

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH)
Components of Participating Organizations	This Funding Opportunity Announcement is developed as a Common Fund initiative (http://commonfund.nih.gov/) through the Office of Strategic Coordination, Division of Program Coordination, Planning and Strategic Initiatives, Office of the NIH Director (http://dpcpsi.nih.gov/osc/). This FOA will be administered by the National Institute of Dental and Craniofacial Research (http://www.nidcr.nih.gov/) on behalf of the NIH.
Funding Opportunity Title	NIH Director's Early Independence Awards (DP5)
Activity Code	DP5 Early Independence Award/Cooperative Agreement
Announcement Type	Reissue of RFA-RM-10-019
Related Notices	None
Funding Opportunity Announcement (FOA) Number	RFA-RM-11-007
Companion FOA	None
Number of Applications	Only up to two applications per institution are allowed as defined in Section III. 3. Additional Information on Eligibility .
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.310
FOA Purpose	The NIH Director's Early Independence Award Program supports exceptional investigators who wish to pursue independent research directly after completion of their terminal doctoral/research degree or clinical residency, thereby foregoing the traditional post-doctoral training period.

Key Dates

Posted Date	November 10, 2011
Open Date (Earliest Submission Date)	December 30, 2011
Letter of	December 30, 2011

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Intent Due Date	
Application Due Date (s)	January 30, 2012, by 5:00 PM local time of applicant organization.
AIDS Application Due Date (s)	Not Applicable
Scientific Merit Review	June 2012
Advisory Council Review	August 2012
Earliest Start Date (s)	September 1, 2012
Expiration Date	January 31, 2012
Due Dates for E.O. 12372	Not Applicable http://grants.nih.gov/grants/policy/nihgps_2010/nihgps_ch10.htm#construction_grants_intergov

Required Application Instructions

It is critical that applicants follow the instructions in the [SF 424 \(R&R\) Application Guide](#), except where instructed to do otherwise (in this FOA or in a Notice from the [NIH Guide for Grants and Contracts](#)). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in [Section IV](#). When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Recent trends have demonstrated an increase in the length of the traditional scientific training period with a concomitant increase in the time it takes for scientists to establish independent research careers. Although traditional post-doctoral training is likely to be most appropriate for the large majority of newly graduated doctoral-level researchers, there is a small pool of young researchers who have the intellect, scientific creativity, drive and maturity to flourish independently without the need for traditional post-doctoral training. Reducing the amount of time they spend in training would provide them the opportunity to start highly innovative research programs as early in their careers as possible. The fresh perspective brought by these investigators should also help broaden and invigorate the research programs at their respective institutions.

The NIH Director's Early Independence Awards provide an opportunity for exceptional junior scientists, who have already established a record of innovation and research productivity, to have an accelerated entry into an independent research career. It is also an opportunity for research intensive institutions to invigorate their research departments by recruiting outstanding, early career scientists. Exceptional graduate students or clinicians nearing the completion of their PhD (or equivalent) or for clinicians (MD or equivalent) the end of their medical residency may contact appropriate Institutional scientific leaders to seek an appointment as an independent research scientist (For a listing of eligible degrees for Early Independence Investigators, please refer to Section 1. Eligible Applicants). Alternatively, Institutions may actively recruit eligible junior scientists to apply for support through this program. In either event, the Institution will be expected to provide substantial support for the junior scientist as detailed below. At the time of application, the Early Independence investigator must be within twelve months before or after the completion of their PhD (or equivalent) or for clinicians within twelve months before or after the completion of their medical residency (or equivalent) training. The date of degree receipt is that which appears on the official transcript for the degree. The time of application is the date when the application is submitted electronically to NIH through Grants.gov. In addition, at the time of application, the Early Independence investigator must not have served as a post-doctoral fellow following a previous doctoral degree for more than one year. By the end of the award period, the Early Independence investigator is expected to be competitive for continued funding of his/her research program and for a permanent research position.

In the application, the prospective Early Independence investigator and the prospective Grantee Institution will be required to provide:

Early Independence PD(s)/PI(s):

- Statement of how an Early Independence Award would enable entry into an independent research position and why this would be of benefit to the PD(s)/PI(s) career;
- Evidence of exceptional scientific creativity and productivity;
- A research plan in a scientific area relevant to the NIH mission for which the investigator has demonstrated expertise;
- Strong letters of recommendation from current and previous scientific mentors offering a detailed assessment of the prospects for a successful early transition to research independence; achievements as a graduate student; and the potential for future scientific contributions.

Grantee Institution:

- Plans for full integration of the Early Independence investigator into the scientific community at the institution and evidence that the institution and existing faculty are committed to his/her success;
- Evidence that the proposed research project will complement existing scholarly activities at the

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institution and will enhance the research capabilities of the institution;

- Evidence that the Early Independence investigator will be appointed into an independent research position.
- A detailed description of the laboratory space to be provided to the Early Independence investigator and the availability of research support staff;
- A detailed description of the availability of the equipment, supplies and shared resources required by the Early Independence PD(s)/PI(s), and a plan for guaranteeing access to those resources;
- Description of career enhancement opportunities available to the Early Independence PD(s)/PI(s), equivalent to those offered to assistant professors;
- Evidence that the Early Independence PD(s)/PI(s) will have the necessary Institutional commitment to conduct full-time, independent research, excepting the minimal clinical commitments required for clinician researchers and minimal, optional teaching commitments;
- Description of opportunities for the Early Independence PD(s)/PI(s) to apply for additional research funding without being required to do so.

The NIH recognizes a unique and compelling need to promote diversity in the biomedical, behavioral, clinical and social sciences research workforce. The NIH expects all of its efforts to diversify the workforce to lead to the recruitment of the most talented researchers from all groups; to improve the quality of the educational and training environment; to balance and broaden the perspective in setting research priorities; to improve the ability to recruit subjects from diverse backgrounds into clinical research protocols; and to improve the Nation's capacity to address and eliminate health disparities. Grantee institutions are always encouraged to consider talented researchers from diverse backgrounds underrepresented in biomedical research, including underrepresented racial and ethnic groups, persons with disabilities and women for participation in all NIH-funded research opportunities.

Section II. Award Information

Funding Instrument	Grant
Application Types Allowed	New The OER Glossary and the SF 424 (R&R) Application Guide provide details on these application types.
Funds Available and Anticipated Number of Awards	The NIH Common Fund intends to commit approximately \$4,000,000 in FY 2012. Approximately 10 awards are anticipated, contingent upon availability of funds and receipt of a sufficient number of meritorious applications.
Award Budget	Awards will be for up to \$250,000 in direct costs per year, plus applicable Facilities and Administrative (F&A) costs.
Award Project Period	Five years

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

Eligible Organizations

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Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or 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 Other Than Institutions of Higher Education

- 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)

For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Governments

- Eligible Agencies of the Federal Government including the NIH Intramural Program

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.

Foreign components, as [defined](#) in the NIH Grants Policy Statement, **are** allowed.

Required Registrations

Applicant organizations must complete the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. Applicants must have a valid Dun and Bradstreet Universal Numbering System (DUNS) number in order to begin each of the following registrations.

- [Central Contractor Registration \(CCR\)](#) – must maintain an active registration, to be renewed at least annually
- [Grants.gov](#)
- [eRA Commons](#)

All Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) must also work with their institutional officials to register with the eRA Commons or ensure their existing eRA Commons account is affiliated with the eRA Commons account of the applicant organization.

All registrations must be completed by the application due date. Applicant organizations are strongly encouraged to start the registration process at least 4-6 weeks prior to the application due date.

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Eligible Individuals (Program Director(s)/Principal Investigator(s))

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

At the time of application, the individual either 1) within the preceding twelve months must have received a terminal doctoral degree or completed medical residency or 2) within the following twelve months must complete all the requirements for a doctoral degree or complete a medical residency. The date of degree receipt is that which appears on the official transcript for the degree. The time of application is the date when the application is submitted electronically to NIH through Grants.gov. In addition, at the time of application, the PD(s)/PI(s) must not have served as a post-doctoral fellow following a previous doctoral degree for more than one year.

At the time of funding to the grantee Institution, the Early Independence investigator must have received a PhD, MD, DO, DC, DDS, DVM, OD, DPM, ScD, EngD, Dr PH, DNSc, ND (Doctor of Naturopathy), PharmD, DSW, PsyD, or equivalent doctoral degree from an accredited domestic or foreign institution (it is the responsibility of the sponsoring institution to determine if a foreign doctoral degree is equivalent). Certification by an authorized official of the degree-granting institution that all degree requirements have been met is also acceptable.

A PD/PI is permitted only a single application for an Early Independence Award.

2. Cost Sharing

This FOA does not require cost sharing as defined in the [NIH Grants Policy Statement](#).

3. Additional Information on Eligibility

Number of Applications

An applicant organization (identified as having a unique DUNS number) may submit up to two applications in response to this FOA.

NIH will not accept any application in response to this FOA that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application. NIH will not accept any application that is essentially the same as one already reviewed.

Section IV. Application and Submission Information

1. Requesting an Application Package

Applicants must download the SF424 (R&R) application package associated with this funding opportunity using the "Apply for Grant Electronically" button in this FOA or following the directions provided at [Grants.gov](#).

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the [SF424 \(R&R\) Application Guide](#), except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in

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the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

For information on Application Submission and Receipt, visit [Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications](#).

Letter of Intent

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

By the date listed in [Part 1. Overview Information](#), prospective applicants are asked to submit a letter of intent that includes the following information:

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

The letter of intent should be sent to:

Ravi Basavappa, Ph.D.
Office of Strategic Coordination
Office of the Director, NIH
1 Center Drive, MSC 0189
Building 1, Room 203
Bethesda, MD 20892-0189
Telephone: (301) 594-8190
Fax: (301) 435-7268
Email: earlyindependence@mail.nih.gov

Required and Optional Components

The forms package associated with this FOA includes all applicable components, mandatory and optional.

Please note that some components marked optional in the application package are required for submission of applications for this FOA. Follow all instructions in the SF424 (R&R) Application Guide to ensure you complete all appropriate “optional” components.

Page Limitations

All page limitations described in the SF424 Application Guide and the [Table of Page Limits](#) must be followed.

Other Project Information Component

Item 10. Facilities & Other Resources (no page limit). In addition to the required information detailed in the [SF424 \(R&R\) Application Guide](#), applicant institution officials must address each of the following items:

- During the award period, the Early Independence Investigator must be scientifically independent. The appointment need not be permanent or tenure-track. Describe in detail the position into which

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the Early Independence Investigator will be appointed and how the candidate's independence will be protected during the course of the award.

- Describe the Institutional organizational structure within which the Early Independence PD/ PIs position will be administered (School, Department, etc.), and explain how this administrative structure will best meet the goal of supporting the success of the Early Independence PD/PI. Include details of responsibilities for integrating the Early Independence Investigator and their scientific project into the institutional culture and the faculty community. Describe the management of problematic situations as well as institutional expectations related to the retention or transfer of the candidate at the end of the funding period.
- Describe details of the laboratory space to be provided to the Early Independence Investigator including physical structure and space layout along with the availability of support staff, including physical structure and space layout.
- Describe other administrative and support functions that will be available to the Early Independence Investigator (for example, human resources, supply and equipment ordering systems, administrative assistance, etc.)
- Describe the institutional commitment to the Early Independence Program. Matching funds are not required; however, an appropriate level of institutional support is expected. Institutional commitment to the development of the candidate as a successful and independent research scientist will be given considerable attention during the review and selection process.
- Describe career enhancement plans for the newly-hired Early Independence Investigator. Provide plans for assessing and monitoring the annual progress of the candidate supported by this award. Describe any additional plans for ensuring the success of Early Independence Investigators as productive, independent investigators.
- Describe plans for integrating each Early Independence Investigator into Institutional scientific and administrative activities at the institution. What scientific collaborative activities (attendance at faculty meetings, laboratory meetings, participation in Institutional scientific retreats, etc.) and career development resources (courses in laboratory management and grant writing, etc.) will be available to ensure the Early Independence Investigator is successful? What support from senior colleagues and leadership of the Program will be available to the Early Independence Investigator?
- The primary goal of each Early Independence Investigator is to establish an independent scientific research program. If Early Independence Investigators have an interest in teaching, what opportunities will be available?
- Describe expectations and opportunities for the Early Independence Investigator to establish a record of independent funding by submitting and accepting grants from sources other than the Early Independence Award.

Only for applications Involving Federal Agencies including the NIH Intramural Research Program:

The requests from research intensive federal agencies, including the NIH intramural program, will not include salary and related fringe benefits for career, career conditional or other federal employees (civilian or uniformed service) with permanent appointments under existing position ceilings or any costs related to administrative or facilities support (equivalent to Facilities and Administrative costs).

In general, the budget requests will be limited to the incremental costs required for the proposed research project. These costs may include salary for staff to be specifically hired under a temporary appointment for the project, consultant costs, equipment, supplies, travel, and other items typically listed under Other Expenses. While support for extramural collaborators may be requested in a separate grant application, funds can be requested for services by an external investigator or contractor as a subcontract/consortium including the applicable indirect (F&A costs) of the contractor/collaborating institution.

Justification must be provided for all requested support and for the Federal employees who will be committed to the project although no funds are requested in the application.

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Applicants should indicate the number of person-months devoted to the project, even if no funds are requested for salary and fringe benefits.

For funded applications involving the NIH Intramural Research Program, appropriate funding will be provided by the NIH Intramural Program. NIH intramural scientists will participate in this program as PD (s)/PI(s) in accord with the Terms and Conditions provided in this FOA. Intellectual property will be managed in accord with established policy of the NIH in compliance with Executive Order 10096, as amended, 45 CFR Part 7; patent rights for inventions developed in NIH facilities are NIH property unless NIH waives its rights. Moreover, should an extramural application include the collaboration with an intramural scientist, no funds for the support of the intramural scientist may be requested in the application. The intramural scientist may submit a separate request for intramural funding as described above.

PHS 398 Research Plan Component

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

PHS398 Cover Letter: The PHS398 cover letter must include the list of referees (including name, department, and institution).

Research Strategy

Organize the Research Strategy as a single document using the instructions provided below. Start each section of the document with the appropriate section heading. Suggested page lengths for each section are given in parentheses.

1. **Rationale for omitting post-doc (one page):** Why would skipping the typical post-doctoral fellowship benefit your long-term scientific career? How would receipt of this award enable your entry into an independent research career?
2. **Evidence of training capability and leadership (one-half page):** What activities have prepared you to lead a laboratory, train laboratory staff, and perhaps mentor students and post-doctoral fellows?
3. **Host institution interactions (one-half page):** What arrangements have you made with your host institution to provide you with the support and feedback necessary to establish your research program while maintaining your intellectual independence? How will you try to integrate yourself as an active member in your institution's scientific community?
4. **Research challenge (one page):** What is the scientific challenge that you wish to address in your research? Why is this challenge significant to the biomedical/behavioral research community? What is the expected impact of your research on this challenge? Why did you choose this particular challenge to begin your independent research career?
5. **Approach (seven pages):** What is your experimental approach in addressing your research challenge? What is the logic that makes this scientifically compelling? No preliminary data are required, but will be accepted if provided.
6. **Innovation (one page):** What are the particularly innovative aspects of your proposed research?
7. **Relationship to previous work (one-half page):** How is the proposed research related to your

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research as a student? How does it differ?

8. **Timeline (one-half page):** What is the timeline for accomplishing intermediate steps in your award period? This should include steps in establishing a functioning laboratory, meeting career development objectives, as well as achieving your scientific objectives.

Resource Sharing Plan

Individuals are required to comply with the instructions for the Resource Sharing Plans (Data Sharing Plan, Sharing Model Organisms, and Genome Wide Association Studies; GWAS) as provided in the SF424 (R&R) Application Guide.

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan..

Appendix

Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

3. Submission Dates and Times

[Part I. Overview Information](#) contains information about Key Dates. Applicants are encouraged to submit in advance of the deadline to ensure they have time to make any application corrections that might be necessary for successful submission.

Organizations must submit applications via [Grants.gov](#), the online portal to find and apply for grants across all Federal agencies. Applicants must then complete the submission process by tracking the status of the application in the [eRA Commons](#), NIH's electronic system for grants administration.

Applicants are responsible for viewing their application in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

4. Intergovernmental Review (E.O. 12372)

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 only as described in the [NIH Grants Policy Statement](#).

6. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF 424 (R&R) Application Guide. Paper applications will not be accepted.

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Applicants must complete all required registrations before the application due date. [Section III. Eligibility Information](#) contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit [Applying Electronically](#).

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF 424(R&R) Application Package. Failure to register in the Commons and to include a valid PD(s)/PI(s) Commons ID in the credential field will prevent the successful submission of an electronic application to NIH.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the Central Contractor Registration (CCR). Additional information may be found in the SF424 (R&R) Application Guide.

See [more tips](#) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness by the Center for Scientific Review and responsiveness by [components of participating organizations](#), NIH. Applications that are incomplete and/or nonresponsive will not be reviewed.

Letters of Reference:

Letters of reference are an important component of the Early Independence Award application. Applicants must arrange to have at least three and no more than five letters of reference submitted on their behalf. Applications that are missing letters of reference will be considered non-responsive and will not be reviewed. Late letters will not be accepted. Applicants are responsible for monitoring the submission of letters to ensure that three letters have been submitted prior to the submission deadline. Applicants are encouraged to check the status of their letters in their Commons accounts.

Letters may be submitted beginning December 30, 2011 and must be submitted no later than 5:00 p.m. (EST) January 30, 2012.

To submit a letter of reference, the referee will need the following information:

- Funding Opportunity Number (FOA) for this announcement: RFA-RM-11-007;
- The applicant's Commons User Name (Note: Referees do not need 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 first and last name (note – the name must match exactly the applicant's name in the Commons);

The URL to the letter submission page

<https://public.era.nih.gov/commons/public/reference/submitReferenceLetter.do?mode=new>;

Letters of reference are confidential. Applicants will not have access to the letters. E-mail confirmations will be sent to both 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.

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

Instructions for Referees:

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 the applicant's claim to possess the scientific, leadership and management skills necessary to conduct successful, completely independent research. When possible, give specific examples that illustrate these qualities. A template for the reference letter is available at <http://commonfund.nih.gov/earlyindependence/>. The use of this template is strongly encouraged.

Note: The letter submission page can be accessed without signing into the Commons, and referees do not need to be registered in the Commons. Referees must provide the applicant's Commons User Name (User ID) and the other information below:

REFEREE INFORMATION (the individual providing the letter of reference):

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)

APPLICANT INFORMATION (applicants must send this information to their referees):

Applicant's Commons User Name (User ID), (Required) (Important – this must be the applicant's, not the referee's, Commons User Name (User ID). The letter will not be linked to the appropriate application if the Applicant's User Name is not entered here.)

Applicant's Last Name (Required). (Note: must match exactly the applicant's name in Commons)

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Confirmation Number (Required only when resubmitting a letter, that is, when submitting a revised or changed/corrected letter for the current FOA)

E-mail 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 only when submitting a revised or changed/corrected letter. Please print the confirmation email for your records.

Post Submission Materials

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Applicants are required to follow the instructions for post-submission materials, as described in [NOT-OD-10-115](#).

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the [NIH mission](#), all applications submitted to the NIH in support of biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

For this particular announcement, note the following:

The NIH Director's Early Independence Awards are designed to accelerate the entry of exceptional junior investigators into positions of independent research by providing support within one year of receipt of the terminal research degree or completion of residency, thereby omitting the traditional post-doctoral training period. Accordingly, though all review criteria described below will be used, the emphases will be on the qualities of the investigator and on the environment provided by the host institution. Substantial preliminary data are not expected; rather, the approach should be made compelling primarily by the logic of the arguments presented.

Overall Impact

Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s)

Is the Early Independence PD(s)/PI(s) well suited to the project? Has the Early Independence PD(s)/PI(s) demonstrated appropriate experience, training, and skills to conduct highly innovative research? Has the Early Independence PD(s)/PI(s) demonstrated the leadership and management abilities necessary to successfully conduct completely independent research? Do the letters of recommendation indicate that the candidate has the scientific and leadership skills to manage an independent laboratory? Is the Early Independence PD(s)/PI(s) at a juncture in his/her career at which the Early Independence Award would substantially accelerate his/her independent research career? Would the Early Independence PD(s)/PI(s) long term career likely benefit by this acceleration?

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Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Is the logic of the approach compelling despite the lack of supporting preliminary data? Is the scope of the project appropriately ambitious for someone who, though highly qualified, is still just establishing an independent research program?

Environment

Will the scientific environment contribute to the probability of success of the Early Independence PD (s)/PI(s)? Will the situation of the Early Independence investigator provide sufficient separation from previous mentors to promote true intellectual independence? Are the plans for institutional support, equipment, staffing, and other physical resources available to the Early Independence investigator adequate? Will the research activities within the Institution help foster the development for the Early Independence Investigator? Will the Early Independence investigator benefit from unique features of the scientific environment and collaborative arrangements? How will the scientific project fit in with other research efforts within the unit? Is there evidence that the Early Independence Investigator will have the necessary Institutional commitment to conduct full-time, independent research for the duration of this award? Will the Early Independence investigator be given appropriate access to facilities and resources? Are shared institutional resources being made available to the Early Independence PD(s)/PI(s)? Are the plans for appointing and integrating the Early Independence investigator into the Institutional scientific culture adequate and appropriate? Will the research activities and resources provided to the Early Independence investigator assist in the development and strengthening of their career? Are the strategies for addressing potential problems adequate? Are benchmarks for the success of the Early Independence Investigator presented? Are the proposed plans and criteria to monitor the long term success of the select Early Independence Investigator adequate?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact/priority score, but will not give separate scores for these items.

Protections for Human Subjects

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For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the [Human Subjects Protection and Inclusion Guidelines](#).

Inclusion of Women, Minorities, and Children

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the [Human Subjects Protection and Inclusion Guidelines](#).

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the [Worksheet for Review of the Vertebrate Animal Section](#).

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmissions

Not Applicable.

Renewals

Not Applicable.

Revisions

Not Applicable.

Additional Review Considerations

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As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact/priority score.

Applications from Foreign Organizations

Not Applicable

Select Agent Research

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) [Data Sharing Plan](#); 2) [Sharing Model Organisms](#); and 3) [Genome Wide Association Studies \(GWAS\)](#).

Budget and Period of Support

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

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by an appropriate Scientific Review Group as convened by the Center for Scientific Review, in accordance with [NIH peer review policy and procedures](#), using the stated [review criteria](#). Review assignments will be shown in the eRA Commons.

As part of the scientific peer review, all applications:

- May undergo a selection process in which only those applications deemed to have the highest scientific and technical merit of applications under review will be discussed and assigned an overall impact/priority score.
- Will receive a written critique.

Those candidates identified as being the most outstanding will be invited to Bethesda, MD for interview in June 2012. Interviews will be conducted by the Center for Scientific Review Special Emphasis Panel (excluding Mail Reviewers) convened specifically for the review of the Early Independence Award applications. The scores assigned after interview by the panel members will be used to calculate the overall impact/priority score for the application.

Appeals of initial peer review [will not be accepted for applications](#) submitted in response to this FOA.

Applications will be assigned to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review by the Council of Councils. The following will be considered in making funding decisions:

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

The final funding decisions will be made by the Director, Program Coordination, Planning, and Strategic Initiatives, Office of the Director, NIH.

3. Anticipated Announcement and Award Dates

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

Information regarding the disposition of applications is available in the [NIH Grants Policy Statement](#).

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 as described in the [NIH Grants Policy Statement](#).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions described in [Section IV.5. Funding Restrictions](#). 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.

Any application awarded in response to this FOA will be subject to the DUNS, CCR Registration, and Transparency Act requirements as noted on the [Award Conditions and Information for NIH Grants](#) website.

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](#). More information is provided at [Award Conditions and Information for NIH Grants](#).

Cooperative Agreement Terms and Conditions of Award

Not Applicable.

3. Reporting

When multiple years are involved, awardees will be required to submit the [Non-Competing Continuation Grant Progress Report \(PHS 2590\)](#) annually and financial statements as required in the [NIH Grants Policy Statement](#).

A final progress report, invention statement, and the expenditure data portion of the Federal Financial

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Report are required for closeout of an award, as described in the NIH Grants Policy Statement.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over \$25,000. See the [NIH Grants Policy Statement](#) for additional information on this reporting requirement.

Section VII. Agency Contacts

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

Application Submission Contacts

[Grants.gov Customer Support](#) (Questions regarding Grants.gov registration and submission, downloading or navigating forms)

Contact Center Phone: 800-518-4726

Email: support@grants.gov

GrantsInfo (Questions regarding application instructions and process, finding NIH grant resources)

Telephone 301-435-0714

TTY 301-451-5936

Email: GrantsInfo@nih.gov

eRA Commons Help Desk(Questions regarding eRA Commons registration, tracking application status, post submission issues)

Phone: 301-402-7469 or 866-504-9552 (Toll Free)

TTY: 301-451-5939

Email: commons@od.nih.gov

Scientific/Research Contact(s)

Ravi Basavappa, , Ph.D.

Office of Strategic Coordination

Office of the Director, NIH

1 Center Drive, MSC 0189

Building 1, Room 203

Bethesda, MD 20892-0189

Telephone: 301-594-8190

Email: earlyindependence@mail.nih.gov

Peer Review Contact(s)

Weijia Ni, Ph.D.

Center for Scientific Review (CSR)

Telephone: (301) 237-9918

Email: weijia.ni@nih.gov

Financial/Grants Management Contact(s)

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Mary E. Greenwood
National Institute of Dental and Craniofacial Research (NIDCR)
Telephone: 301- 594-4808
Email: md74u@nih.gov

Section VIII. Other Information

Recently issued trans-NIH [policy notices](#) may affect your application submission. A full list of policy notices published by NIH is provided in the [NIH Guide for Grants and Contracts](#). All awards are subject to the terms and conditions, cost principles, and other considerations described in the [NIH Grants Policy Statement](#).

Authority and Regulations

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.

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



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