

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/osci/). 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 NIH Director's Early Independence Awards
Announcement Type	New
Related Notices	<ul style="list-style-type: none"> • October 12, 2010 - See Notice NOT-OD-11-013 This Notice announces a correction of the eligibility window for clinicians with the M.D. or other clinical doctorates.
Funding Opportunity Announcement (FOA) Number	RFA-RM-10-019
Companion FOA	None
Number of Applications	Only two applications per institution are allowed, as defined in Section III. 3. Additional Information on Eligibility. In this case, Institutions are identified by having a unique DUNS number." Section III. 3. Additional Information on Eligibility .
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.310
FOA Purpose	<p>This FOA issued by the National Institutes of Health, solicits applications for the NIH Director's Early Independence Award (DP5) from institutions/organizations that propose to appoint and support exceptional, early career scientists directly following the completion of their Ph.D. (or equivalent) or M.D. (or equivalent) training into an independent academic research position, thereby omitting the traditional post-doctoral training period from their career path.</p> <p>At the time of appointment to the grantee Institution, the Early Independence PI 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</p>

	all degree requirements have been met is also acceptable.
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Key Dates

Posted Date	October 6, 2010
Open Date (Earliest Submission Date)	December 21, 2010
Letter of Intent Due Date	December 21, 2010
Application Due Date(s)	January 21, 2011, by 5:00 PM local time of applicant organization.
AIDS Application Due Date(s)	Not Applicable
Scientific Merit Review	March/April 2011
Advisory Council Review	August/September 2011
Earliest Start Date (s)	September 1, 2011
Expiration Date	January 22, 2011
Due Dates for E.O. 12372	Not Applicable

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.**

Apply for Grant Electronically

A compatible version of [Adobe Reader](#) is required for download. For Assistance downloading this or any Grants.gov application package, please contact Grants.gov Customer Support at <http://grants.gov/CustomerSupport>.

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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 most appropriate for the majority of new Ph.D.s and M.D.s, there is a pool of talented young scientists 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 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 launch an independent research program. 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 Ph.D. (or equivalent) or for clinicians (M.D.s 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 complete 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 PI must be within twelve months before or after the completion of their Ph.D. (or equivalent) or for clinicians within twelve months before or after the completion of their medical residency (or equivalent) training. By the end of the award period, the PI 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 PI and the prospective Grantee Institution will be required to provide:

Early Independence PI:

- 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 PI 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 institution and will enhance the research capabilities of the institution;
- Evidence that the Early Independence PI will be appointed into an independent research position.
- A detailed description of the laboratory space to be provided to the Early Independence PI 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 PI, and a plan for guaranteeing access to those resources;
- Description of career enhancement opportunities available to the Early Independence PI, equivalent to those offered to assistant professors;
 - Evidence that the Early Independence PIs 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 PIs 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 total amount of funds available for these awards is approximately \$4,000,000, in FY 2011, contingent upon receiving scientifically meritorious proposals. 10 awards are anticipated from this solicitation.
Award Budget	Awards will be for up to \$250,000 in direct costs each year for five years, plus applicable Facilities and Administrative (F&A) costs to be determined at the time of award.
Award Project Period	5 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

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)

Governments

Eligible Agencies of the Federal Government including the NIH intramural program

Non-domestic (non-U.S.) Entities (Foreign Organizations) are not eligible to apply. Foreign (non-U.S.) components of U.S. Organizations are not 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 be renewed at least annually
- [Grants.gov](#)
- [eRA Commons](#)

The Program Director/Principal Investigator (PD/PI) must work with his/her 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 four (4) weeks prior to the application due date.

Eligible Individuals (Project Director/Principal Investigator)

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

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.

At the time of appointment to the grantee Institution, the Early Independence PI 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

Applicant organizations (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.

Applications Involving Federal Agencies

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.

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

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. Use the PHS398 Modular Budget component provided in the SF424 (R&R) Application Package and SF424 (R&R) Application Guide (see specifically Section 5.4, "Modular Budget Component," of the Application Guide. Conformance to the requirements in 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.

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/PI
- 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 application submission. 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, with the following exceptions or additional requirements (see also Frequently Asked Questions (FAQs) at <http://commonfund.nih.gov/earlyindependence/faq.asp>):

- Specific Aims – 1 page maximum
- Research Strategy – 12 pages maximum
- 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](#), applicants 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 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 PI's 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 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.

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 affiliation, and institution).

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.

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:

The PD/PI must include his/her 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/PI 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 the [Office](#) of Strategic Coordination, 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 may be considered non-responsive and may 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 21, 2010 and must be submitted no later than 5:00 p.m. (EST)

January 21, 2010.

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

- Funding Opportunity Number (FOA) for this announcement: RFA-RM-10-019;
- 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://commons.era.nih.gov/commons/reference/submitRefereeInformation.jsp>);
- The letter of reference submission dates – December 21, 2010 - January 21, 2011. Deadline for receipt of letters is 5:00 p.m. (EST).

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.

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 may be submitted to the Commons at (<https://commons.era.nih.gov/commons/reference/submitRefereeInformation.jsp>) beginning December 21, 2010, and must be submitted no later than 5:00 p.m. (EST), January 21, 2011. Late letters will not be accepted and applications with fewer than three letters may not be reviewed. Letters must be submitted electronically – paper copies will not be accepted.

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

In two pages or less, describe the applicant's qualities that support 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.

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)
- Funding Opportunity Number (FOA) of this announcement: RFA-RM-10-019 (Required)
- 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

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

Applications that are complete and responsive to this FOA will be evaluated for scientific and technical merit by an appropriate peer review group convened by CSR and in accordance with NIH peer review procedures (<http://grants1.nih.gov/grants/peer/>), using the review criteria stated below. All candidates who are identified as the most outstanding will be invited to NIH for interviews. Interviews will be conducted by a panel of distinguished outside experts. In addition, the Council of Councils (CoC), NIH, will conduct the final level of review. The Director, NIH, will make the final selection of awardees based on the outcome of the initial peer review, the recommendations of the CoC, and programmatic considerations. Final selection of awardees will be in September 2011.

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).

Reviewers will also emphasize project, investigator, and institutional environment as they relate to the probability of a successful, independent research experience.

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 PI well suited to the project? Has the Early Independence PI demonstrated appropriate experience, training, and skills to conduct highly innovative research? Has the Early Independence PI 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?

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?

Environment

Will the scientific environment contribute to the probability of success of the Early Independence PI? Are the plans for institutional support, equipment, staffing, and other physical resources available to the Early Independence PI adequate? Will the research activities within the Institution help foster the development for the Early Independence Investigator? Will the Early Independence PI 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 Early Independence Investigators hired under this initiative will have the necessary necessary Institutional commitment to conduct full-time, independent research for the duration of this award? Will Early Independence Investigators be given appropriate access to facilities and resources? Are shared institutional resources being made available to Early Independence Investigators? Are the plans for appointing and integrating Early Independence Investigators 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

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

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(s) convened by the Center for Scientific Review (assignments will be shown in the eRA Commons), in accordance with [NIH peer review policy and procedures](#), using the stated [review criteria](#).

As part of the scientific peer review, all applications will:

- Undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review), will be discussed and assigned an overall impact/priority score.
- Receive a written critique.

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 NIH Council of Councils. . The following will be considered in making funding decisions:

- 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.

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 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.

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the *NIH Grants Policy Statement* as part of the NGA. 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](#).

An NIH Program Staff member, referred to as the Program Official, will be assigned to each Early Independence Investigator award. The Program Official will function as the primary scientific and programmatic contact for the grantee.

An annual grantee meeting to be held near Washington D.C. is planned for exchange of information among investigators, and applicants must budget travel costs associated with travel to this meeting. The P.I. is normally expected to attend this meeting.

In general, each Early Independence awardee will receive at least one administrative site visit during the funding period.

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 Financial Status Report are required when an award is relinquished when a recipient changes institutions or when an award is terminated.

Section VII. Agency Contacts

We encourage 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)

Examine your eRA Commons account for review assignment and contact information (information appears two weeks after the submission due date)

Weijia Ni, Ph.D.

Center for Scientific Review (CSR)

Telephone: (301) 237-9918

Email: weijia.ni@nih.gov

Financial/Grants Management Contact(s)

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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