**Department of Health and Human Services**

**Part 1. Overview Information**

<table>
<thead>
<tr>
<th>Participating Organization(s)</th>
<th>National Institutes of Health (NIH)</th>
</tr>
</thead>
</table>
| Components of Participating Organizations | National Cancer Institute (NCI)  
National Heart, Lung, and Blood Institute (NHLBI) |
| Funding Opportunity Title | The Effect of Racial and Ethnic Discrimination/Bias on Health Care Delivery (R01) |
| Activity Code | R01 Research Project Grant |
| Announcement Type | Reissue of PA-08-083 |
| Related Notices | None |
| Funding Opportunity Announcement (FOA) Number | PA-11-162 |
| Companion FOA | PA-11-163, R21 Exploratory/Developmental Grant, PA-11-164, R03 Small Grant Program |
| Number of Applications | See Section III. 3. Additional Information on Eligibility |
| Catalog of Federal Domestic Assistance (CFDA) Number(s) | 93.393, 93.394, 93.395, 93.399, 93.233, 93.837, 93.838, 93.839 |

**FOA Purpose**

This funding opportunity announcement (FOA) encourages the submission of research project grant applications from institutions/organizations that propose to: (1) improve the measurement of racial/ethnic discrimination in health care delivery systems through improved instrumentation, data collection, and statistical/analytical techniques; (2) to enhance understanding of the influence of racial/ethnic discrimination in health care delivery and its association with disparities in disease incidence, treatment, and outcomes among disadvantaged racial/ethnic minority groups; and (3) to reduce the prevalence of racial/ethnic health disparities through the development of interventions to reduce the influence of racial/ethnic discrimination on health care delivery systems in the United States (U.S.).

**Key Dates**

<table>
<thead>
<tr>
<th>Posted Date</th>
<th>March 17, 2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open Date (Earliest Submission Date)</td>
<td>May 5, 2011</td>
</tr>
<tr>
<td>Letter of Intent Due Date</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>
Application Due Date(s) | Standard dates apply, by 5:00 PM local time of applicant organization.
---|---
AIDS Application Due Date(s) | Standard dates apply, by 5:00 PM local time of applicant organization.
Scientific Merit Review | Standard dates apply
Advisory Council Review | Standard dates apply
Earliest Start Date(s) | Standard dates apply
Expiration Date | May 8, 2014
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.

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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   Section V. Application Review Information
   Section VI. Award Administration Information
   Section VII. Agency Contacts
   Section VIII. Other Information

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

PURPOSE

This funding opportunity announcement (FOA) encourages the submission of research project grant applications from institutions/organizations that propose to: (1) improve the measurement of racial/ethnic discrimination in health care delivery systems through improved instrumentation, data collection, and statistical/analytical techniques; (2) to enhance understanding of the influence of racial/ethnic discrimination in health care delivery...
and its association with disparities in disease incidence, treatment, and outcomes among disadvantaged racial/ethnic minority groups: and (3) to reduce the prevalence of racial/ethnic health disparities through the development of interventions to reduce the influence of racial/ethnic discrimination on health care delivery systems in the United States (U.S.).

BACKGROUND

Racial/ethnic minorities suffer disproportionate morbidity and mortality from chronic diseases such as cancer, heart disease, diabetes and stroke. Although racial/ethnic differences in morbidity and mortality can be partially explained by differences in lifestyle, health behavior and financial access to care, these factors do not entirely explain differences in incidence, treatment or outcomes. The Institute of Medicine (IOM) report on unequal treatment (http://www.nap.edu/openbook.php?isbn=030908265X) as well as several other reviews show that racial/ethnic minorities also less frequently receive appropriate care which has an adverse impact on their health outcomes including higher recurrence rates, poorer survival experiences and higher morbidity and mortality. An association between perceived discrimination and poorer health status has also been found. The IOM report concluded in part that “(1) Racial/ethnic disparities in healthcare occur in the context of broader historic and contemporary social and economic inequality and evidence of persistent racial and ethnic discrimination in many sectors of American life; (2) health systems, healthcare providers, patients and utilization managers may contribute to racial and ethnic disparities in healthcare; and (3) that health provider bias, stereotyping, prejudice and clinical uncertainty may contribute to racial and ethnic disparities in health care.” The Trans-US Department of Health and Human Services Health Disparities Progress Review Group also recognized the need to discuss the impact of racism as a fundamental cause of health disparities.

The IOM committee recommended that additional research be conducted to provide insight into how and why racial/ethnic disparities occur and to test interventions and strategies to eliminate them, including research that provides further elucidation on: (1) patient, provider and institutional contributions to healthcare disparities; (2) the relative contributions of provider bias, stereotyping, prejudice, and uncertainty to racial/ethnic disparities in diagnosis, treatment, and outcomes of care; and (3) the role of non-physician healthcare professionals, pharmacists, allied health professional and non-professional staff contribution to healthcare disparities.

The National Research Council (http://www.nap.edu/catalog.php?record_id=10887) defined racial discrimination as the “(1) differential treatment on the basis of race that disadvantages a racial group and, (2) treatment on the basis of inadequately justified factors that disadvantages a racial group. For the purposes of this program announcement race is defined as a continuously evolving social construct used to categorize individuals into groups that have typically been based on the physical characteristics (e.g. skin color, hair texture or other distinctive characteristics, etc.) of an individual or their ancestors. Ethnicity refers to cultural groups that have been typically defined by a common language, religion, nationality or heritage. This program announcement focuses on examining overt as well as subtle racial/ethnic discriminatory behavior and processes perceived or experienced by historically disadvantaged racial/ethnic minority groups and their contribution to persistent disparities in the receipt of quality health care and disease outcomes that have been observed among these populations.

Racial/ethnic bias is hypothesized to contribute to disparities in health through five key pathways. These include increased exposure and susceptibility to (1) economic and social deprivation; (2) toxic substances and hazardous conditions; (3) socially inflicted mental and physical trauma directly experienced or witnessed; (4) targeted marketing of potentially harmful commodities such as tobacco, alcohol and illicit drugs; and (5) inadequate or degrading medical care.

The influence of non-clinical characteristics, either actual or perceived, on provider perception of racial/ethnic minority patients might also have an impact on the health care received by patients. Physician recommendations and referrals have been shown to contribute to racial disparities in referrals for kidney transplantation and receipt of some cardiovascular procedures. Several mechanisms through which providers potentially contribute to racial/ethnic disparities in health have been suggested. These include provider bias against racial/ethnic minorities, uncertainty in their interactions with minority patients, beliefs or stereotypes regarding the health behavior of minority patients and patient response to perceived provider mistreatment or other negative racial experiences. In one report, 63% of the 76 participants in a cross-sectional survey indicated that they had experienced discrimination in their interactions with their health care provider because of their race or color. Similarly, 29% of African Americans and more than 10% of Latino/Hispanic, Filipino, and Korean respondents in
the King County [Seattle, Washington] Health and Ethnicity Survey of 1995-1996 reported that they had experienced discrimination when seeking or obtaining health care due to their race or ethnicity. In interviews conducted among African Americans after the survey, perceived discriminatory experiences reported by participants included differential treatment, negative attitudes, being treated as if they were unintelligent, being ignored, inappropriate allegations and racist remarks. This highlights the importance of culturally competent relationships between patients and providers which have been defined as collaborative partnerships that facilitate successful and satisfactory delivery of care.

Experiences with racial/ethnic discrimination in the healthcare setting are not limited to patients. In a recent national cross-sectional survey, October 2006-February 2007, 60% of African-American; 33% of Asian; 17% of Hispanic/Latino(a) 42% of other race and 30% of Non-Hispanic white physicians reported the perception that patients refused their care because of their race/ethnicity. There is little empirical research however; that directly examines how patient biases towards providers affect receipt of appropriate health care.

Negative experiences in the health care setting may profoundly impact attitudes towards receiving care and influence further utilization of health care services. Data from the National Co-morbidity Study show that although African Americans had more favorable attitudes towards seeking mental health services than whites prior to using them the reverse was true after using them. Nearly 27% of African American respondents to the King County Survey reported that as a result of a discriminatory event that they were more hesitant to seek health services, 25.6% avoid the health care facility, 23.1% avoid the provider, 15.4% stopped using specific services, 10.3% avoid the personnel involved and 7.7% use services less frequently while only 25.6% did not change their behavior. Other studies have found no association between perceived discrimination and utilization of preventive health care services.

Racial/ethnic discrimination also has the potential to influence the health of racial/ethnic minorities through its association with changes in mental and physiologic states and through its influence on participation in high-risk behaviors such as excessive alcohol consumption and substance abuse. Several studies have examined the effect of racial discrimination on mental health and, in general, show that racial discrimination can be a significant source of stress for racial/ethnic minority populations and is associated with decreases in the sense of well-being including self-esteem, happiness, life satisfaction; and increased psychosis, hopelessness, anxiety, anger and substance abuse. Perceived discrimination has also been found to be associated with depression. Studies that have examined the influence of self-reported experiences with racial/ethnic bias and physiologic changes have however, provided inconsistent results. For example, some studies have shown an association between discrimination related stress and increases in blood pressure while others have not. Other research suggests that the association between perceived racial discrimination and increases in blood pressure is dependent upon coping styles. A few studies have also shown that individuals that experience discrimination and other sources of stress have a higher prevalence of chronic disease behavioral risks such as cigarette smoking alcohol and substance abuse.

**RESEARCH SCOPE**

This FOA specifically encourages:

- Descriptive and analytical studies that examine racial/ethnic discrimination as a risk factor for racial/ethnic disparities in disease incidence, treatment, and outcomes;
- The development of data resources including the identification and/or development of new data collection modalities and the evaluation of existing data collection instruments/modalities;
- Development of innovative methods of measuring racial/ethnic discriminatory behavior, perception of exposure to racial/ethnic discrimination and novel approaches to the analysis of quantitative and qualitative data for the purpose of describing discriminatory behavior and exposure to racial/ethnic discrimination;
- Examination of the prevalence of institutional racism in health care delivery systems or policies and its contribution to racial/ethnic health disparities;
- The development and evaluation of interventions that enhance cross-cultural communication and reduce discriminatory behavior, the perception of exposure to racial/ethnic discrimination, and health-related consequences of racial/ethnic discrimination; and
- Studies that examine bias/discriminatory attitudes, beliefs and behaviors that may influence/limit access to diagnostic technologies and therapies for racial/ethnic minorities, particularly in areas for which serious
disparities exist such as cancer and cardiovascular disease.

- Studies that examine the biological and psychosocial pathways that link exposure to discrimination and health.
- All proposed studies should be sufficiently powered to provide adequate control for potential confounders including, but not limited to, gender, age, income, disability, and other factors that might explain racial/ethnic differences in study outcomes. Applicants are strongly encouraged to submit applications that go beyond simply identifying an association between race and an outcome as the sole measure of racial/ethnic discrimination. Studies that measure the prevalence, causes, and effects of racial discrimination; explanatory mechanisms that lead to discriminatory behavior, mediating factors; and processes in health delivery systems are of particular interest.

Studies should address at least one of the following:

- Employ new, novel, or innovative methods for measuring the prevalence, cause and effects of racial/ethnic discrimination/bias, explanatory mechanisms that lead to discriminatory behavior or mediating factors and processes in healthcare delivery systems;
- Directly examine the prevalence of racial/ethnic discrimination/bias or patient perception of racial/ethnic discrimination against racial/ethnic minority patients;
- Examine the prevalence of negative perceptions/or stereotypes that providers may have of racial/ethnic minority patients that may influence referral and/or receipt of appropriate healthcare services;
- Examine private, governmental, or public institutional policies or practices that may negatively and disproportionately impact racial/ethnic minority receipt of appropriate healthcare services;

NOTE: For this FOA, The National Heart, Lung and Blood Institute (NHLBI) is only interested in receiving applications for studies that have an intervention component.

Examples of research topics and approaches that would be relevant areas of investigation under this FOA include, but are not limited to:

1. METHODOLOGY FOR MEASURING RACIAL/ETHNIC DISCRIMINATION

   - The importance and sensitivity surrounding the topic of racial/ethnic discrimination mandates the development and utilization of measures that assure the accuracy of reported data including both construct and criterion validity. Appropriate studies include those that develop and evaluate innovative methods for measuring physician and other health care provider bias and/or use of stereotypes with racial/ethnic minority patients, patient exposure to racial/ethnic discrimination, and patient strategies used to cope with exposure to racial/ethnic discrimination in health delivery systems. With the exception of studies that examine patient perception of exposure to discriminatory behavior, studies should go beyond simply identifying an association between race and health outcomes as a measurement of discrimination. Methods for assessing the influence of patient bias towards health care providers from non-concordant racial/ethnic groups are also of interest.

2. DISCRIMINATORY BEHAVIOR BY PROVIDERS OR OTHER STAFF IN THE HEALTH CARE SETTING

   - Studies that employ innovative methods for measuring provider attitudes, beliefs, and behaviors towards racial/ethnic minority patients including perceptions that are likely to influence recommendations, referral patterns, and receipt of appropriate care.

3. PATIENT PERCEPTION OF THE RECEIPT OF DISCRIMINATORY CARE

   - Studies that examine factors that influence patient experiences and perception of racial/ethnically biased health care and its relationship to trust of health care providers and its influence on the future utilization of health care services including compliance with provider recommendations, delays in seeking care, and continuity in care.
   - Studies that examine racial/ethnic concordance, provider communication styles and their relationship to patient perception of the receipt of racially/ethnically biased care.

4. INSTITUTIONAL RACISM
• Studies that examine the impact of health delivery system practices and policies such as patient dumping, Medicare nursing care bed certification limits, privatization, closure or relocation of public hospitals, or other policies that may adversely impact the supply of racial/ethnic minority health care providers and how this might relate to racial/ethnic disparities in access to care, health status and outcomes.

• Studies of health delivery systems, health care policies, and changes to systems and policies that have a disparate impact on racial/ethnic minorities and the roles that they might play in racial/ethnic health disparities including the utilization of health services and receipt of appropriate care by members of racial and ethnic minority populations.

• Studies that focus on measurement of organizational factors and relationships between organizational entities such as treatment agencies and other health, social services, and criminal justice system agencies as they relate to the disproportionate use and availability of health care services among racial/ethnic minorities.

• The role of public and institutional policies as they relate to the disproportionate use, availability or satisfaction with health care services among racial/ethnic minorities.

• The association between racial/ethnic stigma and gaps between health care needs (e.g. treatment, prevention, and related services) and service availability.

• The role of economic and personal costs as they relate to the disproportionate use, availability, and satisfaction with health care services among racial/ethnic minorities.

• Studies of policy shifts (privacy policies, treatment immediacy, cost variation) in service delivery and their affect on racial/ethnic minority populations.

5. THE EFFECTS OF RACIAL/ETHNIC DISCRIMINATION OR PERCEPTION OF DISCRIMINATION ON RECEIPT OF HEALTH CARE SERVICES AMONG RACIAL/ETHNIC MINORITY PATIENTS

• Patient beliefs systems, personal biases and attitudes, and their impact on relationships with providers and on the utilization of health care services and receipt of appropriate care.

• Patient experiences or perceptions of racially/ethnically biased health care and its influence on the future utilization of health care services and willingness to comply with physician recommendations.

• The role of racial/ethnic stigma and discrimination on the willingness to seek health care.

• Studies to assess the role of culture, behaviors, and attitudes on perceived racial and ethnic discrimination in the delivery and access to quality care.

• Stereotype threat and its relationship to health care utilization.

6. INTERVENTION STUDIES

• Studies that test interventions designed to reduce provider bias and/or patient perception of racial/ethnic discrimination or consequences designed to ensure the receipt of quality medical care among racial/ethnic minority patients are of particular interest. Proposed interventions should be based on empirical data from adequately powered preliminary/pilot studies that support the need for and potential benefit from the specific intervention in the proposed target population.

• Studies that assess the relationship between perceived health care discrimination and use of intervention, prevention, and treatment services.

Section II. Award Information

<table>
<thead>
<tr>
<th>Funding Instrument</th>
<th>Grant</th>
</tr>
</thead>
</table>
| **Application Types Allowed** | New  
Renewal  
Resubmission  
Revision |
<p>| The [OER Glossary](<a href="http://grants.nih.gov/grants/guide/pa-files/P">http://grants.nih.gov/grants/guide/pa-files/P</a> A-11-162.html) and the SF 424 (R&amp;R) Application Guide provide details on these application types. |
| <strong>Funds Available and Anticipated Number of Awards</strong> | The number of awards is contingent upon NIH appropriations, and the submission of a sufficient number of meritorious applications. |</p>
<table>
<thead>
<tr>
<th>Award Budget</th>
<th>Application budgets are not limited, but need to reflect actual needs of the proposed project.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Award Project Period</td>
<td>Scope of the proposed project should determine the project period. The maximum period is 5 years.</td>
</tr>
</tbody>
</table>

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)

For profit Organizations

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

Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American tribal organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations
- Non-domestic (non-U.S.) Entities (Foreign Organizations)

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

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

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

All Program 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 (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.

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.

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 may submit more than one application, provided that each application is scientifically distinct.

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.

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.

**PHS 398 Research Plan Component**

All instructions in the SF424 (R&R) Application Guide must be followed.

**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:

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

**Appendix**

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

**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.

**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.** See [Section III. Eligibility Information](#) contains information about registration.

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

- All PD/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](#) 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.

**Requests of $500,000 or more for direct costs in any year**

Applicants requesting $500,000 or more in direct costs in any year (excluding consortium F&A) must contact NIH program staff at least 6 weeks before submitting the application and follow the Policy on the Acceptance for Review of Unsolicited Applications that Request $500,000 or More in Direct Costs as described in the SF 424 (R&R) Application Guide.

**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**

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.

**Overall Impact**

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

**Scored Review Criteria**

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

**Significance**

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

**Investigator(s)**

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?

**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 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?

**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

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

Renewals

For Renewals, the committee will consider the progress made in the last funding period.

Revisions

For Revisions, the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

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) (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:

- 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.

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](http://grants.nih.gov/grants/policy/), and [Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities](http://grants.nih.gov/grants/policy/). More information is provided at [Award Conditions and Information for NIH Grants](http://grants.nih.gov/grants/policy/).

### 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)](http://grants.nih.gov/grants/forms/nih-forms.html) 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.

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](http://www.fsrs.gov) on all subawards over $25,000. See the [NIH Grants Policy Statement](http://grants.nih.gov/grants/policy/) 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)

- **Vickie L. Shavers, Ph.D.**
  - Applied Research Program
  - Division of Cancer Control and Population Sciences (DCCPS)
  - National Cancer Institute (NCI)
  - 6130 Executive Boulevard, EPN Room 4005, MSC 7344
  - Bethesda, MD 20892-7344 (for U.S. Postal Service express or regular mail)
  - Rockville, MD 20852 (for express/courier delivery)
  - Telephone: 301-594-1725
  - E-mail: shaversv@mail.nih.gov
Josephine Boyington, Ph.D., M.P.H.
National Heart, Lung, and Blood Institute (NHLBI)
6701 Rockledge Drive, Suite 10118, MSC 7936
Bethesda, MD 20892-7936
Telephone: 301-435-0446
E-mail: boyingtonje@nhlbi.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).

Financial/Grants Management Contact(s)

Cammie La
Office of Grants Administration
National Cancer Institute (NCI)
6120 Executive Boulevard, EPS Room 243, MSC 7150
Bethesda, MD 20892-7150 (for regular mail)
Rockville, MD 20852 (for express/courier delivery)
Telephone: (301) 496-8649
Email: lac@mail.nih.gov
Mary S. Baylor
Senior Grant Specialist
Office of Grants Management
National Heart Lung and Blood Institute (NHLBI)
Rockledge II, Suite 7133
6701 Rockledge Drive
Bethesda, MD 20892
Telephone: (301)435-0480 Office
Email: baylorm@nhlbi.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
Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see Help Downloading Files.