

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH)
Components of Participating Organizations	<i>Eunice Kennedy Shriver</i> National Institute of Child Health and Human Development (NICHD)
Funding Opportunity Title	Disclosure of HIV-Status to Children in Low- and Middle-Income Country Settings (R21)
Activity Code	R21 Exploratory/Developmental Research Grant Award
Announcement Type	New
Related Notices	None
Funding Opportunity Announcement (FOA) Number	RFA-HD-12-205
Companion FOA	RFA-HD-12-197, R01 Research Project Grant
Number of Applications	See Section III. 3. Additional Information on Eligibility .
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.865
FOA Purpose	<p>This Funding Opportunity Announcement (FOA) issued by the <i>Eunice Kennedy Shriver</i> National Institute of Child Health and Human Development, National Institutes of Health, solicits grant applications from institutions/organizations that propose exploratory and observational studies of disclosure of HIV infection status to children infected and affected by HIV infection in low-resource settings and for HIV-infected women (and other caretakers) disclosing their HIV status to their children, or both. Proposed studies may use program data, questionnaires, interviews, focus groups and other appropriate methods, to assess the predictors, barriers, perceptions, and currently used approaches to pediatric HIV disclosure in low-resource settings. Also of interest are evaluations of observed and self-reported psychological, behavioral, and medical effects in the child and family unit after disclosure for the purpose of devising disclosure intervention models that can be further evaluated and implemented in that setting. The development or adaptation of interventions to assist families in disclosing, if deemed appropriate, are also encouraged. Applications in response to this FOA may deal with disclosing to HIV-infected children their own HIV status and/or assisting HIV-infected mother, fathers, and other caretakers in disclosing their HIV status to their children or both. In the body of this FOA, "disclosure" is meant to include any of these processes, and "adult" is meant to include any caretaker responsible for the well-being of the child(ren).</p>

Key Dates

Posted Date	February 9, 2011
Open Date (Earliest Submission Date)	October 29, 2011
Letter of Intent Due Date	October 29, 2011
Application Due Date(s)	November 29, 2011, by 5:00 PM local time of applicant organization.
AIDS Application Due Date(s)	Not applicable
Scientific Merit Review	February/March 2012
Advisory Council Review	May 2012
Earliest Start Date(s)	July 2012

Expiration Date	November 30, 2011
Due Dates for E.O. 12372	Not Applicable

Required Application Instructions

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

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/Objectives

This FOA issued by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH), solicits grant applications from institutions/organizations that propose exploratory and observational studies of disclosure of HIV infection status to children infected and affected by HIV infection in low-resource settings and for HIV-infected women (and other caretakers) disclosing their HIV status to their children, or both. Proposed studies may use program data, questionnaires, interviews, focus groups and other appropriate methods, to assess the predictors, barriers, perceptions, and currently used approaches to pediatric HIV disclosure in low-resource settings. Also of interest are evaluations of observed and self-reported psychological, behavioral, and medical effects in the child and family unit after disclosure for the purpose of devising disclosure intervention models that can be further evaluated and implemented in that setting. The development or adaptation of interventions to assist families in disclosing, if deemed appropriate, are

also encouraged. Applications in response to this FOA may deal with disclosing to HIV-infected children their own HIV status and/or for assisting HIV-infected mother, fathers, and other caretakers in disclosing their HIV status to their children or both. In the body of this FOA, "disclosure" is meant to include any of these processes, and "adult" is meant to include any caretaker responsible for the well-being of the child(ren).

Background

Programs to improve prevention of mother-to-child transmission are reaching ever greater numbers of pregnant women worldwide, and programs to diagnose, treat and improve survival of HIV-infected children are continuing to reach greater numbers of children in lower-resource settings – especially sub-Saharan Africa. In addition, the increasing availability of antiretroviral therapy (ART) means that HIV-infected individuals are living longer and are increasingly likely to have children. It thus becomes increasingly important to understand the current practice, barriers and facilitators, cultural influences, and effects of disclosing to HIV-infected children their HIV status and of HIV-infected mothers and fathers disclosing their status to their children. It is essential to develop effective, validated HIV-disclosure intervention approaches that are appropriate for the cultural, developmental, and gender context, and that HIV treatment program personnel can be trained to use for assisting children, mothers, fathers, and families with HIV disclosure to children in low-resource settings.

Disclosure of a child's HIV infection to the child in an appropriate manner has long been recommended in the United States [AAP 1999, reaffirmed 2009]. Rather than a single event, disclosure generally represents an ongoing, dynamic process that takes place over many visits and several years, based on multiple factors, including the child's developmental level, child's health status, approaching age of potential sexual debut, and the parent/caretaker's readiness for disclosure to the child [Lesch 2007]. Disclosing to children their HIV status can be associated with less parental depression [Lipson 1994], higher self-esteem [Lipson 1994] and fewer behavioral problems in the child, closer relationship between the child and parent/caregiver [Wiener 1998], improvement in the child's understanding of and coping with their medical condition [Funck-Brentano, 1997], increased adherence to medications [Mellins 2004], and even greater improvement in immunologic status (CD4 count) [Sherman 2000]. On the other hand, some studies have also demonstrated increase in stress levels following disclosure [Funck-Brentano, 1997]. Disclosure to HIV-infected children entering adolescence also provides the opportunity for counseling about prevention of HIV transmission prior to sexual debut (AAP 1999/2009).

A mother's disclosure of her own HIV diagnosis to her HIV-infected and uninfected children can be difficult. Many women avoid or delay disclosure to their children because they feel they do not know how to do it and they worry that their children will disclose the information to others [Corona 2006; Murphy 2008]. Disclosure by HIV-infected fathers and other caretakers to their children is also expected to be difficult but has not been studied.

The WHO and most national pediatric HIV guidelines [South Africa 2005; Zambia 2007; Ethiopia 2008; Uganda 2003] recommend developmentally appropriate disclosure to children. Unfortunately, the resources available for training providers in low-resource setting about pediatric HIV disclosure are largely based on the Western disclosure model and experience [Abrams, ICAP pediatric clinical manual. ANECCA 2004].

A study of disclosure in pediatric HIV clinics in Soweto, South Africa, revealed that primary caregivers of children with HIV typically do not disclose to their children that they have HIV infection, despite the fact that these children often ask questions about their own illness [Kouyoumdjian 2005]. In Zambia, only 38% of 11-15 year-old youth enrolled in HIV care were aware of their diagnosis, even though the majority was receiving antiretroviral therapy [Menon JAIDS 2007]. Overall, youth evinced

high rates of mental health problems; however, rates of emotional problems were higher among the youth whose infection status had not been disclosed. Among similarly aged HIV-uninfected children whose mothers were HIV-infected in South Africa, only 44% had been told of their mother's HIV infection; male children and children whose mothers had never been married were significantly less likely to be told of their mothers' diagnosis [Palin AIDS Behav 2008].

Disclosure of mothers' or children's HIV diagnosis to children in lower-resource settings is further impeded by the very low rate with which women, diagnosed with HIV infection during antenatal care, disclose their HIV infection to their husbands and partners in such settings [Medley Bull WHO 2004].

As millions of children infected and affected by HIV in low-resource settings are expected to survive childhood through adolescence and into adulthood, there is an increasing need for evidence-based approaches to disclosure of HIV diagnosis to children. The profound lack of data about effective and appropriate disclosure models and near absence of published disclosure intervention studies and longitudinal studies of the effects of disclosure on children and family over time highlight the need for investigation of disclosure practices and barriers in these settings and for trials of disclosure interventions.

Scope/Work to be Performed

Applications using a range of methods, including use of program data, participant observation, surveys of individuals, focus groups and in-depth interviews, are requested which will assess the predictors, barriers, perceptions, and currently used approaches to HIV disclosure process in low-resource settings as well as the observed psychological, behavioral, social and medical effects in the child and family after disclosure. These data will be used for the development of acceptable, appropriate and effective methods for pediatric HIV disclosure in low-resource settings, and for training HIV care program personnel in these settings in use of such methods.

The scope of this research will include studies of disclosing to HIV-infected children their own HIV status, HIV-infected women (and fathers and other caretakers) disclosing their HIV status to their HIV-uninfected and/or HIV-infected children, or both. Applications may be submitted by a US-based or international PI collaborating with investigators working with the target low-resource setting population.

Examples of research include but are not limited to those listed below:

- Examination of predictors, barriers, and perceptions of current disclosure practices. Such studies could involve perspectives from HIV-infected/affected children, parents/caretakers, healthcare personnel (multiple levels and categories), representatives of organizations involved in providing HIV care and services, and community members.
- Observational studies of observed and reported psychological, behavioral, social, and medical outcomes in children and/or the children's caretakers/family following disclosure. Research should focus on immediate as well as longer term outcomes.
- Studies that explore the characteristics of the child and/or family and the disclosure process associated with positive and negative psychological, behavioral, and medical measures after disclosure.
- Studies that evaluate the uptake and acceptability to parents/caregivers of current disclosure protocols and actual practices for disclosing to children in low-resource settings and demographic, clinical, behavioral, cultural, and guardianship factors related to disclosure status. Aspects of disclosure practices could include, but would not be limited to, methods of assessment of readiness of child and parent/caretaker for disclosure, intended age/developmental stage and timing of disclosure, and setting (e. g., clinic, home, other) where disclosure takes place.

- Comparison of outcomes among existing approaches to disclosure that differ by interpersonal approach (e.g., individual, family, or group counseling), location (e.g., occurring in clinic, at home, other locations), personnel involved (e.g., physician, nurse, counselor, other), use of specific methodologies or measurements (e.g., assessment of child or family readiness).
- The initial development or adaptation of interventions to assist families in disclosing, if deemed appropriate.

Section II. Award Information

Funding Instrument	Grant
Application Types Allowed	New The OER Glossary and the SF 424 (R&R) Application Guide provide details on these application types.
Funds Available and Anticipated Number of Awards	The number of awards is contingent upon NIH appropriations, and the submission of a sufficient number of meritorious applications. NICHD intends to commit an estimated total of \$500,000 to fund 3-5 awards in fiscal year 2012. Future year amounts will depend on annual appropriations.
Award Budget	For this funding opportunity, budgets up to \$ \$250,000 direct costs per year and time periods up to two years with two-year direct cost total awards not exceeding \$275,000 may be requested.
Award Project Period	The total project period for an application submitted in response to this funding opportunity may not exceed two years.

NIH grants policies as described in the [NIH Grants Policy Statement](#) will apply to the applications submitted and awards made

in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions:

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

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

Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

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.

Applications may be submitted by a US-based or a non-US-based PD/PI collaborating with investigators working with the target low-resource setting population.

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.

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

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:

George K Siberry, MD, MPH

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

6100 Executive Boulevard, Room 4B11-H

Bethesda, MD 20892-7510

Rockville, MD 20852 (for express/courier service; non-USPS service)

Telephone: 301-496-7350

FAX: 301-496-8678

Email: siberryg@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,

PHS 398 Research Plan Component

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

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.

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. [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.

Upon receipt, applications will be evaluated for completeness by the Center for Scientific Review and responsiveness by NICHHD, NIH. Applications that are incomplete and/or nonresponsive 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](#).

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.

The R21 exploratory/developmental grant supports investigation of novel scientific ideas or new model systems, tools, or technologies that have the potential for significant impact on biomedical or biobehavioral research. An R21 grant application need not have extensive background material or preliminary information. Accordingly, reviewers will focus their evaluation on the conceptual framework, the level of innovation, and the potential to significantly advance our knowledge or understanding. Appropriate justification for the proposed work can be provided through literature citations, data from other sources, or, when available, from investigator-generated data. Preliminary data are not required for R21 applications; however, they may be included if available.

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

Not Applicable

Renewals

Not Applicable

Revisions

Not Applicable

Additional Review Considerations

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

Applications from Foreign Organizations

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 (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 submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review by the National Advisory Child Health and Human Development (NACHHD) Council. 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.
- Geographic location of proposed studies and ability to contribute added diversity to the information base.
- Feasibility of conducting the proposed studies in the proposed locations, including access to appropriate populations and adequacy of available research infrastructure

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 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](#) 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)

George K. Siberry, M.D., M.P.H.

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Section VIII. Other Information

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