

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://grants.nih.gov/grants/new_investigators/innovator_award/); all NIH Institutes and Centers are participating. This FOA is being administered by the National Institute of General Medical Sciences (NIGMS) on behalf of the NIH.

Title: 2009 NIH Director's New Innovator Award Program (DP2)

Announcement Type

This Funding Opportunity Announcement (FOA) is a reissue of [RFA-RM-08-014](#).

Request for Applications (RFA) Number: RFA-RM-09-003

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 29, 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 27, 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 (Activation Date): October 31, 2008 – Frequently Asked Questions (FAQs) at http://grants.nih.gov/grants/new_investigators/innovator_award/faq_2009.htm

Expiration Date: May 28, 2009

Due Dates for E.O. 12372

Not Applicable

Additional Overview Content

Executive Summary

- **Purpose.** The NIH Director's New Innovator (DP2) Award program was created in 2007 to support a small number of new investigators of exceptional creativity who propose bold and highly innovative new research approaches that have the potential to produce a major impact on broad, important problems in biomedical and behavioral research. The New Innovator Awards complement ongoing efforts by NIH and its Institutes and Centers to fund new investigators through R01 grants, which continue to be the major sources of NIH support for new investigators. The competition for the New Innovator Award in fiscal year 2009 will proceed in two phases. The first phase is a pre-application phase in response to [PAR-09-013](#). 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 New Innovator Awardees will be selected from this group of applicants.
- **Mechanism of Support.** This FOA will utilize the DP2 grant mechanism. Pre-applications for 2009 New Innovator Awards were solicited under [PAR-09-013](#). Applicants should read both FOAs.
- **Funds Available and Anticipated Number of Awards.** Total funding available is approximately \$55.7 million for the five-year period. It is anticipated that up to 24 awards will be made in 2009.
- **Budget and Project Period.** Awards will be for up to \$300,000 in direct costs each year for five years. Standard F&A costs will be determined at the time of award.
- **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 in response to [PAR-09-013](#) are eligible to submit full applications under this FOA. Recipients of the New Innovator Award (DP2) are required to commit 25% of their research effort to activities supported by the New Innovator 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 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 institutions 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 New Innovator Award is designed to support new investigators of exceptional creativity who propose bold and highly innovative new research approaches that have the potential to produce a major impact on broad, important problems in biomedical and behavioral research. 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 research proposed for a New Innovator Award may be in any scientific area relevant to the mission of NIH (biological, behavioral, clinical, social, physical, chemical, computational, engineering, and mathematical sciences) but need not be in a conventional biomedical or behavioral discipline. The focus is on innovation and potential impact.

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

Section II. Award Information

1. Mechanism of Support

This FOA utilizes the DP2 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 intends to commit up to \$55.7 million dollars in FY2009 to fund up to 24 grants for the five-year period, contingent upon the availability of funds and the submission of a sufficient number of meritorious applications.

Awards will be for up to a total of \$1.5 million in direct costs (average of \$300,000 per year) for a five-year budget/project period, plus applicable Facilities and Administrative costs to be determined at the time of award.

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

You may submit an application if your institution/organization is a domestic institution that has any of the following characteristics:

- 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
- 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-09-013](#) 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.

Applicants must hold an independent research position at a domestic (U.S.) institution as of September 19, 2009 and must have received their most recent doctoral degree (e.g., Ph.D., M.D., D.D.S., D.V.M., PharmD or equivalent) or completed their medical internship and residency no earlier than 1999 and no later than the due date for pre-applications. NIH intramural investigators are not eligible for support under this program.

For the purpose of this FOA, “independent research position” means a position that automatically confers eligibility, by the applicant’s institutional policy, for an investigator to apply for R01 grants, with an appropriate commitment of facilities to be used for the conduct of the proposed research. Investigators still in training or mentored status (postdoctoral fellows) are not eligible to apply unless they have a written commitment of an independent faculty position as of September 19, 2009 that is certified by submission of the application from that institution.

Applicants must meet the definition of “new investigator.” For the purpose of this FOA, “new investigators” are defined as those applicants who have never been the PI on an R01 or equivalent grant (e.g., R23, R29, R33, R37, DP1, DP2, U01, P01 or center grant) or leader of a P01 or center grant peer-reviewed project that was reviewed in the applicant’s name. Multiple PIs have the same leadership status on grants as individual PIs; therefore, applicants who have served as one of multiple PIs on any ineligible grant are no longer considered new investigators and are not eligible to apply for a New Innovator Award. Current or past recipients of K awards are eligible except for the following: K99/R00 or other Independent Scientist and other non-mentored career awards (K02, K04, K05, K24, and K26). Applicants may submit or have an R01 (or equivalent) grant application pending concurrently with their New Innovator Award application. However, if that pending grant is awarded in Fiscal Year 2009 with a start date of September 30 or earlier, the applicant is no longer eligible to receive the New Innovator Award. Awardees are required to commit at least 25% of their research effort each year to activities supported by the New Innovator Award. Women and members of groups underrepresented in biomedical or behavioral research are especially encouraged to apply.

There are no citizenship or residency requirements.

For more detail regarding eligibility requirements, see FAQs on the New Innovator web site at

<http://nihroadmap.nih.gov/newinnovator/>.

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

None

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 designated as PD/PI 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 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 [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 PIs are not allowed.

ADDITIONAL APPLICATION INSTRUCTIONS

The application items include all those required for the New Innovator Award pre-applications (X02) submitted under [PAR-09-013](#). 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 submit information on human and animal subjects.

Because these applications and most NIH applications with due 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 application components will be included in a subsequent Notice.

The following instructions are specific to the New Innovator Award (DP2) 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 as SF424 (R&R) Other Project Information component attachments for the application to be considered complete:

- I. Abstract:** An abstract, of no more than 300 words (and not exceeding one page) describing goals of the project. 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:** An essay of no more than 10 pages that addresses (1) the significance and potential impact of the project, (2) what makes the approaches exceptionally innovative and how the applicant will address risks and challenges, and (3) the applicant's qualifications for this award. A scientific plan should be provided, written with a level of detail appropriate for reviewers who are broadly knowledgeable but who may not be directly involved in the proposed area of research. To focus the essay on the goals of the New Innovator Award program and the review criteria for applications, presentation of the proposed research as a series of specific aims is discouraged. Preliminary data are allowed but not required. Bibliographic citations (references), figures, and illustrations may be included, but must fit within the 10-page limit. The essay should include the following sections within the 10-page limit, in the following order, with the headings shown:
 - 1. Project description:** Describe the scientific problem that you propose to address, its importance, and how solving this problem would have a major impact on a broad area of biomedical/behavioral science. Why is the planned research uniquely suited to the New Innovator Award program, rather than a traditional grant mechanism? How is this project distinct from other research that may be supported in your laboratory?

2. Innovativeness: State clearly and concisely what makes your project unusually innovative. If the approaches entail a high degree of risk, what will you do if these approaches are not successful?

3. Investigator qualifications: Provide evidence to support your claim of innovativeness and creativity in your research. For example, which personal qualities and experiences demonstrate your inclination to challenge paradigms and take intellectual risks, develop unique collaborations, integrate diverse sources of information, or develop novel approaches when new challenges or opportunities arise?

IV. Biographical sketch: A two-page biographical sketch for the PD/PI only. (Use the format for biographical sketches shown in Section 4.5.2 of the Application Guide, **omitting Section C, Research Support.**) Biographical sketches for other key personnel should not be submitted and will not be accepted. A request for an exception to the eligibility requirement of time from last doctoral degree must be specifically justified in this section of the application and must be based upon additional medical training, such as a clinical fellowship, or unusual circumstances, such as time away from research for care of young children or for military service. Requests will be considered on a case-by-case basis when the application is received. Applications from investigators who exceed the time from last doctoral degree or completion of medical internship/residency and who fail to provide a well-justified request for an exception to this eligibility requirement will not be reviewed.

V. 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 the Application Guide, Part III, Section 3.1.8). The effort commitment statement (described below) must be included in this document. Applicants must also include a brief statement of the facilities to be used for the conduct of the research.

VI. Effort Commitment: Awardees are required to commit at least 25% of their research effort to the project supported by the New Innovator Award. In their list of current and pending support, applicants must include a statement that, if chosen to receive an award, the applicant will commit a minimum of 25% of his/her research effort to the project supported by the New Innovator Award.

VII. 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.

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 up to \$1.5 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 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 with the 10-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 28, 2009 (Earliest date an application may be submitted to Grants.gov)

Letters of Intent Receipt Date(s): Not applicable

Application Due Date(s): May 27, 2009

Peer Review Date(s): June 2009

Advisory Council to the Director Review Date: 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 Center for Scientific Review, NIH. 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

Applications that are complete and responsive to this FOA will be evaluated by a specially constituted, multidisciplinary group of outside experts.

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.

The review criteria will emphasize the importance and potential impact of the scientific problem in biomedical and behavioral research, the novelty and innovativeness of the approach, and evidence of the PD's/PI's potential for creative and innovative research as a "new investigator." Specifically, reviewers will evaluate:

The scientific problem to be addressed: The importance of the scientific problem and the likelihood that, if successful, the project will have a major impact on a broad area of biomedical or behavioral research.

Innovativeness of the research proposed: Evidence that the proposed scientific problem and/or the approaches are significantly more innovative and creative than would normally be expected, especially for a new investigator, and evidence that the investigator has considered and addressed the potential risks and challenges.

Investigator qualifications: Evidence of the investigator's creativity and potential for innovation and the commitment of the investigator to devote 25% or more of his/her research effort on the New Innovator Award project.

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

Significance: Does this study address an important biomedical, behavioral, clinical, or translational 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, 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, 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. Sharing Research Data

Not Applicable

The following resource sharing policies do not apply to this FOA:

- Data Sharing Plan. Not Applicable
- Sharing Model Organisms. Not Applicable
- Genome Wide Association Studies (GWAS). Not Applicable

3. Anticipated Announcement and Award Dates

Awardees will be notified in September 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-RM-09-003](#). 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" references 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 New Innovators Awards, please use the following acknowledgement: "This work was funded by the National Institutes of Health through the NIH Director's New Innovator Award Program, grant number DP2-OD-xxxxxx. Information on the New Innovator Award Program is at http://grants.nih.gov/grants/new_investigators/innovator_award/."

2b. As indicated in the FOA, awardees are expected to commit at least 25% of their research effort to the project supported by the New Innovator Award.

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

2d. Since the full budget/project period funding for this award is issued from one fiscal year's appropriation, an extension of time for a period after August 31, 2014 is not allowable. Therefore, it is imperative that the Final Financial Status Report and the Federal Cash Transactions Report be submitted by September 30, 2014.

3. Reporting

Awardees will be required to submit a scientific progress report on September 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. Information about where to submit progress reports and other documentation will be provided at the time of award.

Section VII. Agency Contacts

Many questions are addressed in the FAQs on the New Innovator web site at http://grants.nih.gov/grants/new_investigators/innovator_award/faq_2009.htm. 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):

Richard Okita, Ph.D.
Program Director, Pharmacological and Physiological Sciences Branch
National Institute of General Medical Sciences
National Institutes of Health
Building 45, Room 2As49, MSC 6200
Bethesda, MD 20892-6200
Telephone: (301) 594-4469
Email: newinnovator@nih.gov (e-mail is the strongly preferred method for inquiries)

2. Peer Review Contact(s):

Richard Okita, Ph.D.
Program Director, Pharmacological and Physiological Sciences Branch
National Institute of General Medical Sciences
National Institutes of Health
Building 45, Room 2As49, MSC 6200
Bethesda, MD 20892-6200
Telephone: (301) 594-4469
Email: newinnovator@nih.gov (e-mail is the strongly preferred method for inquiries):

3. Financial/Grants Management Contact(s):

Marcia F. Cohn
Grants Management Officer
National Institutes of General Medical Sciences
National Institutes of Health
Building 45, MSC 6200
Bethesda, MD 20892-6200
Telephone: (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:

Not applicable.

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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Extramural

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