

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 FOA is developed as an NIH Roadmap Initiative, <http://nihroadmap.nih.gov>. All NIH Institutes and Centers are participating. This FOA is being administered by the National Institute of General Medical Sciences (NIGMS) on behalf of NIH.

Title: 2009 NIH Director's Pioneer Award Program (DP1)

Announcement Type

This is reissue of [RFA-RM-08-013](#).

Request for Applications (RFA) Number: RFA-RM-09-001

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](#).

Note: Electronic application submission is required for this FOA. The new Adobe versions of the application forms are not yet available.

Please check back in December to download the application package. See Notice [NOT-OD-08-117](#).

Catalog of Federal Domestic Assistance Number(s)

93.310

Key Dates

Release/Posted Date: October 27, 2008

Opening Date: April 15, 2009 (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 Due Date(s): May 15, 2009

Reference Letter Submission/Receipt Dates: April 15, 2009 – 5:00 pm (EDT) May 15, 2009

Peer Review Date(s): June 2009

Advisory Council to the Director Review Date: August 2009

Earliest Anticipated Start Date(s): September 30, 2009

Additional Information: To Be Available Date (October 17, 2008): Frequently Asked Questions (FAQs) at <http://nihroadmap.nih.gov/pioneer/faq.apsx>

Expiration Date: May 16, 2009

Due Dates for E.O. 12372

Not Applicable

Additional Overview Content

Executive Summary

- **Purpose.** The NIH Director's Pioneer Award Program complements NIH's traditional, investigator-initiated grant programs by supporting individual scientists of exceptional creativity who propose pioneering and possibly transformative approaches to addressing major biomedical or behavioral challenges. To be considered pioneering, the proposed research must reflect ideas substantially different from those already being pursued in the investigator's laboratory or elsewhere. The NIH Director's Pioneer Award Program is a [High-Risk Research](#) initiative of the NIH Roadmap for Medical Research. The 2009 Pioneer Award competition will proceed in two phases. The first phase is a pre-application phase in response to [PAR-09-012](#). Pre-applications will be evaluated by a group of external reviewers, and those investigators whose submissions are judged to be the most outstanding will be notified of the opportunity to submit full applications under this FOA. The 2009 Pioneer awardees will be selected from this group of applicants.
- **Mechanism of Support.** This FOA will utilize the DP1 grant mechanism. Pre-applications for 2009 Pioneer Awards were solicited under [PAR-09-012](#). Applicants must read both FOAs.
- **Funds Available and Anticipated Number of Awards.** Total funding available is approximately \$5 million for the five-year period. It is anticipated that at least 5-10 awards will be made in 2009.
- **Budget and Project Period.** Awards will be for up to \$500,000 in direct costs each year for five years.
- **Eligible Institutions/Organizations.** Institutions/organizations listed in [Section III, 1.A.](#) are eligible to apply.
- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Only investigators who submitted a pre-application (X02), in response to [PAR-09-012](#) are eligible to submit full applications under this FOA. Recipients of the Pioneer Award (DP1) are required to commit the major portion (at least 51%) of their research effort to activities supported by the Pioneer Award. Applicants who were not selected for an award in prior years may submit pre-applications this year. There are no citizenship or residency requirements.
- **Number of PDs/PIs.** Only one PD/PI (i.e., no multiple PDs/PIs) may be designated on the application.
- **Number of Applications.** Applicants may submit only one application as a PD/PI in response to this FOA. There is no limit to the number of applications that an institution may submit.
- **Resubmissions.** Resubmission applications are not allowed. All applications must be submitted as "new" regardless of any previous submissions to the Program.
- **Renewals.** Renewal applications are not permitted in response to this FOA.
- **Special Date(s).** This FOA uses non-standard due dates. See [Receipt, Review and Anticipated Start Dates](#).
- **Application Materials.** See [Section IV.1](#) for application materials.
- **General Information.** For general information on SF424 (R&R) Application and Electronic Submission, see these Web sites:
 - 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: <http://era.nih.gov/ElectronicReceipt/>
- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY 301-451-5936.

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Part II - Full Text of Announcement

Section I. Funding Opportunity Description

1. Research Objectives

The NIH Director's Pioneer Award Program is a unique aspect of the NIH Roadmap for Medical Research (<http://nihroadmap.nih.gov>). Pioneer Awards are 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 on a broad area of biomedical or behavioral research, and the term “award” is used to mean a grant for conducting research, rather than a reward for past achievements. To be considered pioneering, the proposed research must reflect ideas substantially different from those already being pursued in the investigator's laboratory or elsewhere. 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 proposed research may be in any scientific area relevant to the mission of NIH but 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.

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

Section II. Award Information

1. Mechanism of Support

This announcement utilizes the DP1 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.

2. Funds Available

This is a Roadmap initiative. The NIH Common Fund has set aside sufficient funds in FY2009 to provide at least 5-10 awards, contingent upon the availability of funds and the submission of a sufficient number of meritorious applications.

Awards will be for up to \$500,000 in direct costs each year for five years, plus applicable Facilities and Administrative costs to be determined at the time of award.

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
- U.S. Territory or Possession
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- Regional Organizations
- Other(s):
 - Eligible Agencies of the Federal Government
 - Faith-based or Community-based Organizations

Foreign organizations are not eligible to apply.

1.B. Eligible Individuals

Applicants must have submitted a pre-application under [PAR-09-012](#) to be eligible to submit a full application in response to this FOA. The full application may not be significantly different from what was proposed in the X02 application. Significant differences between the full application and the X02 may result in the full application not being reviewed.

Recipients of the Pioneer Award (DP1) are required to commit the major portion (at least 51%) of their research effort to activities supported by the Pioneer Award. Applicants who were not selected for an award in prior years may submit pre-applications this year. There are no citizenship or residency requirements. NIH intramural investigators are not eligible for support under this program.

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

Resubmissions of applications will not be allowed under this FOA.

Renewals applications are not allowed under this FOA.

Applicants may submit only one application as a PD/PI in response to this FOA. There is no limit to the number of applications institutions may submit. All applications will be considered “new” applications, regardless of any previous applications to the Pioneer Award Program.

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.

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.
- The 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.
- This registration/affiliation must be done by the AOR/SO or his/her designee who is already registered in the Commons.

Note that for this FOA, only one PD/PI will be allowed (i.e., no multiple PD/PIs).

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

Note 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 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/PI's assigned eRA Commons User ID). Agency-specific instructions for such fields are clearly identified in the Application Guide. For additional information, see "Frequently Asked Questions – Application Guide, [Electronic Submission of Grant Applications](#)."

The SF424 (R&R) application has several components. Some components are required, others are optional. The forms package associated with this FOA in Grants.gov/APPLY 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

Optional Components:

Cover Letter Component: Note: Cover letters should be submitted only when submitting a **Changed/Corrected Application** after the submission date, and should include an explanation for the late submission.

SPECIAL INSTRUCTIONS

Applications proposing multiple PD/PIs are not allowed.

ADDITIONAL APPLICATION INSTRUCTIONS

The application items include all those required for the Pioneer Award pre-applications (X02) submitted under [PAR-09-012](#). The contents of these items must be substantially the same as those submitted in the pre-application. In addition, applicants submitting full applications in response to this FOA must arrange to have three letters of reference submitted on their behalf and must submit information on human and animal subjects.

Because these applications and most NIH applications with receipt dates after January 1, 2009 must be submitted using Adobe forms, there may be minor changes to the field numbers on the required application forms and to the location where documents are uploaded. Detailed instructions for completing the required application components indicated above will be included in a subsequent Notice.

The following instructions are specific to the Pioneer Award (DP1) applications and are exceptions to the general SF424 instructions. Applications that do not conform to the specific instructions detailed below will not be reviewed.

All of the following must be submitted on the SF424 (R&R) Other Project Information Component for the application to be considered complete. The text must be substantially the same as that submitted in the pre-application in response to [PAR-09-012](#). Only minor changes, such as fixing typographical errors, will be allowed.

I. Abstract: The abstract text, which describes the goals of the project, must be substantially the same as that submitted for the pre-application in response to [PAR-09-012](#). Only minor changes, such as fixing typographical errors, will be allowed. As indicated in [PAR-09-012](#), the abstract must have no more than 300 words and must not exceed one page. The abstract must contain text only – no figures, animations, or web links to provide further information.

II. Public Health Relevance Statement: A brief statement written in plain language about how the proposed research can positively impact public health.

III. Essay: The essay text must be substantially the same as that submitted in the pre-application in response to [PAR-09-012](#). Only minor changes, such as fixing typographical errors, will be allowed. For completeness, a description of the essay requirements as indicated in [PAR-09-012](#) follows. 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 the investigator's qualifications to engage in groundbreaking research. The essay should describe the investigator's view of the major challenges in biomedical or behavioral research to which he/she can make seminal contributions. The scientific plan should be provided in broad terms because the research plan is expected to evolve during the tenure of the grant. The essay should include the following in the order given with the headings as shown:

1. 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?

2. 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.

3. How the Planned Research Differs From My Past or Current Work: Describe how the project represents a new and distinct direction for your research.

4. Suitability for Pioneer Award Program: Why is the planned research uniquely suited to the stated goal of the Pioneer Award program, rather than a traditional grant mechanism?

Literature 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. Do not include links to websites to provide further information. No animations (movies) are allowed in any documents.

Note that the description of the most significant research accomplishment and the human subjects/animal subjects information also will be attached using this item number.

IV. Summary of the Investigator's Most Significant Research Accomplishment. The text must be substantially the same as that submitted in the pre-application in response to [PAR-09-012](#). Only minor changes, such as correction of typographical errors, will be allowed. This is limited to one page. Publications or similar documents will not be accepted.

V. Biographical Sketch: A two-page biographical sketch for the PD/PI only. (Use the sample format shown in the URL in Section 4.5.2 of the Application Guide (**omitting Section C, Research Support**)). Only the Biographical Sketch of the applicant should be submitted. No other persons should be designated as key personnel and no other biographical sketches should be uploaded.

VI. List of Current and Pending Research Support: 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 Section 3.1.1.8 of the Application Guide.) The effort commitment statement (described below) must be included in this document. Applicants must also provide a brief statement of the facilities to be used for the conduct of the research in this document.

VII. Effort Commitment: Awardees are required to commit at least 51% of their research effort to the project supported by the Pioneer Award. Applicants must include a statement to indicate that, if chosen to receive an award, the applicant will commit a minimum of 51% of his/her research effort to the project supported by the Pioneer Award. This statement must be included in the list of current and pending support.

VIII. Human Subjects / Animal Subjects: If applicable, provide information regarding human subjects protection, inclusion plans, animal welfare, IRB, and IACUC assurance as described in the SF424 instructions.

IX. Letters of Reference: Applicants must arrange to have three (and no more than three) letters of reference submitted on their behalf. Applications with fewer than three letters of reference may be considered non-responsive and may not be reviewed. Late letters will not be accepted. Applicants are responsible for monitoring the submission of their letters to ensure that three letters have been submitted prior to the submission deadline. Applicants can check the status of their letters in the application grant folder in the Commons.

Referees may submit letters from April 15, 2009 to 5:00 pm (EDT), May 15, 2009 at <https://commons.era.nih.gov/commons/reference/submitRefereelInformation.jsp> (Note: The letter writer does not need a Commons account to submit a letter.)

To submit letters, referees will need the following information from the applicant:

- **Funding Opportunity Number (FOA)** for this announcement RFA-RM-09-001;
- **The applicant's Commons User Name** (Note: Referees do not have to be registered in the Commons and do not need their own Commons User Name – only the Commons User Name of the applicant is required);
- **The applicant's last name** (note – the name must match exactly the applicant's name in the Commons);
- **The URL to the letter submission page** (<https://commons.era.nih.gov/commons/reference/submitRefereelInformation.jsp>)

Applicants are encouraged to send the instructions for referees at (<http://nihroadmap.nih.gov/pioneer/LettersofReferenceFormat.aspx>) to each of their referees along with the information above. Letters of reference are confidential. Applicants will not have access to the letters.

Email confirmations will be sent to the applicant and the referee. The confirmation sent to the applicant will include the referee's name and the date and time the letter was submitted. The confirmation sent to the referee will include the referee

and applicant's names, a confirmation number, and the date and time the letter was submitted. Referees should record the confirmation number as it is required when submitting revisions to reference letters.

Note: Because email can be unreliable, it is the applicant's responsibility to check the status of his/her letters of reference periodically in the Commons.

Applicants are encouraged to send the following instructions to their referees:

Instructions for Referees:

Letters **may** be submitted to the Commons at <https://commons.era.nih.gov/commons/reference/submitRefereeInformation.jsp>

beginning April 15, 2009, and **must** be submitted no later than 5:00 p.m. (EDT), May 15, 2009. Late letters will not be accepted and applications with fewer than three letters may not be reviewed. Letters must be submitted electronically – paper copies will not be accepted.

The applicant's name should be placed at the top of the letter. Although signatures are not required, the letter must include a signature block with the referee's full name, title, institution, and contact information.

In two pages or less, describe the applicant's qualities 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 proposed research area.

The following information is required and must be entered on the letter submission page at the time of submission:

- **Referee** Information:
- **Referee's** First and Last Name (Required)
- **Referee's** Middle Initial (MI) (Not Required)
- **Referee's** Email Address (Required)
- **Referee's** Institution/Affiliation (Required)
- **Referee's** Department (Required)

Note: The letter submission page can be accessed without signing into the Commons, and referees do not have to be registered in the Commons. Referees must provide the applicant's Commons User Name and the other information detailed in this section.

- **Applicant Information** (to be provided to referees by applicants):
- **Applicant's** Commons User Name (Required)
- **Applicant's** Last Name (Required). (Note: must match exactly the applicant's name in the Commons)
- **Funding Opportunity Number** (FOA) of this announcement RFA-RM-09-001 (Required)
- **Confirmation Number** (Required only when resubmitting a letter for the current FOA)

Email confirmations will be sent to both the applicant and the referee following submission of the letter. The email confirmation will include a Confirmation Number that will be required when resubmitting letters. Please print the confirmation email for your records.

Note: If you submitted letters for Pioneer Award applicants in a prior year, you must submit new letters of reference this year. Previously submitted letters will not be retrieved.

Please see the detailed instructions on submitting letters of reference at <http://nihroadmap.nih.gov/pioneer/LettersofReferenceFormat.aspx> and the Frequently Asked Questions at

<http://nihroadmap.nih.gov/pioneer/faq.aspx>. Send questions to Pioneer@NIH.gov.

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

- The **Budget request** is entered only on Line 16. Awards are for up to \$2.5 million in direct costs for the five-year budget/project period. Funds may be requested for personnel (including co-investigators and collaborators), supplies, equipment, sub-contracts, and other allowable costs. Only the five-year total – \$2.5 million - should be entered on Line 16. A detailed budget is not requested and will not be accepted.
- No other documentation, such as letters of collaboration or biographical sketches of other personnel will be accepted. Information about personnel other than the PD/PI is not required, but may be included within the 3-5-page essay.

Format specifications for Text (PDF) Attachments: All attachments must be in PDF format. Follow format specifications for PDF attachments in the Application Guide (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_Ver2.pdf)

3. Submission Dates and Times

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

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

Opening Date: April 15, 2009 (Earliest date an application may be submitted to Grants.gov)

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

Application Due Date(s): May 15, 2009

Reference Letter Submission Dates: April 15, 2009 – May 15, 2009

Peer Review Date(s): June 2009

Advisory Council to the Director Review Date(s): August 2009

Earliest Anticipated Start Date(s): September 30, 2009

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 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.**

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.

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 weekdays (Monday – Friday, excluding Federal holidays) to view the application image to determine if any further action is necessary.

- 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 FOA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. 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 FOA must **not** include an “Introduction” describing the changes and improvements made, and the text must **not** be marked to indicate the changes from the previous unfunded version of the application.

4. Intergovernmental Review

This initiative is not subject to [intergovernmental review](#).

5. Funding Restrictions

All 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 and Information

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

Not applicable.

Appendix Materials

Appendices are not allowed and will not be accepted. Applications that contain attachments other than those specified may be rejected during the agency validation process.

Resource Sharing Plan(s)

The following resource sharing plans will be requested as just-in-time information if an award is being considered:

- Data Sharing Plan.
- Sharing Model Organisms.
- Genome Wide Association Studies (GWAS).

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

Review of applications for this FOA will be conducted by an interview process. Investigators with outstanding submissions will be interviewed by a panel of distinguished external scientists. The interviews will be held in June 2009 on or near the NIH Campus in Bethesda, MD. A second level of review will be conducted, without further interviews, by the Advisory Committee to

the Director (ACD), NIH. The Director, NIH, will make the final selection of awardees based on the evaluations of the interview panel, the recommendations of the ACD, and programmatic considerations. Final selections will be announced publicly, and awards made, by the end of September 2009.

Applications that are complete and responsive to this FOA will be evaluated for scientific and technical merit by an appropriate peer review group in accordance with NIH peer review procedures (<http://grants1.nih.gov/grants/peer/>), using the review criteria stated below.

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.

The goals of NIH supported research are to advance our understanding of biological systems, to improve the control of disease, and to enhance health.

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. 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 (taking into consideration the investigator's career stage) and the demonstrated ability of the investigator to devote at least 51% of his/her effort on to activities supported by the Pioneer Award.
- **The suitability for Pioneer Award mechanism:** Evidence that the proposed project carries much higher levels of risk and potential impact than typical of NIH-supported research projects and evidence that the proposed project represents a distinctly new scientific direction.

The following criteria also will be used in assessing the merit of applications:

Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Approach: Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well-integrated, well-reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

Innovation: Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches or methodologies, tools, or technologies for this area?

Investigator: Is the PD/PI appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator?

Environment: Do(es) the scientific environment(s) in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment(s), or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

2.A. Additional Review Criteria

In addition to the above criteria, the following items will continue to be considered in the determination of scientific merit and the rating:

Protection of Human Subjects from Research Risk: The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed. See the "Human Subjects Sections" of the PHS398 Research Plan component of the SF424 (R&R).

Inclusion of Women, Minorities and Children in Research: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research will be assessed. Plans for the recruitment and retention of subjects will also be evaluated. See the "Human Subjects Sections" of the PHS398 Research Plan component of the SF424 (R&R)

Care and Use of Vertebrate Animals in Research: If vertebrate animals are to be used in the project, the adequacy of the plans for their care and use will be assessed. See the "Other Research Plan Sections" of the PHS398 Research Plan component of the SF424 (R&R).

Biohazards: If materials or procedures are proposed that are potentially hazardous to research personnel and/or the environment, determine if the proposed protection is adequate.

2.B. Additional Review Considerations

For this FOA, only overall costs and project duration are to be submitted with the application.

2.C. Resource Sharing Plan(s)

Will be expected if an award is considered likely, or an explanation of why sharing is not possible.

3. Anticipated Announcement and Award Dates

Awardees will be notified in August 2009. Public announcement of the awards will be made in September 2009. Awards will begin September 30, 2009.

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 [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 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](#).

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.

1. This award provides funding for an application submitted in response to RFA OD-09-001. This grant should be administered in accordance with the guidelines described in this specific announcement. These guidelines are in addition to the standard "Terms and Conditions" referenced in Section III of this Notice of Grant Award.

2a. When issuing statements, press releases, and other documents describing projects or programs funded as a NIH Director's Pioneer Award, 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-OD-xxxxxx. Information on the Pioneer Award Program is at <http://nihroadmap.nih.gov/pioneer/>.

2b. As indicated in the FOA, awardees are expected to commit at least 51% of their research effort to the project supported by the Pioneer Award.

2c. Awardees are expected to attend an annual symposium in the Bethesda, MD, area.

3. Reporting

Awardees will be required to submit a scientific progress report on June 1 of each year describing the progress made under this grant and to submit a final progress report, Final Invention Statement, and Financial Status Report at the end of the budget/project period.

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):

Ravi Basavappa, Ph.D.
National Institute of General Medical Sciences
National Institutes of Health
Building 45, Room 2As19e, MSC 6200
Bethesda, Maryland 20892-6200
Phone: 301-594-0828
Email: pioneer@nih.gov (e-mail is the strongly preferred method for inquiries)

2. Peer Review Contact(s):

Ravi Basavappa, Ph.D.
National Institute of General Medical Sciences
National Institutes of Health

Building 45, Room 2As19e, MSC 6200
Bethesda, Maryland 20892-6200
Phone: 301-594-0828
Email: pioneer@nih.gov (e-mail is the strongly preferred method for inquiries)

3. Financial/Grants Management Contact(s):

Marcia F. Cohn
Grants Management Officer
National Institute of General Medical Sciences
National Institutes of Health
Building 45, MSC 6200
Bethesda, Maryland 20892-6200
Phone: 301-594-3918
FAX: 301-480-2554
Email: cohnm@mail.nih.gov

Section VIII. Other Information

Required Federal Citations

Use of Animals in Research:

Recipients of PHS support for activities involving live, vertebrate animals must comply with PHS Policy on Humane Care and Use of Laboratory Animals (<http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf>) as mandated by the Health Research Extension Act of 1985 (<http://grants.nih.gov/grants/olaw/references/hrea1985.htm>), and the USDA Animal Welfare Regulations (<http://www.nal.usda.gov/awic/legislat/usdaleg1.htm>) as applicable.

Human Subjects Protection:

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

Data and Safety Monitoring Plan:

Data and safety monitoring is required for all types of clinical trials, including physiologic toxicity and dose-finding studies (Phase I); efficacy studies (Phase II); efficacy, effectiveness and comparative trials (Phase III). Monitoring should be commensurate with risk. The establishment of data and safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risks to the participants ("NIH 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 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 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" (<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-02-005.html>. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (<http://escr.nih.gov/>). It is the responsibility of the applicant to provide in the project description and elsewhere in the application as appropriate, the official NIH identifier(s) for the hESC line(s) to be used in the proposed research. Applications that do not provide this information will be returned without review.

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.pubmedcentral.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 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:

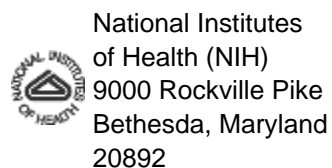
This program is described in the Catalog of Federal Domestic Assistance at <http://www.cfda.gov/> and is not subject to the intergovernmental review requirements of Executive Order 12372. Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 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/>.

[Weekly TOC for this Announcement](#)
[NIH Funding Opportunities and Notices](#)



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