### Department of Health and Human Services

#### Part 1. Overview Information

<table>
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<tr>
<th><strong>Participating Organization(s)</strong></th>
<th>National Institutes of Health (NIH)</th>
</tr>
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</table>
| **Components of Participating Organizations** | Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)  
National Institute of Allergy and Infectious Diseases (NIAID)  
Fogarty International Center (FIC) |
| **Funding Opportunity Title** | Biomedical/Biobehavioral Research Administration Development (BRAD) Award [G11] |
| **Activity Code** | G11 Extramural Associate Research Development Award (EARDA) |
| **Announcement Type** | Reissue of PAR-08-096 (EARDA) and PAR-10-172 (IEARDA) |
| **Related Notices** | NOT-HD-11-010 |
- October 7, 2011 - See Notice NOT-HD-11-026. The purpose of this Notice is to Close-out of the Extramural Associates Research Development Award (EARDA) Program and Clarification of the Eligibility of Current and Previous EARDA Grantees for Participation in the Biomedical/ Biobehavioral Research Development (BRAD) Program (G11).  
- August 25, 2011 - See Notice NOT-HD-11-024. The purpose of this Notice is to correct the level of effort for the Program Director/Principal Investigator (PD/PI). |
<p>| <strong>Funding Opportunity Announcement (FOA) Number</strong> | PAR-11-270 |
| <strong>Companion FOA</strong> | None |
| <strong>Number of Applications</strong> | Section III. 3. Additional Information on Eligibility. |
| <strong>Catalog of Federal Domestic Assistance</strong> | 93.865, 93.989 |</p>
<table>
<thead>
<tr>
<th>(CFDA) Number(s)</th>
<th>FOA Purpose</th>
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<tr>
<td></td>
<td>This Funding Opportunity Announcement (FOA) issued by The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), the Fogarty International Center (FIC), and the National Institute of Allergy and Infectious Diseases (NIAID), encourages applications from eligible domestic and foreign institutions that propose to build capacity in their research administration infrastructures. The Biomedical Biobehavioral Research Administration Capacity Development (BRAD) Program (G11) promotes the establishment of rigorous and externally supported biomedical and biobehavioral research and/or research-related training programs by providing support for strengthening institutional research administration infrastructures. This program provides training in NIH policies and procedures through distance learning and an NIH Residency Training Program. Additionally, funds are provided to strengthen existing or facilitate the establishment of new research administration infrastructures such as Offices of Sponsored Projects (OSP), Offices of Research and Sponsored Projects (ORSP), or components of such entities. The goal of the BRAD program is to enable eligible institutions to develop research support infrastructures that will facilitate the thorough oversight and administrative management of extramural grant awards, foster and facilitate ongoing research activities at the institution, and serve as the main organizational entity for the technical development of grant proposal submissions and oversight.</td>
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| Key Dates |  |
|-----------|  |
| **Posted Date** | July 21, 2011 |
| **Open Date (Earliest Submission Date)** | August 23, 2011 |
| **Letter of Intent Due Date** | August 23, 2011, June 30, 2012, June 29, 2013 |
| **Application Due Date(s)** | September 23, 2011, July 31, 2012, July 31, 2013, by 5:00 PM local time of applicant organization. |
| **AIDS Application Due Date(s)** | Not Applicable |
| **Scientific Merit Review** | October/November 2011, October/November 2012, October/November 2013 |
| **Advisory Council** | January 2012, January 2013, January 2014 |
Review

<table>
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<tr>
<th>Earliest Start Date(s)</th>
<th>April 2012</th>
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<tbody>
<tr>
<td>Expiration Date</td>
<td>August 1, 2013</td>
</tr>
<tr>
<td>Due Dates for E.O. 12372</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

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://www07.grants.gov/contactus/contactus.jsp.

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Purpose

This initiative is designed to encourage the development of a cadre of leaders in research
administration who can develop and implement strategies for strengthening the research administration support infrastructures at non-research intensive institutions that play prominent roles in educating the next generation of biomedical and biobehavioral scientists. The goal is to support the training of research administrators and to establish new or augment and strengthen the operations of existing Offices of Sponsored Projects (OSPs), Offices of Research and Sponsored Projects (ORSPs), or similar units. Eligible applicants include both United States (U.S.) domestic institutions and foreign institutions of higher education that meet the eligibility criteria. The purpose of the Biomedical Biobehavioral Research Administration Development (BRAD) program is to enable institutions to promote research and to successfully compete for external research support from a range of funding agencies, including private foundations, the NIH and other Federal agencies. Significant barriers to participation in the research enterprise include restricted knowledge and establishment of robust grants policies and procedures, lack of trained research administrators who can provide efficient oversight of grants management tasks, and limited access to and dissemination of funding opportunities.

For the purpose of this FOA, OSPs (and ORSPs) are defined as centralized units tasked with providing students, faculty, and staff with the best available resources to achieve the highest standards of research and scholarship. The sum total of these resources comprises the institution’s research administration support infrastructure, which may include but is not limited to: leadership in research administration, guidance, information and information dissemination, and a range of research-related support services.

Background

The effectiveness and productivity of OSPs (or ORSPs) are directly related to the scope and quality of available resources, which ultimately impact the ability of faculty to successfully compete for external research support, comply with funding agency regulations, and conduct effective research programs. The previous Extramural Associates Research Development Award (EARDA) provided support for capacity development to emerging research institutions thereby creating an environment that encouraged a significant number of individuals from diverse backgrounds to participate in and contribute to biomedical and biobehavioral research. Examples of medium- to longer-term indicators of success for the EARDA program include: increased research productivity, the transfer of knowledge to students, the improved health and well-being of health disparity communities at-large, and recognition of the participating institutions for scholarship.

The new initiative, the BRAD program, will continue to promote capacity development at emerging research institutions domestically and abroad. This initiative reflects the integration of the domestic Extramural Associates Research Development Award (EARDA) and the International Extramural Associates Development Award (IEARDA) program. Similar to the EARDA, the purpose of the IEARDA was to promote the development of research administrative capacity at eligible public and private international institutions of higher education. Since 1997, the NIH has dramatically increased its funding of research and training in developing countries. The IEARDA was developed for institutions in developing countries to receive training in compliance with scientific reporting requirements of NIH and other research funding agencies.

Given the similarities of the needs of eligible domestic and foreign institutions and to promote economies of scale in regard to training, the grant awardees of the domestic EARDA and IEARDA programs have always participated together in the distance learning and the on-site NIH Residency
components of their programs. This FOA is the next step in the integration of the two similar programs.

**BRAD Program Objectives**

Traditionally, OSPs have focused on the review and progression of research proposals through technical and administrative processes. At non-research intensive institutions, research administrators often take leadership roles in strategic planning for sponsored research, in stimulating research, and in identifying innovative ways of creating time for faculty participation in research. Additionally, consideration must be given to a number of complex interacting factors, including continuing professional development for faculty and staff, research support infrastructures, and the institutional culture. Within this context, the BRAD seeks to prepare directors of sponsored programs at eligible institutions for administrative leadership in planning and implementing the biomedical and biobehavioral research agendas at their institutions, to help build "offices of opportunity" for faculty with an interest in research, and to develop and implement faculty-friendly pre- and post-award and compliance processes.

The **BRAD objectives are:**

- To facilitate the development of a well-trained cadre of leaders and managers in research administration by encouraging and supporting continuous professional development for directors of OSPs, research administrators, and grants managers at all levels.
- To increase the effectiveness and productivity of OSPs by promoting the use of best practices in research administration, including but not limited to:
  - Consistency of customer service;
  - Development, implementation, and maintenance of efficient pre-award processes that address and eliminate internal barriers to research;
  - Development, implementation, and maintenance of post-award processes that facilitate financial accountability; and
  - Development, implementation, and maintenance of processes that ensure compliance with Federal, state, and institutional regulations (e.g., compliance with human subject and animal care policies).

The NIH recognizes a unique and compelling need to promote diversity in the NIH-funded biomedical, behavioral, clinical and social sciences workforce. The NIH expects efforts to diversify the workforce to lead to the recruitment of the most talented researchers from all groups; improve the quality of the educational and training environment; balance and broaden the perspective in setting research priorities; improve the ability to recruit subjects from diverse backgrounds into clinical research protocols; and to improve the Nations capacity to address and eliminate health disparities. Accordingly the NIH continues to encourage institutions to diversify their student and faculty populations and thus to increase the participation of individuals currently underrepresented in the biomedical, clinical, behavioral, and social sciences such as: individuals from underrepresented racial and ethnic groups, individuals with disabilities, and individuals from socially, culturally, economically, or educationally disadvantaged backgrounds that have inhibited their ability to pursue a career in health-related research.

Similar to the former EARDA program, the promotion of diversity in the scientific workforce by encouraging the participation of faculty and students in the research enterprise is a priority for the

BRAD program. Additionally, there is an expectation that research and/or research capacity building is already ongoing—in the mission areas of the participating components of the NIH; on inequities in health; and/or on any stage of human development—from preconception to adulthood—to better understand the health of children, adults, families and communities.

**Scope of the BRAD Program**

The BRAD program promotes capacity building in research administration in one or more of three areas of emphasis:

- Processes and work tools that need to be developed, facilitated, and/or acquired to address gaps in existing pre- and post-award processes.
  - For illustrative purposes, institutional processes, include but are not limited to: procedures or functions that create and distribute information and data—electronically or via paper paths. Examples of institutional processes related to research administration and management include processes for proposal routing, financial transactions related to implementation of sponsored research projects, and obtaining various approvals.
  - Work tools (i.e., software, databases, online sources of information regarding regulatory issues and training, etc.) enable research administrators and grants managers to function productively to better serve researchers. Examples include but are not limited to: access to technology and training in its efficient use; knowledge of and ability to apply rules and regulations appropriately and proficiency with the institution’s management; and financial database(s) and software.
- Issues/Challenges that need to be addressed to facilitate the development of a supportive research environment. Examples of issues or challenges (barriers) include but are not limited to:
  - Integration of research support functions into the roles and responsibilities of a select cadre of existing staff; and
  - Institutionalization of continuing professional development for researchers and administrative support staff, and promotion of a culture of research.
- Identification and development of services that support faculty members with an interest in developing externally sponsored research programs.
  - Enabling the institution to serve faculty across the entire research proposal life cycle (i.e., supporting forums for developing research ideas; finding/qualifying resources for external research support; developing the proposal, pre-reviewing the proposal, submitting the proposal; facilitating award implementation and award management; and information dissemination).

**Structure and Governance of the BRAD Program**

The emphasis on program structure and governance is intended to ensure the alignment of BRAD program activities with the strategy and direction of applicant institutions. Accordingly, program governance should focus on people, roles, structures and policies.

**Extramural Associate (PD/PI):**

The Extramural Associate (EA) serves as the PD/PI of the G11 award. In preparing the
application, the EA is strongly encouraged to consult with other faculty and administrators at the applicant institution. This is essential in being able to identify strengths, weaknesses, and needs of the research administration infrastructure, which will form the rationale for the Institutional Research Administration Capacity Building (IRAC) Plan as described below.

As the BRAD Program Director at the awardee institution, the EA is the single point of accountability and has full project authority, within the limits of the established budget and policies, to manage and direct BRAD program resources and to make decisions regarding program direction. The ideal EA should have familiarity with the research scope of the applicant institution, experience in managing a business or other relevant office, and experience in the administration or management of scientific research. The EA must have the support of the applicant institution and the authority to oversee and execute the Institutional Research Administration Capacity Building (IRAC) Plan. The EA must also have the flexibility in regard to academic, professional and service workload responsibilities to carry out the expectations outlined in this FOA.

Co-Investigator

The Co-Investigator is the executive sponsor of the BRAD award, and should be a high ranking official at the applicant institution or his/her designee. Should the institution’s President or Chancellor designate a senior administrator as the Co-Investigator, that individual must have the responsibility and authority to make high-level decisions regarding faculty teaching time commitments, curricula, and research administration-related decisions. Typically, the Co-Investigator is responsible for: (i) championing the project, (ii) obtaining budget approval for the project, and (iii) facilitating the resolution of problems encountered by the EA. The Co-Investigator can also help facilitate sustainability by ensuring the integration of BRAD-supported activities and enhancements into any pre-existing research administration infrastructure.

Mentor:

The EA should designate a mentor who has demonstrated expertise in research administration based on past training and experience at an institution with a sizable research portfolio and a strong Office of Sponsored Research. In addition to providing expertise in research administration, the mentor will assist the EA in identifying training opportunities and provide guidance in developing and implementing pre- and post-award processes at the grantee institution.

Steering Committee:

A steering committee is a group of high-level stakeholders who are responsible for providing guidance on overall strategic direction. The purpose of the Steering Committee is to provide strategic input to the EA and encourage buy-in to the broader organization. The steering committee is usually made up of organizational peers, but may also include members from outside the institution if appropriate.

Program Activities

Pre-Residency Web-Based Training for the EA:
Web-based training will be completed during the April/May timeframe prior to traveling to the NIH for the residency training component. The time devoted to this training component is required and must be completed as a condition of the grant award. NICHD presents a series of training modules which include such topics as an introduction to the NIH, NIH terminology and funding mechanisms, roles of the NIH officials (Scientific Review Officers and Program Officials, etc.), receipt and referral, peer review processes, program funding cycles, grants management basics, use of animals in research, and use of human subjects in research. It is NICHD’s expectation that the EAs will be released from other institutional duties to participate in the web-based training component.

NIH Residency Training:

EA Residency Training Part 1 takes place at the NIH and will be scheduled for a total of three (3) weeks during Year 1 of the grant award (usually during the late May/June timeframe). EA Residency Training Part 2, to be held in year 3 (usually in June), will consist of a 5-day web-based training. Part I will focus on NIH processes and procedures and the knowledge and skills needed to administer NIH and other grant awards. Residency training also includes a broad participation by the NICHD, other NIH Institutes and Centers, other components of the U.S. Public Health Service, and selected public and private sector organizations. NIH staff mentors are assigned to each EA prior to their arrival at the NIH. The EA and the institution must be fully committed to all phases of the EA training. Accordingly, EAs will be expected to adjust their schedules to include all training activities.

Institutional Research Administration Capacity Building (IRAC) Plan:

The purpose of the Biomedical/Biobehavioral Research Administration Development (BRAD) Award (G11) is to provide support for strengthening institutional research administration infrastructures. The BRAD program does not support research projects per se. After participating in the NIH-sponsored training programs, the EA is responsible for carrying out the proposed Institutional Research Administration Capacity Building (IRAC) Plan for developing capacity in research administration at the applicant organization.

Sustainability Initiatives:

During the 4th and 5th years of the 5-year project period, a portion of the budget may be re-programmed—up to $10,000 for international applicants and up to $20,000 for domestic applicants—to support prototype “sustainability initiatives.” Sustainability initiatives include any activities that can help to ensure a sustainable research administration infrastructure after BRAD funding has ended. The purpose of this program component is to enable the PD/PI to collect data to demonstrate the importance of such activities in helping to maintain institutional competitiveness and/or the efficiency and productivity of research administration operations. Potential evidence-based sustainability initiatives will be developed by BRAD awardees as a component of NIH Residency Training.

Section II. Award Information

| Funding Instrument | Grant |

### Application Types Allowed

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<th>New</th>
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<tr>
<td>Resubmission</td>
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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 number of awards is contingent upon NIH appropriations, and the submission of a sufficient number of meritorious applications.

### Award Budget

<table>
<thead>
<tr>
<th>International base awards</th>
<th>Domestic base awards</th>
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<tr>
<td>are limited to $45,000 per year (direct costs), of which up to $10,000 must be allocated in years 4 and 5 for sustainability initiatives. Additionally in year 1, up to $10,000 may be requested for travel related to the NIH Residency Training.</td>
<td>are limited to $85,000 per year (direct costs), of which up to $20,000 must be allocated in years 4 and 5 for sustainability initiatives. In addition, applicants may request up to $5,500 in year 1 for travel related to the NIH Residency Training.</td>
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| F&A Costs | are 8 percent for both domestic and international applicants. |

### Award Project Period

The total project period for applications submitted in response to the funding opportunity may not exceed 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

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
Other

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

Foreign (non-U.S.) components of U.S. Organizations are allowed.

Foreign Institutions

Foreign applicants must be institutions of higher education—public or private—in India and sub-Saharan Africa that meet the criteria below:

- Applicant Institutions with at least three NIH awards (e.g., R01, R03, R21, U01, D43, etc.), through a direct grant or as a subcontract to a U.S. domestic award. Each of these awards should be currently active and/or reflect collaboration on an NIH-funded project within the past three (3) years. Applicants must have an existing research administrative infrastructure (Office of Sponsored Projects, Office of Research and Sponsored Projects, etc.) in place.
- Applicant Institutions with the required electronic connectivity and Internet access for NIH electronic grant submission and post-award administration.

Domestic Institutions

- The applicant organization must offer baccalaureate or advanced degrees in the sciences related to biomedical and behavioral sciences and meet the requirement of receiving research grants and/or cooperative agreements from the NIH totaling not more than $6 million per year (in both direct and F&A/indirect costs) in each of four (4) or more of the last seven (7) years. Note that "NIH research grants and cooperative agreements" includes all extramural awards designated by an activity code starting with R, P (except P20), M, T, K, or U, and also DP1, DP2, and D42. The following activity codes are excluded: C, S, and G.
- Domestic applicant organizations must have a significant enrollment of students from groups that are underrepresented in the biomedical, clinical, behavioral, and social sciences. One of the objectives of the BRAD program is to develop a strong research infrastructure at the recipient institutions, which will enhance participation of individuals from the following underrepresented groups:

  A. Individuals from racial and ethnic groups that have been shown by the National Science Foundation to be underrepresented in health-related sciences on a national basis (see data at http://www.nsf.gov/statistics/showpub.cfm?TopID=2&SubID=27 and the most recent report on Women, Minorities, and Persons with Disabilities in Science and Engineering). The following racial and ethnic groups have been shown to be underrepresented in biomedical research: African Americans, Hispanic Americans, American Indians, Alaska Natives, Native Hawaiians, and other Pacific Islanders. In addition, it is recognized that underrepresentation can vary from setting to setting; individuals from racial or ethnic groups that can be convincingly demonstrated to be underrepresented by the grantee institution should be encouraged to participate in this program

  B. Individuals with disabilities, who are defined as those with a physical or mental impairment that substantially limits one or more major life activities; and
C. Individuals from disadvantaged backgrounds who are defined as:

1. Individuals who come from a family with an annual income below established low-income thresholds. These thresholds are based on family size; published by the U.S. Bureau of the Census; adjusted annually for changes in the Consumer Price Index; and adjusted by the Secretary for use in all health professions programs. The Secretary periodically publishes these income levels at HHS - Poverty Guidelines, Research, and Measurement. For individuals from low income backgrounds, the institution must be able to demonstrate that such participants have qualified for Federal disadvantaged assistance or they have received any of the following student loans: Health Professions Student Loans (HPSL), Loans for Disadvantaged Student Program, or they have received scholarships from the U.S. Department of Health and Human Services under the Scholarship for Individuals with Exceptional Financial Need.

2. Individuals who come from a social, cultural, or educational environment such as that found in certain rural or inner-city environments that have demonstrably and recently directly inhibited the individual from obtaining the knowledge, skills, and abilities necessary to develop and participate in a research career.

NOTE: Recipients of other NIH research capacity building awards, if successful in applying for this award, may have their budgets reduced in areas where there is significant overlap in capacity development for research administration related activities and processes.

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 Directors/Principal Investigators (PD/PIs) 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 four (4) weeks prior to the application due date.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program 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
For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF 424 (R&R) Application Guide.

The special requirements of the BRAD Program include the following:

- The Program Director/Principal Investigator (PD/PI) will serve as the Extramural Associate (EA) for the program. A Ph.D., M.B.A. or equivalent degree is preferred, but not necessary, providing the EA has suitable qualifications overall. The EA is responsible for the day-to-day management of the grant.
- The Co-Investigator of the BRAD award should be a high ranking official at the applicant institution with the authority to make high-level decisions regarding faculty teaching time commitments, curricula, and research administration-related decisions.
- The applicant may choose the multiple PD/PI option, with the EA serving as contact PD/PI and senior faculty or administrators serving as members of the multi-PD/PI team. This structure is strongly encouraged to ensure that the BRAD project has the appropriate level of oversight by the senior leaders of the applicant institution, and to ensure that the proposed IRAC Plan is consistent with the long-term institutional master plan, vision, and mission.

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

Only one application per institution (normally identified by having a unique DUNS number or NIH-IPF number) is allowed.

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. Resubmission applications may be submitted, according to the NIH Policy on Resubmission Applications from the SF 424 (R&R) Application Guide.

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 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 administration capacity development initiative
- 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:

Regina Smith James, M.D.
Director, Division of Special Populations
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
6100 Executive Boulevard, Room 5E03A
Bethesda, MD 20892-7510
(Rockville, MD 20852 for courier or express service)
Telephone: 301-435-2692
Email: rjames@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.

**Facilities & Other Resources**

- Describe the research environment, including the facilities, laboratories, core or multiple user research resources that comprise the existing research infrastructure at the institution. Also
provide a summary of current support for building research capacity as well as support for research training and education. Describe the institution’s enrollment of students from groups that are underrepresented in the scientific workforce, and explain how the expanded research infrastructure will promote their exposure to biomedical and biobehavioral research.

Provide the following data, to the extent possible, in tabular format:

- Number of faculty members in biomedical and behavioral science disciplines with doctorate or equivalent degrees;
- Number of faculty engaged in biomedical and behavioral science research;
- Number of faculty with external research support;
- Evidence (or number) of presentations at local, regional, national, and international meetings;
- Evidence of faculty research collaborations with investigators at other institutions;
- Faculty involved in peer review activities, as members of standing or ad hoc review committees;
- Current student population in the biomedical and behavioral sciences.

Provide information regarding the institution’s current NIH funding in a list or table format. For each project, include the NIH project number, key personnel from the applicant institution and their official role (e.g., PD/PI, subproject director, investigator, etc.), grantee institution, title of project, total amount of grant award (or subcontract or subproject award), and project period (start and completion dates).

**R&R Budget Component**

Follow all instructions provided in the SF424 (R&R) Application Guide with the following modifications:

This FOA will use the non-modular budget. Level of effort for the PD/PI should range from a minimum of 4 person months (25 percent) to a maximum of 6 person months (50 percent). Level of effort attributed to the grant for the Co-Investigator and for administrative research support should be no more than 0.36 person months (3 percent) and 6 person months (50 percent), respectively. The institution can increase the level of effort for the PD/PI, the Co-Investigator and administrative support personnel through "in kind" contributions. Include all personnel other than the PD/PIs in the Other Personnel section, including research administrative staff, coordinators, grants managers, etc.

Support for competency-based training (i.e., for the EA, research administrators, grants managers, etc.), workshops, and for research administration infrastructure development should be itemized in the "Other Category" and justified.

**PHS 398 Research Plan Component**

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

**Specific Aims**
The specific aims section must be restricted to one page. Consider the specific aims section as the master plan for the proposal; and as such, it reflects the steps that the applicant will take to accomplish the proposed objectives for the project period. Keep in mind that a clear measurable goal and objectives will lead into the specific aims; and accordingly, the goal of the specific aims is to provide solutions to the problems or challenges (i.e., objectives) identified.

Research Strategy (Capacity Building Strategy)

The purpose of the Biomedical/Biobehavioral Research Administration Development (BRAD) Award (G11) is to provide support for strengthening institutional research administration infrastructures. The BRAD program does not support research projects per se. The Research Strategy section, which is limited to 12 pages, must provide an Institutional Research Administration Capacity Building (IRAC) Plan that outlines the objectives and approaches for developing capacity in research administration at the applicant organization. The standard PHS 398 instructions should be followed, if relevant to this program, with the additional guidance below. Start each section with the appropriate section heading. Applicants that have multiple Specific Aims may address Significance, Innovation, and Approach for each Specific Aim individually or for all specific Aims collectively.

Significance (Component of Research Strategy)

- Explain the importance of the problem or barrier to research that the proposed institutional research administration capacity building plan will address.
- Identify which aspects of research administration related services that the Plan will address (i.e., pre-award services, post-award services, ethical compliance, etc.) and explain how the proposed plan will improve those services.
- Describe how the research enterprise at the applicant institution will benefit if the proposed aims are achieved.
- Describe how the enhanced research capacity will provide new opportunities for underrepresented students to participate in behavioral or biomedical research.

Innovation (Component of Research Strategy)

- Explain how the proposed plan seeks to challenge existing barriers to research at the BRAD eligible institution, facilitate the development of a supportive research environment, and/or increase the number of faculty that can successfully compete for external research support.
- Describe any novel concepts or approaches to building capacity in research administration at institutions with relatively small research portfolios.

Approach (Component of Research Strategy)

Institutional Research Administration Capacity Building (IRAC) Plan:

- Describe the overall strategy and methodology to be used to accomplish the specific aims of the proposed project.
- Outline the processes and work tools that will be developed and/or acquired to address gaps in existing research support services (i.e., pre-award services, post-award services, ethical
compliance, etc.).

- Describe ways that the applicant will support faculty researchers within the context of the research proposal life cycle (i.e., developing ideas, finding resources, developing the proposal, pre-reviewing the proposal, submitting the proposal, receipt of the award and project implementation, managing the grant award, outcome dissemination, etc.).
- Describe key evidence-based interventions or best practices, work tools, processes, and training methodologies, etc., that will be used to accomplish the specific aims. Be sure to include training strategies for building a cadre of research administrators, grants managers, etc. at the applicant institution.
- Integration -- Indicate how the proposed program of activities relates to and is integrated with the existing administrative research infrastructure (e.g., Office of Sponsored Programs).
- Outreach -- Describe any proposed outreach regionally to help strengthen research administration capabilities.
- Discuss potential problems, alternative strategies and benchmarks for success anticipated to achieve the aims.
- If the applicant organization has received any other research capacity building awards, provide a list of those grants and their objectives. Describe how BRAD support could potentially have a synergistic impact in regard to the outcomes of the other research capacity building initiatives.

Mentoring Plan:

The Mentoring Plan should address mentoring at two levels—research administrative leadership (e.g., the EA and/or director of the office of sponsored programs, etc) and the office of sponsored program (or Grants Office) staff. Oftentimes the deciding factor in the success of capacity building programs is how well organizations develop their most valuable asset: the people. While training opportunities are provided for the EA and other participating staff, mentoring helps to turn the most experienced staff into a training cadre that can share areas of expertise using a mentoring process that is tailored to the organization's specific needs.

Evaluation Plan:

Capacity building is an iterative and complex process; therefore, Evaluation Plans are a requirement under this FOA.

Timeline for Implementation:

Develop a timeline for implementing the proposed Institutional Research Administration Capacity Development Plan, using either a tabular or bulleted format. A sample timeline with a description of the activities to be accomplished each year is provided below only for illustrative purposes.

- Year 1: Adequately staff the office of sponsored programs (OSP); strengthen office communication and computing capabilities; initiate development of pre-award related processes, initiate acquisition of the necessary work tools, initiate planning for the OSP website, develop research policies, establish and activate advisory committee; assess faculty and student training needs and resources; and establish performance measures and collect baseline data for the evaluation plan.
• Year 2: Assess and strengthen accounting and monitoring practices; facilitate direct proposal submissions; develop core training capabilities and materials; conduct workshops; and monitor performance of workshops.
• Year 3: Review and refine sustainability plan for stimulating research; continue training workshops and seminars; continue monitoring quality of training; conduct mid-course reviews; and refine work plan as needed.
• Year 4: Continue to develop and implement strategies to develop research capacity through improved grantsmanship; assess regional needs and plan regional activities; and establish partnerships and other linkages in support of goals.
• Year 5: Implement and assess regional activities; continue training activities; finalize plan for sustainability of research development office; and implement the (process and outcome) evaluation of program.

**Investigators (Component of Research Strategy)**

**Extramural Associate (PD/PI):**

Briefly describe the nominee’s professional background, training, work experience, personal qualifications, knowledge, and skills in relation to the requirements and responsibilities of the BRAD Program. The description should also address the EA’s:

• Rapport with faculty and students, ability to motivate and advise others, and commitment to serve the institution;
• Commitment to and experience in the administration of research;
• Ability to oversee the development and management of a research administrative infrastructure, such as Office of Research or Office of Sponsored Projects (as applicable); and
• Commitment to increasing and strengthening biomedical and behavioral research capacity at the institution.

**Co-Investigator:**

Briefly describe the Co-Investigator’s professional background, work experience, personal qualifications, knowledge and skills, particularly as they relate to his or her ability to fulfill the oversight responsibilities of the BRAD program. The oversight responsibilities include, but are not limited to: ensuring that the EA has the appropriate level of authority to execute the institutional plan, and ensuring the integration of BRAD-supported activities into any existing research infrastructure.

**Mentor:**

The EA's mentor must have demonstrated expertise in research administration based on past training, as well as experience at an institution with a sizable research portfolio and a strong Office of Sponsored Research. Briefly describe the proposed mentor’s professional background, work experience, personal qualifications, knowledge and skills as they relate to his or her ability to fulfill the mentoring responsibility.

Please note that the biographical sketch for the EA’s proposed mentor must be uploaded with
the biosketches of the EA and the Co-investigator.

**Steering Committee:**

A plan must be provided for the appointment of a Steering Committee to help set the agenda, monitor progress, and advise the EA. The steering committee is usually comprised of organizational peers and reflects a combination of direct customers and indirect stakeholders. Describe the composition of the Steering Committee, identifying the role and the desired expertise of members. Do not name specific individuals. Describe how the Steering Committee will function, including the responsibilities of the committee, the frequency of meetings, and any other relevant information.

**Environment and Institutional Commitment (Component of Research Strategy)**

**Environment:**

Briefly describe the institution’s strategic vision for research and discuss how engagement in research will enable the institution to better accomplish the teaching and community service aspects of its mission. Clarify the components of the existing infrastructure that can be improved upon and/or where the infrastructure can be enhanced by adding new components or by addressing identified needs or weaknesses. Discuss the current status of research at the institution and the potential for increasing the level of externally-sponsored research projects. Use the characteristics of the institution, as described under SF 424 Facilities and Other Resources, to make assessments regarding the current status of research at the institution and the potential for increasing the level of faculty participation in research pending a successful implementation of the proposed Institutional Research Administration Capacity Building (IRAC) Plan. This section should also describe the institution’s enrollment of students from groups that are underrepresented in the biomedical, clinical, behavioral, and social sciences (see definitions in Section III. 1. Eligible Applicants) and address the institution’s potential for increasing their exposure to biomedical and behavioral research.

**Multiple PD/PI Leadership Plan**

Describe the Leadership Plan in Section 14 of the Research Plan Component in the SF424 (R&R) as directed in the “Special Instructions for Applications with Multiple PDs/PIs.” Note that the governance and organizational structure of the leadership team for the research administration capacity building project should be described, including communication plans, process for making decisions on scientific direction, and procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the program should be delineated for the PDs/PIs. The Multiple PD/PI Leadership Plan should be uploaded as a pdf file at Item 12 in the "Other Research Plan Section" of the PHS 398 Research Plan Component.

**Letters of Support**

**Institutional Commitment Letter:**

Support from the top is indispensable for making externally supported research programs a
reality. Without such support, organizational change does not occur. Therefore an institutional Letter of Commitment must be provided by the President or designated high ranking official (i.e., Provost, Vice-President for Research, Dean, etc.) as evidence of institutional commitment to capacity building in research administration. Institutional commitment is also reflected by the provision of adequate staff, facilities, and support processes and resources that can contribute to the planned capacity building efforts.

Letters of Support:

Provide three letters of support from colleagues (scanned for electronic submission) who have worked with the Extramural Associate (PD/PI) and/or have knowledge of his/her effectiveness in working with a team and ability to successfully communicate and coordinate across organizational boundaries. Each letter should include the referee’s name, title, institutional affiliation, address, telephone and fax numbers, and e-mail address. Support letters must be included in the Letters of Support attachment. To comply with this requirement, it is recommended that all reference letters be obtained from the referring individuals as far in advance of the application deadline as possible.

The Letters of Support should be scanned into a pdf file and attached as item 17 in the PHS 398 Research Plan Component.

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, with the following modification:

- Generally, Resource Sharing Plans (Data Sharing Plan, Sharing Model Organisms, GWAS Sharing Plan) are expected, but they are not applicable for this FOA.

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.

Foreign Organizations

Foreign (non-US) organizations must follow policies described in the NIH Grants Policy Statement, and procedures for foreign organizations described throughout 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. Activities and other purposes for which funds may be used include but are not limited to:

- Development and implementation of pre-award processes and services (e.g., stimulating new grant proposals, disseminating funding information, and managing the development and submission of proposals);
- Development and implementation of post grant award processes and services (e.g., monitoring spending, billing, effort reporting, providing financial reports, performing closeout activities);
- Development of systems aimed at enabling the grantee institution to better comply with research-related Federal and state statutes and regulations;
- Support for information systems including website development and management and database development;
- Recruitment/support of research administrators in the OSP to assist in developing and managing pre-award services—support may be requested for up to 6 person months (0.5 FTE), and justification must be provided;
- Support for facilitating compliance (use of human subjects and animals in research, biosafety, training in OMB circulars, technology transfer issues, etc.);
- Continuing professional development aimed at enhancing faculty competitiveness in securing external research support, such as conduct of institutional and/or regional workshops on grantsmanship, research process and design, statistical tools, research ethics, consortium research arrangements, and research management.
- Competency-based training for research administrators/grant managers to ensure that support staff has the requisite knowledge and skills to provide efficient pre- and post-award services throughout the life cycle of the research proposal. Professional development in research administration and grants management may include participation at local workshops (seminars, learning communities, or the train-the-trainer models) or at national meetings on research administration, e.g., the Society of Research Administrators International (SRA) or the National Council of Research Administrators (NCURA). The training budget may include travel, membership and registration fees, and courses;
● E-learning—some institutions sponsor online training opportunities that might be extended to others outside of their home institution; and
● Mentorship for the EA -- Support may be requested for the mentor to travel to the grantee institution, or for the EA to travel to the mentor's institution. No salary may be requested for the mentor.

Funds may not be used for:

● Research infrastructure (such as laboratories)
● Research projects
● Alterations and Renovations

### 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](http://grants.nih.gov/grants/guide/pa-files/PAR-11-270.html) contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit [Applying Electronically](http://grants.nih.gov/grants/guide/pa-files/PAR-11-270.html).

**Important reminders:**

All PD/PIs 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/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](http://grants.nih.gov/grants/guide/pa-files/PAR-11-270.html) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness by the Center for Scientific Review, NIH. Applications that are incomplete will not be reviewed.

**Post Submission Materials**

Applicants are required to follow the instructions for post-submission materials, as described in [NOT-OD-10-115](http://grants.nih.gov/grants/guide/pa-files/PAR-11-270.html).

**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:

Investments in research administration, which encompass pre-award processes as well as post-award research management processes, have a synergistic impact in regard to increasing faculty participation in research, increasing competitiveness for external research support, improving research project management, and ultimately increasing the diversity of the scientific workforce. Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood that the project will lead to a more supportive research environment and an effective and productive Office of Sponsored Programs (OSP) that will have a synergistic impact on overall institutional research capacity and competitiveness in securing external research support.

**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?

Is the proposed project well justified in terms of addressing deficiencies or gaps in the existing research administration infrastructure? Are processes and/or work tools identified that need to be developed, facilitated, or acquired to address current gaps in the infrastructure? Does the proposal target one or more areas of emphasis for improving faculty support within the context of the research proposal cycle? How will completion of the aims change the research environment and the operation of the OSP (or an Office of Research Development, as applicable) in a way that promotes faculty effectiveness in developing competitive research proposals?

**Investigator(s)**

Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage
Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Does the Extramural Associate (PD/PI) have the ability to provide scientific and/or administrative leadership and direction? Has he/she demonstrated the ability to perform in a team environment to accomplish objectives that require coordination across multiple organizational entities? Does the PD/PI have the requisite authority to implement the proposed Institutional Research Administration Capacity Building (IRAC) Plan?

Are the qualifications, experience, position and commitment of the Co-Investigator and his/her ability to provide oversight as well as delegate authority to the PD/PI to implement the proposed IRAC Plan adequate?

Does the proposed mentor have the experience in research administration as well as experience in mentoring to facilitate the continuing professional development of the EA as well as advise the EA regarding best practices in research administration?

**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?

Does the application identify critical research administration infrastructure needs (i.e., effective information dissemination; staffing the OSP and grants management function, training OSP and grants management staff, stimulating interest in research, institutional-based professional development for faculty in research project development and management, etc), and seek creative ways, within the context of a non-research institution, to address those needs?

**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?

Does the Institutional Research Administration Capacity Building (IRAC) Plan adequately
identify specific needs/weaknesses within the applicant’s existing research administration infrastructure, establish reasonable specific aims, as well as identify best practices (i.e., interventions, work tools, and processes) that can effectively address and eliminate targeted deficiencies and gaps? Are the plans for providing competency based training in research administration and grants management for support staff adequate? What is the likelihood that accomplishing the specific aims would increase both the level and quality of research at the applicant institution?

Are the roles and responsibilities of the Steering Committee appropriate? Is the composition of the committee appropriate for its identified roles and responsibilities? Has the applicant adequately described the member selection criteria?

In regard to the required plan for evaluating the effectiveness of program implementation and its impact on the research administration infrastructure, does the applicant identify the capacities that will be assessed as well as the indicators and measures that will be used to assess the anticipated outcomes?

**Environment**

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Does the applicant’s high-level leadership exhibit solid support for strengthening institution’s research administration infrastructure as a pre-requisite to increasing the level and quality of research? What comments in the Official’s letter best demonstrates the strength of his/her resolve to support efforts to make the changes necessary to begin to change the trajectory of the institution in terms of increasing the level and quality of research in a sustainable fashion?

**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.

- In assigning an overall impact/priority score, reviewers should evaluate the extent to which efforts are made to institutionalize program activities to facilitate sustainability, either through their integration into a pre-existing research administration support entity and/or through policy, as appropriate.

**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**

For Resubmissions, the committee will evaluate the application as it is currently presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

**Renewals**

Not applicable.

**Revisions**
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

Reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

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 NICHD, 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 (generally the top half of applications under review), will be discussed and assigned an overall impact/priority score.
- Will receive a written critique.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate
NIH Institute or Center. Applications will compete for available funds with all other recommended applications. Following initial peer review, recommended applications will receive a second level of review by the appropriate national Advisory Council or Board. 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.
- For domestic institutions, preference will be given to non-research intensive institutions that propose to build and/or enhance the research infrastructure and research training capacity. Additionally, a program "diversity" goal, to provide opportunities for students from groups underrepresented in the scientific workforce to have exposure to biomedical and biobehavioral research and to consider research as a career option, is desirable.

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.

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 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)
Jean L. Flagg-Newton, PhD  
*Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)  
Telephone: 301-435-2722  
Email: flaggnej@mail.nih.gov

Jeanne McDermott, PhD  
Fogarty International Center (FIC)  
Telephone: 301-496-1492  
Email: Jeanne.mcdermott@nih.gov

Nancy Touchette, PhD  
National Institute of Allergy and Infectious Diseases (NIAID)  
Telephone: 301-451-2486  
Email: ntouchette@niaid.nih.gov

**Peer Review Contact(s)**

Sherry Dupere, Ph.D  
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**Financial/Grants Management Contact(s)**

Bonnie Jackson  
*Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)  
Telephone: 301-496-5482  
Email: jacksobo@mail.nih.gov

Bruce Butrum  
Fogarty International Center (FIC)  
Telephone: 301-496-1670  
Email: bruce.butrum@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

Office of Extramural Research (OER)

National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892

Department of Health and Human Services (HHS)

NIH . . . Turning Discovery Into Health

Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see Help Downloading Files.