomedical and behavioral research is defined broadly in this announcement as encompassing scientific investigations in the biological, behavioral, clinical, social, physical, chemical, computational, engineering, and mathematical sciences. The NDPA is meant to support individuals who intend to pursue new research directions that are not already supported by other mechanisms. The program is not intended simply to expand the funding of persons already well supported for a particular project.

#### **Background**

The NIH's success depends on the creativity of investigator-initiated research, much of it supported by the R01 grant mechanism. Many scientists who participated in the development of the NIH Roadmap, however, expressed the view that additional means might be necessary to identify scientists with ideas that have the potential for high impact, but may be too novel, span too diverse a range of disciplines, or be at a stage too early to fare well in the traditional peer review process. A group of distinguished outside consultants proposed that NIH implement a completely new program to encourage highly innovative biomedical research with the great potential to lead to significant advances in human health. This program would complement NIH's traditional, investigator-initiated grant programs. Unlike most NIH grant mechanisms, the NDPA is designed not to support projects but rather to support highly creative and pioneering people.

This RFA announces a fourth NDPA competition for approximately 5 -10 new awards of \$500,000 in direct costs per year for five years that will be made in Fiscal Year 2007. It is a requirement that awardees commit the major portion (at least 51%) of their research effort to activities supported by the NDPA. Individuals who are unable to meet this requirement should not apply.

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

# **Section II. Award Information**

# 1. Mechanism of Support

This Funding Opportunity Announcement (FOA) will use the DP1 award mechanism. The applicant will be solely responsible for planning, directing, and executing the proposed project.

#### 2. Funds Available

Sufficient funds have been set aside in 2007 to provide 5-10 awards. The awards will be for \$500,000 in direct costs each year for five years.

# **Section III. Eligibility Information**

#### 1. Eligible Applicants

#### 1.A. Eligible Institutions

You may submit an application(s) if your institution/organization has any of the following characteristics:

- Public/State Controlled Institution of Higher Education
- Private Institution of Higher Education
- Nonprofit with 501(c)(3) IRS Status (Other than Institution of Higher Education)
- Nonprofit without 501(c)(3) IRS Status (Other than Institution of Higher Education)
- Small Business
- For-Profit Organization (Other than Small Business)
- State Government
- U.S. Territory or Possession
- Indian/Native American Tribal Government (Federally Recognized)
- Indian/Native American Tribal Government (Other than Federally Recognized)
- Indian/Native American Tribally Designated Organization
- Non-domestic (non-U.S.) Entity (Foreign Organization)
- Hispanic-serving Institution
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Regional Organizations
- Eligible agencies of the Federal government
- Faith-based or community based organizations

#### 1.B. Eligible Individuals

Investigators eligible for the NDPA must be U.S. citizens, non-citizen nationals, or permanent residents of the United States **at the time of application** who are currently engaged in research. The research proposed need not be in a conventional biomedical or behavioral discipline; if the individual's experience is in non-biological areas, however, he/she must demonstrate a commitment to exploring topics of biomedical or behavioral relevance. This initiative is to support **new research directions**, and individuals may not request funds to expand currently funded research. If selected, individuals must show evidence of institutional infrastructure support. Awardees are required to commit the major portion (at least 51%) of their research effort to activities supported by the NDPA. Nominees and applicants who were not selected for an award in prior years may submit

applications this year. Investigators at all career levels are eligible. Those at early to middle stages of their careers, and women and members of groups underrepresented in biomedical or behavioral research are especially encouraged to apply.

**Applicants must:** (1) update their citizenship status in their eRA Commons Profile prior to application; and (2) include a statement in their biographical sketch that they meet the citizenship eligibility requirement, as follows, "I am eligible to apply for a Pioneer Award because I am a \_\_\_\_\_ (U.S. citizen, non-citizen national, permanent resident of the United States).

#### 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

Applicants may submit only one application as a PD/PI in response to this RFA.

# 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, link to <a href="http://www.grants.gov/Apply/">http://www.grants.gov/Apply/</a> and follow the directions provided on that Web site.

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

- Grants.gov (<a href="http://www.grants.gov/GetStarted">http://www.grants.gov/GetStarted</a>) and
- eRA Commons (<a href="http://era.nih.gov/ElectronicReceipt/preparing.htm">http://era.nih.gov/ElectronicReceipt/preparing.htm</a>)

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

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

1) Organizational/Institutional Registration in Grants.gov/Get Started

- Your organization will need to obtain a <u>Data Universal Number System (DUNS) number</u> and register with the <u>Central Contractor Registration (CCR)</u> 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 <a href="mailto:support@grants.gov">support@grants.gov</a>

#### 2) Organizational/Institutional Registration in the eRA Commons

- To find out if an organization is already Commons-registered, see the "<u>List of Grantee Organizations</u>
   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 <a href="mailto:commons@od.nih.gov">commons@od.nih.gov</a>

- 3) Project Director/Principal Investigator (PD/PI) Registration in the NIH eRA Commons: Refer to the <u>NIH eRA</u> <u>Commons System (COM) Users Guide</u>.
  - The individual designated as the PD/PI on the application must also be registered in the NIH eRA Commons. It is not necessary for PDs/PIs to register with Grants.gov.
  - The PD/PI must hold a PD/PI account in the Commons and must be affiliated with the applicant organization. This account cannot have any other role attached to it other than the PD/PI.
  - This registration/affiliation must be done by the Authorized Organization Representative/Signing Official (ARO/SO) or their designee who is already registered in the Commons.
  - Both the PD/PI and AOR/SO need separate accounts in the NIH eRA Commons since both are authorized to view the application image.

Note that if a PD/PI is also an NIH peer-reviewer with an Individual DUNS and CCR registration, that particular DUNS number and CCR registration are for the individual reviewer only. These are different than any DUNS number and CCR registration used by an applicant organization. Individual DUNS and CCR registration should

be used only for the purposes of personal reimbursement and should not be used on any grant applications submitted to the Federal Government.

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 <u>Grants.gov</u> and the <u>Commons</u>. 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 SF424 (R&R) Application Guide for this FOA through <u>Grants.gov/Apply</u>.

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 usable for more than one FOA.

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

Telecommunications for the hearing impaired: TTY 301-451-0088.

#### 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 <u>Grants.gov/APPLY.</u>

The SF424 (R&R) Application Guide is critical to submitting a complete and accurate application to NIH. There are fields within the SF424 (R&R) application components that, 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 is comprised of data arranged in separate components. Some components are required, others are optional. The forms package associated with this FOA in <u>Grants.gov/APPLY</u> will include all applicable components, required and optional. A completed application in response to this FOA will include the following components:

#### **Required Components:**

SF424 (R&R) (Cover component)

Research & Related Other Project Information Component

Research & Related Senior/Key Person Profile Component

#### **Optional Components:**

PHS 398 Cover Letter Component

Note: Cover letters should be included only when submitting changed/corrected or late applications. **Do not submit cover letters with initial submissions.** 

Foreign Organizations (Non-domestic (non-U.S.) Entity)

NIH policies concerning grants to foreign (non-U.S.) organizations can be found in the *NIH Grants Policy Statement* at: <a href="http://grants.nih.gov/grants/policy/nihgps">http://grants.nih.gov/grants/policy/nihgps</a> 2003/NIHGPS Part12.htm# Toc54600260.

The following applies to foreign organizations:

- Charge back of customs and import fees is not allowed.
- Format: Every effort should be made to comply with the format specifications, which are based upon a standard U.S. paper size of 8.5" x 11" within each PDF.
- Organizations must comply with Federal/NIH policies on human subjects, animals, and biohazards.
- Organizations must comply with Federal/NIH biosafety and biosecurity regulations. See <u>Section VI.2.</u>,
   "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 or that augment existing U.S. resources.

The application to be submitted to Grants.gov must include:

Area of Science Designation: Applicants must choose a research area from the following list:

- (01) Behavioral and Social Sciences
- (02) Clinical and Translational
- (03) Instrumentation and Engineering

- (04) Molecular, Cellular, and Chemical Biology
- (05) Pathogenesis and Epidemiology
- (06) Physiological and Integrative Systems
- (07) Quantitative and Mathematical Biology

The area of science is designated by entering the two-digit code in the "Applicant Identifier" field on the SF424 Cover Page Component. **Only one category may be designated.** Category selection will assist staff in assigning applications to evaluators and is not intended to limit the areas of biomedical research.

- Effort Commitment: Awardees are required to commit the major portion (at least 51%) of their research effort to activities supported by the NDPA. In their list of current and pending support, applicants must include a statement in the biographical sketch that, if chosen to receive an award, the applicant will commit a minimum of 51% of their research efforts to Pioneer Award activities.
- An abstract of no more than 300 words and no more than one page describing the goals of the project.
   This document is uploaded on the Research & Related Other Project Information Component form, Item
   6.)
- An essay of 3-5 pages that addresses the investigator's innovative vision for, and the significance of, the biomedical or behavioral problem to be addressed, and his/her qualifications to engage in groundbreaking research. The essay should describe the individual's view of the major challenges in biomedical or behavioral research to which he/she can make seminal contributions. No detailed scientific plan should be provided since the research plan is expected to evolve during the tenure of the grant. The essay should include the following sections within the 3-5 page limit:
- o **Project description:** What is the scientific problem that will be addressed, and why is this important? What are the pioneering, and possibly high-risk, approaches that, if successful, might lead to groundbreaking or paradigm-shifting results?
- o **Evidence of innovativeness:** What concrete evidence can you provide for your claim of innovativeness? For example, qualities common to many highly innovative people include an interest in, and the ability to integrate, diverse sources of information; an inclination to challenge paradigms and take intellectual risks; persistence in the face of failure; an ability to attract the right collaborators; and the energy and concentration necessary to plan and execute effective strategies for accomplishing goals.
- o **How the planned research differs from your past or current work:** Describe how the project represents a new and distinct direction for your research.

o **Suitability for NDPA program**: Why is the planned research uniquely suited to the stated goal of the NDPA program, rather than a traditional grant mechanism?

References are not required, but if included, must fit within the five-page limit. Figures and illustrations may be included, but must also fit within the five-page limit. The essay is uploaded on the Research & Related Other Project Information Component form, Item 7.

- A two-page biographical sketch. (Use the format for biographical sketches shown in Part III of the Application Guide, omitting Section C, Research Support.) This document is uploaded on the Research & Related Senior/Key Person Component form.
- A list of current and pending research support from all sources, including current year direct costs and percent effort devoted to each project. (Use the format shown in Part III of the Application Guide.)
   This document is uploaded on the Research & Related Senior/Key Person Component form.
- A one-page description of the applicant's single most significant research accomplishment.
   (Publications or other documents will not be accepted.) This document is uploaded on the Research & Related Other Project Information form, Item 11, "Other Attachments".

Format specifications for Text (PDF) Attachments: All attachments must be in PDF format. Follow format specifications for PDF attachments on page I-17 in the Application Guide.) Fonts: Use an Arial, Helvetica, Palatino, Linotype, or Georgia typeface, a black font color, and a font size of 11 points or larger. Type density: Including characters and spaces, must be no more than 15 characters per inch. Type may be no more than six lines per inch. Page margins: Use standard paper size (8 ½ " x 11). Use at least one-half inch margins (top, bottom, left, and right) for all pages. Avoid using a two-column format as it can cause difficulties when reviewing the document electronically. Do not include any information in a header or footer of the attachment. A header will be self-generated that references the name of the PD/PI. Page numbers for the footer will be system-generated in the complete application, with all pages sequentially numbered.

Special requirements for completing the SF424 (R&R) application are in Section IV.6, below.

#### 3. Submission Dates and Times

See Section IV.3.A for details.

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

Opening Date: December 1, 2006 (Earliest date an application may be submitted to Grants.gov) Letters of Intent Receipt Date(s): Not applicable.

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 Receipt Date(s): January 16, 2007

Letters of Reference Submission Date(s): January 16, 2007, 5:00 p.m. (EST)

Peer Review Date(s): April, 2007

Advisory Council to the Director Date(s): August, 2007 Earliest Anticipated Start Date(s): September 30, 2007

#### 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 NIH

To submit an application in response to this FOA, applicants should access this FOA via <a href="http://www.grants.gov/Apply">http://www.grants.gov/Apply</a> and follow steps 1-4. Note: Applications must only be submitted electronically. PAPER APPLICATIONS WILL NOT BE ACCEPTED.

#### 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 submission/receipt date(s). (See Section IV.3.A. for all dates.) If an application is not submitted by the receipt date(s) and time, the application may be delayed in the review process or not reviewed.

Once an application package has been successfully submitted through Grants.gov, any 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 business days to view the application image.

- If everything is acceptable, no further action is necessary. The application will automatically move forward for processing by the Division of Receipt and Referral, Center for Scientific Review, NIH, after two business days.
- 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 the AOR/SO determines that warnings should be addressed. Reminder: warnings do not stop further application processing. If an application submission results in warnings (but no errors) it will automatically move forward after two business days if no action is taken. Please remember that some warnings may not be applicable or may need to be addressed after application submission.
- 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 <u>eRA Commons</u> <u>Helpdesk</u> 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 <a href="NIH late policy">NIH late policy</a> 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 days.

Upon receipt, applications will be evaluated for completeness and eligibility by NIH staff. Incomplete applications will not be reviewed.

There will be an acknowledgement of receipt of applications from Grants.gov and the <u>Commons</u>. Information related to the assignment of an application to a Scientific Review Group is also in the Commons.

The Commons will send e-mail notifications to both the applicant and the referee acknowledging receipt of a letter of reference

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

#### 4. Intergovernmental Review

This initiative is not subject to *intergovernmental review*.

#### 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*.

# 6. Other Submission Requirements

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

The NIH requires the PD/PI 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.

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 "Registration FAQs – Important Tips -- <u>Electronic Submission of Grant Applications</u>."

#### **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, <u>Electronic Submission of Grant Applications</u>."

#### **Research Plan Component Sections**

Not applicable.

#### Foreign Applications (Non-domestic (non-U.S.) Entity)

Except as noted in Section IV, #2, application instructions for foreign entities are identical to those for domestic institutions.

All application instructions outlined in the SF 424 (R&R) Application Guide are to be followed, incorporating "Just-in-Time" information concepts, with the following additional requirements for Pioneer Award applications. Applications that do not conform to the specific instructions detailed below will not be reviewed. Please see the Frequently Asked Questions on the Pioneer Web site at <a href="http://nihroadmap.nih.gov/pioneer/fag.aspx">http://nihroadmap.nih.gov/pioneer/fag.aspx</a>.

#### 1. SF424 (R&R) (COVER COMPONENT):

Fill out each section using the instructions below. Note that items that are starred (\*) in the application are mandatory.

Item Number and Title	Instructions
	Check "Application". (See Section IV. 3C for information on Changed/Corrected Applications.)
2. Date Submitted	Enter date in this format: mm/dd/yyyy.
Applicant Identifier	Enter two-digit code for Area of Science. Only one area may be selected.

	01 - Behavioral and Social Science
	02 - Clinical Research
	03 - Instrumentation and Engineering
	04 - Molecular and Cellular Biology
	05 - Pathogenesis and Epidemiology
	06 - Physiological and Integrative Systems
	07 - Quantitative and Mathematical Biology
3. Date Received by State	Leave blank.
State Application Identifier	Leave blank
4. Federal Identifier	Leave blank
5. Applicant Information	Enter information for Applicant Organization
Organizational DUNS	Must match the number entered in the eRA Commons Institutional Profile for the applicant organization.
Legal Name	Enter the legal name of the Applicant Organization
Department	Enter the name of the primary organizational department, service,
	laboratory, or equivalent level within the organization that will undertake the assistance activity.
Division	Enter the name of the primary organizational division, office, or major subdivision that will undertake the assistance activity.
Address	Enter the address for the Applicant Organization
6. Employer Identification Number (EIN or TIN)	Enter the EIN or TIN as assigned by the Internal Revenue Service. If

	organization is not in the U.S., enter "44-4444444. If you have a 12-digit
	EIN established for grant awards from NIH or other PHS agencies, enter all
	12 digits.
7. Type of Applicant	This information is for the <b>Applicant Organization</b> , not a specific individual.
8. Type of Application	Must be "New"
Person to be contacted on matters involving this	Enter information for the Administrative or Business Official, not the
application	PD/PI. This person is the individual to be notified if additional information is
	needed and/or if an award is made.
9. Name of Federal Agency	Pre-populated
10. Catalog of Federal Domestic Assistance Number	Pre-populated: 93.310 – Trans-NIH Research Support
<b>3</b>	Т р р р л л л л л л л л л л л л л л л л
11. Descriptive Title of Applicant's Project	Limited to 81 characters, including spaces and punctuation
221 Descriptive Title of Applicant of Florest	punited to 52 shardeters, including spaces and punited atom
12. Areas Affected by Project	Enter "n/a" for not applicable
22. Areas Areacea by Froject	Enter the for not applicable
13. Proposed Project	Enter start date: 09/30/2007; Enter end date: 09/29/2012.
13. Proposed Project	Enter start date. 09/30/2007, Enter end date. 09/29/2012.
14 Commonstant Birthists of	Enter the Communicational District in the formation Only and Chate
14. Congressional Districts of	Enter the Congressional District in the format: 2 character State
a. Applicant	Abbreviation – 3 character District Number. Examples: CA-005 for
	California's 5 <sup>th</sup> district, CA-012 for California's 12 <sup>th</sup> district. If outside the
	U.S., enter 00-0000. To locate your congressional district, visit the
	Grants.gov Web site.
Congressional Districts of	Enter the Congressional District in the format: 2 character State
b. Project	Abbreviation – 3 character District Number. Examples: CA-005 for
	California's 5 <sup>th</sup> district, CA-012 for California's 12 <sup>th</sup> district. If all districts for
	a state are affected, enter "all" for the district number. Example: MD-all for
	all congressional districts in Maryland. If nationwide (all districts in all
	states) enter US-all. To locate your congressional district, visit the
	Grants.gov Web site. Attach an additional list of Project Congressional
	Districts on page 2 (Item 21), if needed.

15. Project Director/Principal Investigator Contact Information	Enter information for <b>PD/PI</b> here.
16. Estimated Project Funding  a. Total Estimated Project Funding	Enter <b>\$2,500,000</b>
b. Total Federal & Non-Federal Funds	Enter \$2,500,000
c. Estimated Program Income	Enter "0" (Zero)
17. Is Application Subject to Review by State Executive Order 12372 Process?	Check "No"
18. Statement and Signatures (Complete Certification)	Read statement in box 18. Check "I agree" box to provide required certifications and assurances. This field is required.
19. Authorized Representative (Signing Official)	Completed by the AOR/SO.
20. Pre-Application	Leave Blank.
21. List of Project Congressional Districts	See item 14b above.

#### 2. RESEARCH & RELATED OTHER PROJECT INFORMATION COMPONENT:

Fill out each section using the instructions below. Note that items that are starred (\*) in the application are mandatory.

Item Number and Title	Instructions
1. Are Human Subjects Involved?	Check "No" (Note: This information will be requested at the time of award)
2. Are Vertebrate Animals Used?	Check "No" (Note: This information will be requested at the time of award)
3 4.	Answer as appropriate.

5. a. Activities Outside U.S./International  Collaborators	Answer as appropriate.
5.b. Identify Countries	Enter the countries with which international cooperative activities are involved.
5.c. Optional Explanation	Do not use. Foreign justifications are not required at the time of application. Item 11 is used to upload the "most significant research
6. Project Summary/Abstract	Attach abstract. (Maximum of 300 words and no more than one page;  PDF format).
7. Project Narrative	Attach essay (Maximum of five-pages; PDF format).
8. Bibliography & References Cited	<b>Do not use.</b> If you choose to include references, they must be included in the essay, subject to the 5-page limit.
9. Facilities & Other Resources	Do not use.
10. Equipment	Do not use.
11. Other Attachments	Attach description of your most significant research accomplishment  (one page maximum, PDF format).

Note: Applications found not to comply with the page limit requirements may lead to rejection of the application during agency validation or delay in the review process.

#### 3. SF424 (R & R) SENIOR/KEY PERSON PROFILE COMPONENT:

Fill out each section using the instructions below. Note that items on the application that are starred (\*) are mandatory.

Complete items only for Project Director/Principal Investigator. **Do not submit profiles for other senior/key personnel.** 

Item Title	Instructions
Credential, e.g., agency login	Enter PD/PI's eRA/Common's UserName
Creuential, e.g., agency login	Litter FDF1's exaccommon's osername
Project Role	Prefilled
Other Project Role Category	Leave blank
Attach Biographical Sketch	Attach biographical sketch here (two-page maximum, PDF format). Use
	the format shown on page I-58 of the Application Guide, omitting Section C,
	Research Support (see below).Be sure to include statement indicating your
	citizenship status.
Attach Current & Pending Support	Attach a list of Current and Pending Support here (PDF format). Use the
	format shown on pages III-8 and III-9 of the Application Guide. Be sure to
	include statement affirming that you will devote at least 51% of research
	effort to Pioneer Award project.
Bustilla Canian Kan Banan 1	Do was was
Profile – Senior Key Person 1	Do not use.
Additional Senior/Key Person Profile(s)	Do not use.
Additional Biographical Sketch(es) (Senior/Key Person)	Do not use.
Additional Current and Pending Support(s)	Do not use.

Note: Applications found not to comply with the page limit requirements may lead to rejection of the application during agency validation or delay in the review process.

#### 4. PHS 398 Cover Letter File (Optional):

Cover letters should be included only when submitting Changed/Corrected or late applications. **Do not submit cover letters for initial submissions.** The cover letter should contain **only** the following information:

- 1. PD/PI name
- 2. Funding Opportunity Title: 2007 NIH Director's Pioneer Award Program (DP1)

- 3. For late applications, include an explanation of the delay. (See Late Application Policy in Section 2.14 of the Application Guide.)
- 4. For Changed/Corrected Applications after the submission deadline, include an explanation of the reason for the Changed/Corrected Application.

(See full instructions for submitting the Cover Letter Component in Section 5.2 of the Application Guide. Note: Items 3 – 6 of the Guide do not apply to Pioneer Award applications.)

#### **LETTERS OF REFERENCE:**

Letters of reference are an important component of the application for the NIH Director's Pioneer Award Program (NDPA). Applicants for the NDPA must arrange to have **three** (and no more than three) letters of reference submitted on their behalf to the NIH eRA Commons Web site at <a href="https://commons.era.nih.gov/commons/reference/submitRefereeInformation.jsp">https://commons.era.nih.gov/commons/reference/submitRefereeInformation.jsp</a>.

Letters **may** be submitted beginning December 1, 2006, and **must** be submitted no later than 5:00 p.m. (EST) January 16, 2007.

Applications that are missing letters of reference may be considered non-responsive and may not be reviewed. Late letters will not be accepted.

Submission of a letter of reference requires that the referee provide information including (a) the PI's Commons user name, (b) the PI's first and last name as they appear on the PI's Commons account, and (c) the number assigned to this Funding Opportunity Announcement (RFA-RM-07-005).

Confirmation emails will be sent to both the referee and the applicant following letter submission. The confirmation sent to the applicant will include the referee's name and the date the letter was submitted. The confirmation sent to the referee will include the referee and applicant's names, a confirmation number, and the date the letter was submitted.

The applicant and the AOR/SO may check the status of submitted letters by logging into their Commons account and accessing the "check status" screen for this application. The applicant is responsible for reviewing the status of submitted letters and contacting referees to ensure that letters are submitted by the receipt deadline.

Applicants should provide the following instructions to their referees. This information is also available on the Pioneer Web site at <a href="http://nihroadmap.nih.gov/pioneer/LettersofReferenceFormat.aspx">http://nihroadmap.nih.gov/pioneer/LettersofReferenceFormat.aspx</a>:

#### **Instructions for Referees:**

In two pages or less, describe the qualities the applicant possesses that support his/her claim to scientific innovativeness and creativity. When possible, give specific examples that illustrate these qualities. Address the likelihood that the applicant will conduct groundbreaking research in the area he/she proposes for the NIH Director's Pioneer Award.

Please put the name of the applicant at the top of the letter. Also, be sure to include your name and title in the letter. Letters **may** be submitted to the NIH eRA Commons at <a href="https://commons.era.nih.gov/commons/reference/submitRefereeInformation.jsp">https://commons.era.nih.gov/commons/reference/submitRefereeInformation.jsp</a> beginning December 1, 2006, and **must** be submitted no later than 5:00 p.m. (EST), January 16, 2007.

The following information will be entered by the referee on the on-line form at the time of submission:

- Last name, first name of referee (Required)
- Middle initial (MI) of referee (Not Required)
- Email of referee (Required)
- Commons user name of PI (Required)
- PI's first and last name, as they appear on the PI's Commons account (Required) (will be validated to ensure they match)
- The number assigned to this Funding Opportunity Announcement (Required enter RFA-RM-07-005).
- Reference letter confirmation number (Required only if resubmitting a letter; not required otherwise)
- Referee institution/affiliation (Required)
- Referee department (Required)
- Reference letter two pages maximum; PDF format

After you have submitted your letter, both you and the applicant will receive a confirmation of receipt by email. Your email confirmation will include a Reference Letter Submission Confirmation Number. The Confirmation Number will be required when resubmitting letters. Please print the confirmation email for your records.

Revised letters may be submitted until 5:00 p.m. (EST), January 16, 2007.

Please see the Frequently Asked Questions at <a href="http://nihroadmap.nih.gov/pioneer/faq.aspx">http://nihroadmap.nih.gov/pioneer/faq.aspx</a>. Send question to <a href="mailto:Pioneer@NIH.gov">Pioneer@NIH.gov</a>.

# **Plan for Sharing Research Data**

Not applicable

# **Sharing Research Resources**

# 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 will be evaluated based on the likelihood that the applicant will pursue a pioneering approach to a problem of relevance to biomedical or behavioral research, the absence of alternative funding to pursue this direction; and compelling justification for the advantage of evaluation by the NDPA process rather than by the standard peer review process. In particular, reviewers will evaluate:

- The scientific problem to be addressed: The biomedical or behavioral significance/importance of the
  problem, the likelihood that, if successful, the project will have a significant impact on this problem, and
  the innovativeness of the project.
- The investigator: Evidence for the investigator's claim of innovativeness/creativity (innovation density), and the demonstrated ability of the investigator to devote 51% or more effort on NDPA project.
- The suitability for NDPA mechanism: Evidence that the proposed project is of sufficient risk/impact to make it more suitable for the NDPA than for the traditional NIH grant mechanism and that it is distinct from other research previously or currently conducted by the investigator.

The following will be considered in making funding decisions:

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

Sufficient funds have been set aside in 2007 to provide 5-10 awards. The awards will be for \$500,000 in direct costs each year for five years. Although there are no stipulations on the research agenda, awardees will be required to submit a report on June 1 of each year describing the activities conducted during the year through the NDPA, to submit a final progress report at the end of the grant period, and to participate in an annual symposium on the NIH campus. This symposium will allow awardees to share their ideas, progress, and experience with each other, the research community, and NIH staff.

Applications that are complete and responsive to the RFA will be evaluated electronically by a multidisciplinary group of outside experts. Those candidates who are identified as the most outstanding will be invited to NIH for interviews in July 2007. Interviews will be conducted by a panel of distinguished outside experts. The Advisory Committee to the Director (ACD), NIH, will conduct the final level of review. The Director, NIH, will make the final selection of awardees based on the evaluations by the outside experts, the recommendations of the ACD, and programmatic considerations. Final selections will be publicly announced, and awards made, by the end of September 2007.

#### 2.A. Additional Review Criteria:

Not applicable.

#### 2.B. Additional Review Considerations

Not applicable.

#### 2.C. Sharing Research Data

Not applicable.

#### 2.D. Sharing Research Resources

Not applicable.

#### 3. Anticipated Announcement and Award Dates

Finalists selected for interviews and those applicants not selected for interviews will be notified in May, 2007. Awardees will be notified in August, 2007, and awards will begin September 20, 2007.

# Section VI. Award Administration Information

#### 1. Award Notices

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 <u>NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General.</u>

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 <u>Section IV.5.</u>, "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.

The following terms and conditions will be incorporated into the NoA and will be provided to the PD/PI and the appropriate institutional official at the time of award:

- 2a. When issuing statements, press releases, and other documents describing projects or programs funded with Roadmap funds, please use the following acknowledgement: "This work was funded by the National Institutes of Health through the NIH Director's Pioneer Award Program, grant number DP1-ODxxxxxx. Information on the Pioneer Award Program, which is part of the NIH Roadmap for Medical Research, is at <a href="http://nihroadmap.nih.gov/pioneer/">http://nihroadmap.nih.gov/pioneer/</a>.
- 2b. As indicated in the FOA, awardees are expected to commit the major portion (at least 51%) of their research effort to activities supported by the NIH Director's Pioneer Award.
- 2c. Funds provided should cover travel costs to the annual NIH Director's Pioneer Awards Symposium in Bethesda, Maryland.

#### 3. Reporting

Although there are no stipulations on the research agenda, awardees will be required to submit the Non-Competing Grant Progress Report (PHS 2590) annually and financial statements as required in the NIH Grants Policy Statement. Awardees will also be required to submit progress reports at the end of each grant period and Final Invention Statements and Financial Status Reports at the end of the award.

# **Section VII. Agency Contacts**

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

Judith H. Greenberg, Ph.D.

Director, Division of Genetics and Developmental Biology

National Institute of General Medical Sciences

National Institutes of Health

Building 45, Room 2As25, MSC 6200

Bethesda, Maryland 20892-6200

Phone: 301-594-3555
Fax: 301-480-2228
Email: pioneer@nih.gov

Information about the Pioneer Awards is at <a href="http://nihroadmap.nih.gov/pioneer/">http://nihroadmap.nih.gov/pioneer/</a>. Please see the Frequently Asked Questions at <a href="http://nihroadmap.nih.gov/pioneer/faq.aspx">http://nihroadmap.nih.gov/pioneer/faq.aspx</a>.

The NIH Director's Pioneer Award is among several initiatives being undertaken as a part of the NIH Roadmap. To learn more about the NIH Roadmap see the NIH Roadmap Website at <a href="http://nihroadmap.nih.gov">http://nihroadmap.nih.gov</a>.

# **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 (<a href="http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm">http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm</a>).

#### **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*, <a href="http://grants.nih.gov/grants/guide/notice-files/not98-084.html">http://grants.nih.gov/grants/guide/notice-files/not98-084.html</a>).

#### **Sharing Research Data:**

Investigators submitting an NIH application seeking \$500,000 or more in direct costs in any single year are expected to share data sharing (<a href="http://grants.nih.gov/grants/policy/data\_sharing">http://grants.nih.gov/grants/policy/data\_sharing</a>). A data-sharing plan will be required if an award is to be made.

Investigators should seek guidance from their institutions, on issues related to institutional policies and local 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 priority score.

#### 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 <a href="http://grants.nih.gov/grants/policy/a110/a110\_guidance\_dec1999.htm">http://grants.nih.gov/grants/policy/a110/a110\_guidance\_dec1999.htm</a>. 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.

#### **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 <a href="http://grants.nih.gov/grants/policy/model\_organism/index.htm">http://grants.nih.gov/grants/policy/model\_organism/index.htm</a>). 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 <a href="https://www.nih.gov/grants/policy/model\_organism/index.htm">NIH Grants Policy Statement</a>. A model organism sharing plan will be required if an award is to be made.

#### 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. 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" (<a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html</a>); 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 <a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html</a>.

#### **Human Embryonic Stem Cells (hESC):**

Criteria for federal funding of research on hESCs can be found at <a href="http://stemcells.nih.gov/index.asp">http://stemcells.nih.gov/index.asp</a> and at <a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html</a>. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (<a href="http://escr.nih.gov">http://escr.nih.gov</a>). 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. Applications that do not provide this information will be returned without review.

#### **NIH Public Access Policy:**

NIH-funded investigators are requested to submit to the NIH manuscript submission (NIHMS) system (<a href="http://www.nihms.nih.gov">http://www.nihms.nih.gov</a>) at PubMed Central (PMC) an electronic version of the author's final manuscript upon acceptance for publication, resulting from research supported in whole or in part with direct costs from NIH. The author's final manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process.

NIH is requesting that authors submit manuscripts resulting from 1) currently funded NIH research projects or 2) previously supported NIH research projects if they are accepted for publication on or after May 2, 2005. The NIH Public Access Policy applies to all research grant and career development award mechanisms, cooperative agreements, contracts, Institutional and Individual Ruth L. Kirschstein National Research Service Awards, as well as NIH intramural research studies. The Policy applies to peer-reviewed, original research publications that have been supported in whole or in part with direct costs from NIH, but it does not apply to book chapters, editorials, reviews, or conference proceedings. Publications resulting from non-NIH-supported research projects should not be submitted.

For more information about the Policy or the submission process, please visit the NIH Public Access Policy Web site at <a href="http://publicaccess.nih.gov/">http://publicaccess.nih.gov/</a> and view the Policy or other Resources and Tools, including the <a href="https://publicaccess.nih.gov/">Authors</a> <a href="https://publicaccess.nih.gov/">Manual</a>.

#### 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 (<a href="http://www.hhs.gov/ocr/">http://www.hhs.gov/ocr/</a>) 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 <a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html</a>.

#### **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 <a href="http://www.health.gov/healthypeople">http://www.health.gov/healthypeople</a>.

#### **Authority and Regulations:**

This program is described in the Catalog of Federal Domestic Assistance at <a href="http://www.cfda.gov/">http://www.cfda.gov/</a> and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. 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 <a href="https://www.cfda.gov/">NIH Grants Policy Statement</a>.

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: <a href="http://www.lrp.nih.gov">http://www.lrp.nih.gov</a>.