

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

National Institutes of Health ([NIH \(http://www.nih.gov\)](http://www.nih.gov))

Components of Participating Organizations

Fogarty International Center ([FIC \(http://www.fic.nih.gov\)](http://www.fic.nih.gov))

National Human Genome Research Institute ([NHGRI \(http://www.nhgri.nih.gov/\)](http://www.nhgri.nih.gov/))

National Institute on Dental and Craniofacial Research ([NIDCR \(http://www.nidcr.nih.gov\)](http://www.nidcr.nih.gov))

National Institute of Environmental Health Sciences ([NIEHS \(http://www.niehs.nih.gov\)](http://www.niehs.nih.gov))

National Institute of Mental Health ([NIMH \(http://www.nimh.nih.gov\)](http://www.nimh.nih.gov))

National Institute of Neurological Disorders and Stroke ([NINDS \(http://www.nimh.nih.gov\)](http://www.nimh.nih.gov))

Office of Research on Women's Health ([ORWH \(http://orwh.od.nih.gov\)](http://orwh.od.nih.gov))

National Cancer Institute ([NCI \(http://www.nci.nih.gov/\)](http://www.nci.nih.gov/))

Funding Opportunity Title

Emerging Global Leader Award (K43)

Activity Code

[K43 \(http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=k43&Search.x=0&Search.y=0&sort=ac&Search_Type=Activity&text_prev=\)](http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=k43&Search.x=0&Search.y=0&sort=ac&Search_Type=Activity&text_prev=) International Research Career Development Award

Announcement Type

New

Related Notices

- [December 23, 2015 \(http://grants.nih.gov/grants/guide/notice-files/NOT-CA-16-010.html\)](http://grants.nih.gov/grants/guide/notice-files/NOT-CA-16-010.html) - Notice of National Cancer Institute's Participation in PAR-15-292. See Notice [NOT-CA-16-010 \(http://grants.nih.gov/grants/guide/notice-files/NOT-CA-16-010.html\)](http://grants.nih.gov/grants/guide/notice-files/NOT-CA-16-010.html).
- [NOT-OD-16-004 \(http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-004.html\)](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-004.html) - NIH & AHRQ Announce Upcoming Changes to Policies, Instructions and Forms for 2016 Grant Applications (November 18, 2015)
- [NOT-OD-16-006 \(http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-006.html\)](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-006.html) - Simplification of the Vertebrate Animals Section of NIH Grant Applications and Contract Proposals (November 18, 2015)
- [NOT-OD-16-012 \(http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-012.html\)](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-012.html) - Implementing Rigor and Transparency in NIH & AHRQ Career Development Award Applications (November 18, 2015)
- [August 26, 2015 \(http://grants.nih.gov/grants/guide/notice-files/NOT-TW-15-004.html\)](http://grants.nih.gov/grants/guide/notice-files/NOT-TW-15-004.html) - Notice of Participation of Additional NIH Components in PAR-15-292. See Notice [NOT-TW-15-004 \(http://grants.nih.gov/grants/guide/notice-files/NOT-TW-15-004.html\)](http://grants.nih.gov/grants/guide/notice-files/NOT-TW-15-004.html).

- [July 23, 2015 \(http://grants.nih.gov/grants/guide/notice-files/NOT-TW-15-003.html\)](http://grants.nih.gov/grants/guide/notice-files/NOT-TW-15-003.html) - Notice of New Application Package Required for PAR-15-292. See Notice [NOT-TW-15-003 \(http://grants.nih.gov/grants/guide/notice-files/NOT-TW-15-003.html\)](http://grants.nih.gov/grants/guide/notice-files/NOT-TW-15-003.html).
- [NOT-TW-12-011 \(http://grants.nih.gov/grants/guide/notice-files/NOT-TW-12-011.html\)](http://grants.nih.gov/grants/guide/notice-files/NOT-TW-12-011.html)

Funding Opportunity Announcement (FOA) Number

PAR-15-292

Companion Funding Opportunity

[PAR-15-291 \(http://grants.nih.gov/grants/guide/pa-files/PAR-15-291.html\)](http://grants.nih.gov/grants/guide/pa-files/PAR-15-291.html), [K01 \(http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=k01&Search.x=0&Search.y=0&Search_Type=Activity\)](http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=k01&Search.x=0&Search.y=0&Search_Type=Activity) Research Scientist Development Award - Research & Training

Number of Applications

See [Section III. 3. Additional Information on Eligibility](#).

Catalog of Federal Domestic Assistance (CFDA) Number(s)

93.989, 93.398

Funding Opportunity Purpose

The purpose of the Fogarty Emerging Global Leader Award is to provide research support and protected time to a research scientist from a low- or middle-income country (LMIC) with a junior faculty position at an LMIC academic or research institution. This intensive, mentored research career development experience is expected to lead to an independently funded research career. This Funding Opportunity Announcement (FOA) invites applications from LMIC scientists from any health related discipline that propose career development activities and a research project that is relevant to the health priorities of their country.

Key Dates

Posted Date

July 7, 2015

Open Date (Earliest Submission Date)

November 16, 2015

Letter of Intent Due Date(s)

Not Applicable

Application Due Date(s)

December 16, 2015; December 14, 2016; and December 14, 2017, by 5:00 PM local time of applicant organization. All [types of non-AIDS applications](#) allowed for this funding opportunity announcement are due on these dates.

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

AIDS Application Due Date(s)

December 16, 2015; December 14, 2016; and December 14, 2017, by 5:00 PM local time of applicant organization. All [types of AIDS and AIDS-related applications](#) allowed for this funding opportunity announcement are due on these dates.

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

Scientific Merit Review

March 2016, March 2017, March 2018

Advisory Council Review

May 2016, May 2017, May 2018

Earliest Start Date

July 2016, July 2017, July 2018

Expiration Date

December 15, 2017

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the [SF424 \(R&R\) Application Guide](http://grants.nih.gov/grants/guide/url_redirect.htm?id=12000) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=12000), including [Supplemental Instructions to the SF424 \(R&R\) for Preparing an Individual Research Career Development Award \(CDA\) Application \("K" Series\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=52000) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=52000), except where instructed to do otherwise (in this FOA or in a Notice from the [NIH Guide for Grants and Contracts](http://grants.nih.gov/grants/guide/) (<http://grants.nih.gov/grants/guide/>)). 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.**

There are several options to submit your application to the agency through Grants.gov. You can use the ASSIST system to prepare, submit and track your application online. You can download an application

package from Grants.gov, complete the forms offline, submit the completed forms to Grants.gov and track your application in eRA Commons. Or, you can use other institutional system-to-system solutions to prepare and submit your application to Grants.gov and track your application in eRA Commons. [Learn more \(http://grants.nih.gov/grants/ElectronicReceipt/preparing.htm#2\)](http://grants.nih.gov/grants/ElectronicReceipt/preparing.htm#2).

Apply Online Using ASSIST

Apply Using Downloadable Forms

Problems accessing or using ASSIST should be directed to the [eRA Service Desk \(http://grants.nih.gov/grants/ElectronicReceipt/support.htm#desk\)](http://grants.nih.gov/grants/ElectronicReceipt/support.htm#desk).

Problems downloading forms should be directed to [Grants.gov Customer Support \(http://www.grants.gov/contactus/contactus.jsp\)](http://www.grants.gov/contactus/contactus.jsp).

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

The purpose of the Fogarty Emerging Global Leader Award is to provide research support and "protected time" to a research scientist from a low-or middle-income country (LMIC) who holds a junior faculty position at an LMIC academic or research institution as defined in Section III.1. In many LMIC institutions there is little support for junior faculty with long-term research training to launch an independent research career due to lack of protected time for research activities, inadequate pilot research project funding opportunities, insufficient training in advanced research methodology and data analysis, lack of mentorship in manuscript and grant writing and meager institutional support for developing, submitting and administering research applications and awards. This intensive, mentored research career development experience under the guidance of experienced LMIC and U.S. mentors is expected to foster an independently funded research career for the most promising LMIC junior research scientist faculty. Overall, it is expected that this program will increase the scientific capacity for health research at LMIC institutions and foster long term research collaborations with U.S. scientists.

The award will provide salary and research project support. Awardees are expected to increase their capabilities in advanced research methodology, analysis and data management, research administrative skills, responsible conduct of research, scientific presentation, publication and grants writing. Applications should propose targeted activities and research projects that will propel awardees to become competitive principal investigators for new research project grant funding by the end of the grant period. This FOA invites applications from LMIC research scientists that propose both critically needed career development activities and a research project that is highly relevant to the health priorities of their country. The research activities should take place primarily in the LMIC.

Interests of Participating NIH Institutes, Centers and Offices

The Fogarty International Center (FIC) is interested in applications from individuals at LMIC institutions

seeking to become independent investigators and international research leaders in any therapeutic or scientific area of health priority and scientific importance to the LMIC. FIC is dedicated to advancing the mission of the NIH by supporting and facilitating global health research conducted by U.S. and international investigators, building partnerships between health research institutions in the U.S. and abroad, and training the next generation of scientists to address global health needs. FIC supports a diversity of research and research training grants that advance basic to implementation science with a particular focus on Low- and Middle-Income Countries. The Fogarty Emerging Global Leader Award is responsive to the FIC Strategic Plan (<http://www.fic.nih.gov/about/pages/strategic-plan.aspx>) to build research capacity through individuals, institutions and networks by building future research leaders in the U.S. and in LMICs.

The National Human Genome Research Institute (NHGRI) is interested in applications from individuals pursuing careers as researchers in the area of the ethical, legal, and social implications (ELSI) of genetics and genomics research or the use of genetics in clinical settings. The specific research topic proposed should apply across a broad spectrum of diseases and conditions and should not be specific to just one disease, except to the extent that a particular disease may serve as a model with broader applicability. Examples of topics appropriate for exploration can be found on the ELSI Research Priorities website at: <http://www.genome.gov/27543732> (<http://www.genome.gov/27543732>). NHGRI may also support applications from individuals who are developing methods and research resources that support, or are conducting basic and translational research in: genomic sciences, informatics, implementation of genomics in clinical care (genomic medicine), and cost-effectiveness of genomic interventions. The specific research topic proposed should apply across a broad spectrum of diseases and health conditions and should not be specific to just one disease, except to the extent that a particular disease may serve as a model with broader applicability. Projects that capitalize on unique opportunities to use, as models, diseases and conditions that are more difficult to study in the U.S. because of prevalence or other factors will be considered. Examples of such conditions might include, but are not limited to, sickle cell disease and thalassemias, apoA associated kidney disease, and severe adverse drug reactions with higher frequency outside the U.S., such as Stevens Johnson Syndrome (SJS).

The National Institute of Dental and Craniofacial Research (NIDCR) is interested in applications with a research focus on dental, oral, or craniofacial conditions that occur more frequently in the LMIC or are of a high public health burden; research addressing health disparities in dental, oral, or craniofacial conditions; and research to achieve national or regional goals in oral and dental health such as those articulated by the World Health Organization. Examples include, but are not limited to: working with local communities to establish the best means of delivering preventive oral health care; establishing successful approaches to deliver fluoride to a local population, particularly in areas without potable water; studying oral pre-malignant lesions associated with betel nut use; and studying the interplay of genes and environment in dental, oral, or craniofacial health by leveraging environments specific to the country. The program and these topics are responsive to goals 2, 3, and 4 of the NIDCR Strategic Plan (<http://www.nidcr.nih.gov/research/ResearchPriorities/StrategicPlan/>).

The National Institute of Neurological Disorders and Stroke (NINDS) is interested in supporting mechanistic, epidemiological, prevention, translational and clinical research across the spectrum of neurological, neuromuscular and neurovascular diseases and disorders in all ages. In addition to prevalent neurological disorders and stroke, NINDS is also interested in supporting research in areas of rare and neglected neurological diseases that are relevant to the Low- or Middle-Income Countries (NINDS Disorder Index http://www.ninds.nih.gov/disorders/disorder_index.htm) (http://www.ninds.nih.gov/disorders/disorder_index.htm).

The Office of Research on Women's Health (ORWH) mission is to improve the health of women, and has made strides in doing so by ensuring that women and diverse populations are included in all clinical studies, sex and gender influences in health and disease are explored, and that women have the opportunity to advance in biomedical careers. ORWH will assess applications for their ability to directly

fulfill the goals 4.0 and 6.0 of the NIH Strategic Plan for Women's Health and Sex Differences Research, which can be found at: http://orwh.od.nih.gov/research/strategicplan/ORWH_StrategicPlan2020_Vol1.pdf (http://orwh.od.nih.gov/research/strategicplan/ORWH_StrategicPlan2020_Vol1.pdf).

The National Institute of Environmental Health Sciences (NIEHS) is interested in applications that address or seek to understand how exposures to toxic environmental insults alter biologic processes, are linked to disease initiation, progression or morbidity, and activities that lead to the development of prevention and intervention strategies to reduce environmentally induced diseases in LMICs. Examples of environmental exposures relevant to the mission of the NIEHS include industrial chemicals or manufacturing byproducts, e-waste, metals, pesticides, herbicides, and inhaled toxicants including indoor air pollutants from cooking and other sources (<https://www.niehs.nih.gov/about/strategicplan/>). Topics and disease outcomes of particular interest include airway diseases, CVD and neurological disorders, children's environmental health and the unique vulnerability of developing children to harmful environmental exposures including outcomes such as low birth weight or premature birth, and research exploring exposures during early life stages or critical windows of susceptibility that may directly or indirectly affect the risk of developing disease. Career development applications that focus on the effects of alcohol, chemotherapeutic agents, smoking, except when considered as a secondary smoke exposure as a component in the indoor environment (particularly in children), drugs of abuse, pharmaceuticals, dietary nutrients, and infectious or parasitic agents are better assigned to other institutes.

The National Institute of Mental Health (NIMH) is interested in applications that focus on mental illness and mental disorders in LMICs, specifically conditions and disorders of brain structure and function that affect cognition, social and emotional processing, and behavior and are leading causes of disease burden worldwide, estimated on the basis of disability adjusted life years (DALYs). For example, disorders of interest include, but are not limited to depression, schizophrenia, bipolar disorder, autism spectrum disorders, and posttraumatic stress disorder. NIMH is particularly interested in research that addresses disparities in access to mental health care in LMICs, care for chronic, non-communicable diseases and/or implementation science in LMIC contexts. These themes are consistent with goals C, E, and F of the Grand Challenges in Global Mental Health (i.e., improve treatments and expand access to care; build human resource capacity; and transform health system and policy responses; <http://www.nature.com/nature/journal/v475/n7354/pdf/475027a.pdf> (<http://www.nature.com/nature/journal/v475/n7354/pdf/475027a.pdf>)). NIMH is also interested in applications that target HIV/AIDS related topics of interest such as the epidemiology, natural history and pathogenesis of HIV-associated neurocognitive disorders (HAND) and neuropsychiatric disorders before and after treatment initiation in adult and pediatric populations; examination of the neurobehavioral consequences, with respect to *in-utero* exposure to a dysregulated immune environment and/or antiretroviral medication and consequences of being born to an HIV-positive mother. NIMH encourages development of common standardized assessment instruments with appropriate norms that can provide reliable and valid measurement of the neurobehavioral consequences of HIV and its treatments throughout the age-span in low and medium resource environments; and development of interventions to improve neurobehavioral functioning compromised by HIV/AIDS and its associated conditions that can be implemented in LMICs.

Additional Information

For applications proposing HIV/AIDS research projects, please refer to [FY 2015 Trans-NIH Plan for HIV-Related Research](http://www.oar.nih.gov/strategicplan/fy2015/index.asp) (<http://www.oar.nih.gov/strategicplan/fy2015/index.asp>) for NIH HIV-Related research priorities.

Candidates are encouraged to review answers to frequently asked questions about the Fogarty Emerging Global Leader Award program at <http://www.fic.nih.gov/Programs/Pages/emerging-global-leader.aspx> (<http://www.fic.nih.gov/Programs/Pages/emerging-global-leader.aspx>) which will be updated on a regular basis.

U.S. citizens, non-citizen nationals and permanent residents are not eligible for this K43 award but may apply for the International Research Scientist Development Awards (IRSDA (K01) [PAR-15-291](https://grants.nih.gov/grants/guide/pa-files/PAR-15-291.html) (<http://grants.nih.gov/grants/guide/pa-files/PAR-15-291.html>) or other similar awards at the [NIH K Kiosk](http://grants.nih.gov/training/careerdevelopmentawards.htm) (<http://grants.nih.gov/training/careerdevelopmentawards.htm>)

Section II. Award Information

Funding Instrument

Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

Application Types Allowed

New

Resubmission

The [OER Glossary](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11116) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11116) and the SF424 (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

Award budgets are composed of salary and other program-related expenses, as described below.

Award Project Period

The total project period should be a minimum of 3 years and may not exceed 5 years.

Other Award Budget Information

Salary

NIH will contribute up to \$ 75,000 (for a minimum of 75% effort or 30 hours per week) per year toward the salary of the career award recipient.

The total salary requested must be based on a full-time staff appointment. The salary must be consistent both with the established salary structure at the institution and with salaries actually provided by the institution from its own funds to other staff members of equivalent qualifications, rank, and responsibilities in the department concerned. Applicants must provide in the application detailed information about the total current salary amount that serves as the basis for calculating the salary support requested.

Confirmation of LMIC institutional salary may be required prior to the issuance of an award. Fringe benefits, based on the sponsoring institution's rate and the percent of effort, may be requested in addition to salary.

The sponsoring institution may supplement the NIH salary contribution up to a level that is consistent with the institution's salary scale. However, supplementation may not be from U.S. government funds unless specifically authorized by the U.S. government program from which such funds are derived. In no case may U.S. Department of Health and Human Services funds be used for salary supplementation.

Institutional supplementation of salary must not require extra duties or responsibilities that would interfere with the purpose of the career award.

Other Program-Related Expenses

NIH will contribute \$30,000 per year toward the research development costs of the award recipient, which must be justified and consistent with the stage of development of the candidate and the proportion of time to be spent in research or career development activities.

Research development costs include, but are not limited to, supplies, equipment, technical personnel, tuition or registration fees for activities related to the proposed career development plan, fees for statistical and computational services, and travel to research sites, research meetings, or training, as detailed in Section IV.

Salary for mentors, secretarial and administrative assistants, etc. is not allowed.

Indirect Costs

Indirect Costs (also known as Facilities & Administrative [F&A] Costs) are reimbursed at 8% of modified total direct costs.

NIH grant policies as described in the [NIH Grants Policy Statement](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120) will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

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

Applications must be submitted by academic education or research institutions in LMICs (as defined by the World Bank (<http://data.worldbank.org/about/country-classifications/country-and-lending-groups>); low-income, lower-middle-income, and upper-middle-income countries are included). [NOT-TW-12-011](http://grants.nih.gov/grants/guide/notice-files/NOT-TW-12-011.html) (<http://grants.nih.gov/grants/guide/notice-files/NOT-TW-12-011.html>) 'Notice of Change in Country Eligibility for Fogarty International Training Grants' applies to this FOA.

Foreign Institutions

Only Non-domestic (non-U.S.) Entities (Foreign Institutions) **are** eligible to apply.

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

Foreign components, as [defined in the NIH Grants Policy Statement](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11118) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11118), **are** allowed.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The [NIH Policy on Late Submission of Grant Applications](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-035.html) (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-035.html>) states that failure to complete

registrations in advance of a due date is not a valid reason for a late submission.

- [Dun and Bradstreet Universal Numbering System \(DUNS\) \(http://fedgov.dnb.com/webform\)](http://fedgov.dnb.com/webform) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- [System for Award Management \(SAM\) \(https://www.sam.gov/portal/public/SAM/\)](https://www.sam.gov/portal/public/SAM/) (formerly CCR) – Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
 - [NATO Commercial and Government Entity \(NCAGE\) Code \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11176\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11176) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- [eRA Commons \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123) - Applicants must have an active DUNS number and SAM registration in order to complete the eRA Commons registration. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- [Grants.gov \(http://www.grants.gov/applicants/organization_registration.jsp\)](http://www.grants.gov/applicants/organization_registration.jsp) – Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

International applicants may obtain more information on the registrations required for grants.gov and eRA Commons at: [http://grants.nih.gov/grants/ElectronicReceipt/files/Tips for International Applicants.pdf](http://grants.nih.gov/grants/ElectronicReceipt/files/Tips_for_International_Applicants.pdf) ([http://grants.nih.gov/grants/ElectronicReceipt/files/Tips for International Applicants.pdf](http://grants.nih.gov/grants/ElectronicReceipt/files/Tips_for_International_Applicants.pdf)).

http://grants.nih.gov/grants/ElectronicReceipt/files/international_support.pdf (http://grants.nih.gov/grants/ElectronicReceipt/files/international_support.pdf)
http://grants.nih.gov/grants/ElectronicReceipt/files/international_qa.pdf (http://grants.nih.gov/grants/ElectronicReceipt/files/international_qa.pdf)
http://grants.nih.gov/grants/ElectronicReceipt/preparing_grantsgov_reg.htm (http://grants.nih.gov/grants/ElectronicReceipt/preparing_grantsgov_reg.htm)

Guidance for International Applicants Blocked from Registration Websites: [NOT-OD-11-090 \(http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-090.html\)](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-090.html).

An NIH supported webinar on Electronic Submission of Grant Applications for Foreign Institutions can be found at http://grants.nih.gov/grants/webinar_docs/webinar_20120927.htm (http://grants.nih.gov/grants/webinar_docs/webinar_20120927.htm)

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any candidate 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 U.S. and LMIC mentors and organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities and women are always encouraged to apply for NIH support. Multiple PDs/PIs are not allowed.

An applicant must be an LMIC citizen and may not be a citizen or a non-citizen national of the United

States or have been lawfully admitted for permanent residence (i.e., possess a currently valid Permanent Resident Card USCIS Form I-551, or other legal verification of such status.

Degree and Research Experience Requirements: The candidate should be the principal investigator/project director (PD/PI) of the proposed activities. Candidates must hold at least a masters degree that required a research thesis. Candidates with Ph.D. research training are preferred. This award cannot support advanced degree training. Individuals who are or have been the PD/PI (direct recipient/grantee) of a multi-year independent research grant from an external research funding organization and awarded by the application due date are not eligible.

Faculty Position Requirement: Applicants must currently hold an academic junior faculty position or research scientist appointment supported by an LMIC (as defined by the World Bank (<http://data.worldbank.org/about/country-classifications/country-and-lending-groups>); low-income, lower-middle-income, and upper-middle-income countries are included and [NOT-TW-12-011](http://grants.nih.gov/grants/guide/notice-files/NOT-TW-12-011.html) (<http://grants.nih.gov/grants/guide/notice-files/NOT-TW-12-011.html>) 'Notice of Change in Country Eligibility for Fogarty International Training Grants') academic or research institution and have been in this position for at least one year at the time the application is submitted. For this FOA, junior faculty are defined as those who hold entry to mid-level academic or research scientist positions, including but not limited to instructors, lecturers and assistant professors.

Applicants from Medical Education Partnership Initiative (MEPI): Junior faculty at institutions awarded under [RFA-TW-14-003](http://grants.nih.gov/grants/guide/rfa-files/RFA-TW-14-003.html) (<http://grants.nih.gov/grants/guide/rfa-files/RFA-TW-14-003.html>) "*Research Training for Career Development of Junior Faculty in Medical Education Partnership Initiative (MEPI) Institutions (D43)*" may not submit applications focused on HIV/AIDS or the scientific research areas supported by this grant.

2. Cost Sharing

This FOA does not require cost sharing as defined in the [NIH Grants Policy Statement](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11126). (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11126)

3. Additional Information on Eligibility

Number of Applications

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

The NIH will not accept duplicate or highly overlapping applications under review at the same time. This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see [NOT-OD-11-101](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html) (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html>)).

Candidates may submit research project grant applications concurrently with the K application. However, any concurrent research project grant application may not have substantial scientific and/or budgetary overlap with the career award application.

Level of Effort

At the time of award, the candidate must have a "full-time" appointment at the LMIC academic institution. Candidates are required to commit a minimum of 75% of full-time professional effort (i.e., a minimum of 9

person-months or 30 hours per week) to their career development and research training. Candidates may engage in other duties as part of the remaining full-time professional effort not covered by this award, as long as such duties do not interfere with or detract from the proposed career development program.

Mentors

Before submitting the application, the candidate must identify a primary mentor at his/her LMIC institution and a primary mentor at a collaborating U.S. institution who, together, will supervise the proposed career development and research experience. The LMIC primary mentor should not be a U.S. citizen who holds a joint appointment at the LMIC institution. These primary mentors should be active researchers in the area of the proposed research and be committed both to the career development of the candidate and to the direct supervision of the candidate's research. Candidates are encouraged to identify additional co-mentors to form a mentoring team if this is deemed advantageous for providing expert advice in all aspects of the research career development program. Additional mentors can be from other LMIC or non-U.S, high income countries. The candidate must work with all mentors (primary and co-mentors) in preparing the application.

Institutional Environment

The LMIC institution where the proposed research will be conducted, and the collaborating U.S. institution, if activities at the U.S. institution are proposed, must have strong, well-established records of research and career development activities and faculty qualified in biomedical, behavioral, or clinical research to serve as mentors. The research career development program should maximize the use of U.S. and LMIC research institutional environments, including available facilities and resources.

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 \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11127\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11127).

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the [SF424 \(R&R\) Application Guide \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=12000\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=12000), including [Supplemental Grant Application Instructions \(https://grants.nih.gov/grants/funding/424/SupplementalInstructions.pdf\)](https://grants.nih.gov/grants/funding/424/SupplementalInstructions.pdf) 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.

For information on Application Submission and Receipt, visit [Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=41137\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=41137).

Page Limitations

All page limitations described in the SF424 (R&R) Application Guide and the [Table of Page Limits \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=51132\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=51132) must be followed.

Instructions for Application Submission

The following section supplements the instructions found in the SF 424 (R&R) Application Guide and should be used for preparing an application to this FOA.

SF424(R&R) Cover

All instructions in the SF424 (R&R) Application Guide, including Supplemental Instructions to the SF424

(R&R) for Preparing an Individual Research Career Development Award (CDA) Application (“K” Series), must be followed

SF424(R&R) Project/Performance Site Locations

All instructions in the SF424 (R&R) Application Guide, including Supplemental Instructions to the SF424 (R&R) for Preparing an Individual Research Career Development Award (CDA) Application (“K” Series), must be followed, with the following additional instructions:

Include the applicant institution and all of the collaborating institutions, both U.S. and foreign, as performance sites.

Other Project Information

All instructions in the SF424 (R&R) Application Guide, including Supplemental Instructions to the SF424 (R&R) for Preparing an Individual Research Career Development Award (CDA) Application (“K” Series), must be followed with the following additional instructions:

Does this project involve activities outside of the United States or partnerships with international collaborators? Check YES and list the foreign countries for all of the performance sites listed in the SF 424(R&R) Project/Performance Site Locations Form.

SF424(R&R) Senior/Key Person Profile Expanded

All instructions in the SF424 (R&R) Application Guide, including Supplemental Instructions to the SF424 (R&R) for Preparing an Individual Research Career Development Award (CDA) Application (“K” Series), must be followed.

R&R Budget

All instructions in the SF424 (R&R) Application Guide, including Supplemental Instructions to the SF424 (R&R) for Preparing an Individual Research Career Development Award (CDA) Application (“K” Series), must be followed with the following additional instructions:

Applicants should identify specific expenses such as: (a) non-degree related tuition or registration fees for specific PD/PI career development activities; (b) research expenses such as supplies, equipment and technical personnel; (c) statistical and computational services, including technical personnel and computer time; (d) travel for mentors to collaborating institutions; (e) mentor and grantee communication costs; and (f) PD/PI travel and per diem expenses to field research sites, collaborating institutions, research or networking meetings, or research skills workshops or courses in the appropriate budget for category.

In the Budget Justification, provide detailed information about the total current salary amount that serves as the basis for calculating the salary support requested. Confirmation of LMIC institutional salary may be required prior to the issuance of an award.

PHS 398 Cover Page Supplement

All instructions in the SF424 (R&R) Application Guide, including Supplemental Instructions to the SF424 (R&R) for Preparing an Individual Research Career Development Award (CDA) Application (“K” Series), must be followed.

PHS 398 Career Development Award Supplemental Form

All instructions in the SF424 (R&R) Application Guide, including Supplemental Instructions to the SF424 (R&R) for Preparing an Individual Research Career Development Award (CDA) Application (“K” Series), must be followed, with the following additional instructions:

Candidate Information

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

Candidate's Background

- Describe the candidate's commitment to a health-related research career.
- Describe prior training and research efforts, and how they relate to the objectives and long-term research career plans of the candidate.
- Provide evidence of the candidate's potential to develop into a successful independent researcher (such as lead authorship of and/or significant contribution to research publications in peer-reviewed journals, presentations at international meetings, prior research interests and experience, research fellowships, and letters of reference).
- Include a description of all the candidate's professional responsibilities at the grantee LMIC institution and elsewhere and show the relation of these responsibilities to the proposed activities on the research career development award.
- Explain how the career award will contribute to career goals and further the candidate's research career and justify the candidate's need for an additional mentored research experience to become an independent research scientist.
- Describe how this award will relieve the candidate of current duties so that a greater portion of the candidate's effort (75% full-time professional effort or 30 hours per week) may be devoted to research and related career development activities.

Career Goals and Objectives

- Describe the candidate's career goals and the specific objectives to reach each goal under this award, indicating linkages to prior experience and current research support.

Candidate's Plan for Career Development

- Describe a systematic detailed plan that: (1) shows a logical progression from prior research and training experiences to the research and research career development activities proposed; (2) justifies the need for further research career development to become an independent researcher; and (3) utilizes the relevant research and educational resources of the LMIC institution and U.S. institution (if activities at the U.S. institution are proposed). The candidate and the mentors are jointly responsible for the preparation of the career development plan.
- The plan should include a description of the primary mentors, any secondary co-mentors, and any collaborators, contributors or consultants, as appropriate for the research and career development of the candidate.
- Provide a detailed description of proposed career development activities, including plans to obtain the necessary research skills and experience to launch an independent global health research career. The description of the career development plan should include items such as advanced level courses, seminars, and opportunities for interaction with other scientists. Training in career skills such as grant-writing and making effective scientific presentations, is strongly encouraged. The career development plan must be tailored to the needs of the individual candidate and the ultimate goal of achieving independence as a researcher.
- Describe how the candidate plans to fulfill the requirement that he/she spend at least 75% effort conducting research or participating in research career development activities during each year proposed. A timeline that includes activities and time spent in the LMIC and the U.S., if proposed, is recommended.
- Describe plans for outreach and dissemination of research findings. This may include sharing findings with primary, secondary and undergraduate students in the LMIC and in the U.S., and presenting results in formats useful to teachers, scientists and engineers, health professionals, policy makers, and the general public.

Training in the Responsible Conduct of Research

- All applications must include a plan to fulfill NIH requirements for instruction in the Responsible

Conduct of Research (RCR).

- The plan must address the five, required instructional components outlined in the NIH policy: 1) *Format* - the required format of instruction, i.e., face-to-face lectures, coursework, and/or real-time discussion groups (a plan with only on-line instruction is not acceptable); 2) *Subject Matter* - the breadth of subject matter, e.g., conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics; 3) *Faculty Participation* - the role of the mentor(s) and other faculty involvement in the instruction; 4) *Duration of Instruction* - the number of contact hours of instruction, taking into consideration the duration of the program; and 5) *Frequency of Instruction* –instruction must occur during each career stage and at least once every four years. See also [NOT-OD-10-019 \(http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html\)](http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html).
- Applications lacking a Plan for Instruction in the Responsible Conduct of Research will not be reviewed.

Statements and Letters of Support

All instructions in the SF424 (R&R) Application Guide, including Supplemental Instructions to the SF424 (R&R) for Preparing an Individual Research Career Development Award (CDA) Application (“K” Series), must be followed, with the following additional instructions:

Plans and Statements of Primary Mentors and Co-mentor(s)

- Signed letters from the primary LMIC mentor, the primary U.S. mentor, as well as any co-mentors, are expected to provide an assessment of the candidate’s qualifications and potential for an independent research career. Mentor letters should describe relevant research expertise in the proposed applicant research area and document a record of success in training LMIC researchers, in particular, those who have gone on to become independent researchers in the LMIC that is the focus of the application.
- Together, the mentors should provide evidence of sufficient independent research support to cover the costs of the proposed research project in excess of the allowable costs of this award. Each mentor statement should describe the research support, if any, that will be available to support the proposed candidate research project.
- Mentor statements should describe the career development plan for the candidate (coordinated with the candidate's research strategy) and explain how they will participate in this plan. Mentors should clearly describe how they will coordinate mentoring of the candidate with other proposed mentors, both primary and secondary co-mentors. Mentor statements should describe the mechanism(s) and frequency of communication with the candidate, including the frequency of face to face meetings.
- Both primary mentors (U.S. and LMIC) must agree to provide annual evaluations of the candidate’s progress as required in the annual progress report.

Letters of Support from Collaborators, Contributors and Consultants

- Signed statements must be provided by all additional collaborators and/or consultants confirming participation in the project and describing their specific roles. Collaborators and consultants generally do not need to provide biographical sketches. However, information should be provided clearly documenting the appropriate expertise in the proposed areas of consulting/collaboration. Collaborators/consultants are generally not directly involved in the development of the career of the candidate as an independent researcher.
- The U.S. Institutional Commitment letter should also be submitted, following page limit requirements for this section.
- All letters should be combined and submitted as a single PDF.

Environmental and Institutional Commitment to the Candidate

All instructions in the SF424 (R&R) Application Guide, including Supplemental Instructions to the SF424 (R&R) for Preparing an Individual Research Career Development Award (CDA) Application (“K” Series), must be followed, with the following additional instructions:

Description of Institutional Environment

- Describe the scientific environment at the LMIC institution, resources and facilities that will be available to the candidate, research and career development programs related to the candidate's area of interest and key faculty members and researchers capable of productive collaboration with the candidate. If the candidate plans activities at the collaborating U.S. institution, a description of the relevant U.S. institutional environment must also be provided.

Institutional Commitment to the Candidate’s Research Career Development

- Appropriate officials at the LMIC institution (and the U.S. institution if activities are proposed there) must provide statements of commitment to the candidate's development into a productive, independent global health researcher and to meeting the requirements of this award.
- A letter of support confirming the applicant's ongoing position, start date, the amount of release time for proposed research and the commitment to retain the candidate in his/her current position by the appropriate institutional official should be submitted.
- The LMIC institution must provide commitment to at least 75% or 30 hours per week release time for the award recipient to conduct the proposed research and participate in the proposed career development activities and agree to retain the candidate in his/her current position. It should be clear that the institutional commitment to the candidate is not contingent upon receipt of this career development award.
- The LMIC institution (and the U.S. institution if activities are proposed there) must provide assurances that appropriate time and support for any proposed mentor(s) and/or other staff consistent with the career development plan will be provided.
- The U.S. Institutional Commitment letter should be submitted via "Letters of Support from Collaborators, Contributors, and Consultants", following page limit requirements. The LMIC Institutional Commitment letter should be submitted as directed in Supplemental Instructions to the SF424 (R&R) for Preparing an Individual Research Career Development Award.

Research Plan

All instructions in the SF424 (R&R) Application Guide, including Supplemental Instructions to the SF424 (R&R) for Preparing an Individual Research Career Development Award (CDA) Application (“K” Series), must be followed, with the following additional instructions:

Research Strategy

- Applicants may propose research in any health related discipline.
- A sound research project that is consistent with the candidate’s level of research development and the objectives of his/her career development plan must be provided. The research description should demonstrate the quality of the candidate’s research capabilities thus far, and the proposed research question, design and methodology should be novel, scientifically significant and creative in approach.
- Applicants should provide a detailed explanation of the relevance of the proposed research to the health priorities of the LMIC. Applicants are encouraged to conduct as much of the proposed research as possible in the LMIC.
- The application must also describe the relationship between the mentors' research and the candidate’s proposed research plan. The respective areas of expertise and responsibility should be described for both mentors. Although the candidate's research strategy may be related to the research activities of the mentors, it should not duplicate the mentors' research.

- Applicants are encouraged to propose research related to ongoing NIH and U.S. government supported research initiatives in the LMIC.

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.

Citizenship

Leave this question blank if none of the available citizenship options apply.

Planned Enrollment Report

When conducting clinical research, follow all instructions for completing Planned Enrollment Reports as described in the SF424 (R&R) Application Guide.

PHS 398 Cumulative Inclusion Enrollment Report

When conducting clinical research, follow all instructions for completing Cumulative Inclusion Enrollment Report as described in the SF424 (R&R) Application Guide.

Letters of Reference

Candidates must carefully follow the SF424 (R&R) Application Guide, including the time period for when letters of reference will be accepted (letters are due by the application due date as described in the [NOT-OD-11-079 \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=51144\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=51144)). Applications lacking the appropriate required reference letters will not be reviewed. This is a separate process from submitting an application electronically. Reference letters are submitted directly through the [eRA Commons Submit Referee Information link \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=41146\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=41146) and not through Grants.gov.

3. Submission Dates and Times

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

Organizations must submit applications to [Grants.gov \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11128\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11128) (the online portal to find and apply for grants across all Federal agencies) using ASSIST or other electronic submission systems. Applicants must then complete the submission process by tracking the status of the application in the [eRA Commons \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123), NIH's electronic system for grants administration.

Applicants are responsible for viewing their application before the due date 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 \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11142\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11142).

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 \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

Pre-award costs are allowable only as described in the [NIH Grants Policy Statement](#)

http://grants.nih.gov/grants/guide/url_redirect.htm?id=11143).

6. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (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](#) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11144). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the [Guidelines for Applicants Experiencing System Issues](#) (<http://grants.nih.gov/grants/ElectronicReceipt/support.htm#guidelines>).

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF424(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 System for Award Management (SAM). Additional information may be found in the SF424 (R&R) Application Guide.

See [more tips](#) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11146) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review, NIH. Applications that are incomplete or non-compliant will not be reviewed.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in [NOT-OD-13-030](#) (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-030.html>).

Section V. Application Review Information

NEW Important Update: See [NOT-OD-16-012](#) (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-012.html>) and [NOT-OD-16-006](#) (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-006.html>) for updated review language for applications for due dates on or after January 25, 2016.

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the [NIH mission](#) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11149), 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 should provide their assessment of the likelihood that the proposed career development and research plan will enhance the candidate's potential for a productive, independent scientific research career in a health-related field, taking into consideration the criteria below in determining the overall impact score.

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.

Candidate

- Does the candidate have the potential to develop as an independent and productive researcher addressing scientifically significant topics that reflect the health priorities of the LMIC?
- Are the candidate's prior training and research experience appropriate for this award?
- Does the candidate have the research experience and skills needed to carry out the proposed research?
- Is the candidate's academic, clinical (if relevant), and research record of high quality?
- Is there evidence of the candidate's commitment to meeting the program objectives to become an independent researcher?
- Do the letters of reference from at least three well-established scientists address the candidate's potential for becoming an independent researcher?
- Does the candidate justify the need for three to five years of mentored research experience in order to become an independent scientist?

Career Development Plan

- What is the likelihood that the career development plan will contribute substantially to the scientific development of the candidate leading to research independence?
- Are the content, scope, phasing, and duration of the career development plan appropriate when considered in the context of prior training/research experience and the stated training and research objectives for achieving research independence?
- Are there adequate plans for mentors to monitor and evaluate the candidate's research and career development progress?
- Does the career development plan demonstrate a clear commitment to a research career in the LMIC setting?

Research Plan

- Are the proposed research question, design, and methodology novel, scientifically significant, creative, and of technical merit?
- Is the research plan relevant to the candidate's research career objectives?
- Is the research plan appropriate to the stage of research development and as a vehicle for developing the research skills described in the career development plan?
- If applicable, are there adequate plans for data and safety monitoring of clinical trials?
- Does the research plan address an area of health priority and scientific importance to the LMIC?

Primary Mentors, Co-Mentor(s), Consultant(s), Collaborator(s)

- Are the primary U.S. mentor's and the primary LMIC mentor's research qualifications in the area of the proposed research appropriate?
- Do the primary mentors and any co-mentors adequately address the candidate's potential and his/her strengths and areas needing improvement?
- Is there adequate description of the quality and extent of the primary U.S. mentor's and the primary LMIC mentor's proposed role in providing guidance and advice to the candidate?
- Are the mentors' descriptions of the elements of the research career development activities adequate?
- Is there evidence of the primary U.S. mentor's and the primary LMIC mentor's, any secondary co-mentors, consultant's, collaborator's previous experience in fostering the development of

independent researchers in the LMIC proposed?

- Is there evidence of previous research productivity and peer-reviewed support?
- Is active/pending support relevant to the candidate's proposed research project appropriate and adequate?
- Are there adequate plans for monitoring and evaluating the career development awardee's progress toward independence?
- If a Mentoring Team is proposed, are the qualifications of the members, the quality of the planned roles for advice, and scheduled meeting frequency of the Mentoring Team with the candidate adequate?

Environment & Institutional Commitment to the Candidate

- Is there clear commitment of the LMIC institution to ensure that the required minimum of the candidate's effort will be devoted directly to the research described in the application?
- Are the institutional commitments from the LMIC and U.S. collaborating institutions to the career development of the candidate and for the mentors appropriately strong?
- Are the research facilities, resources and training opportunities at the U.S. and LMIC institutions, including faculty capable of productive collaboration with the candidate, adequate and appropriate?
- Is the environment for scientific and professional development of the candidate of high quality?
- Is there assurance that the LMIC institution intends the candidate to be an integral part of its research program?

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 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 [Guidelines for the Review of Human Subjects \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11175\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11175).

Inclusion of Women, Minorities, and Children

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of children to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the [Guidelines for the Review of Inclusion in Clinical Research \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11174\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11174).

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 \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11150\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

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

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 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.

Training in the Responsible Conduct of Research

All applications for support under this FOA must include a plan to fulfill NIH requirements for instruction in the Responsible Conduct of Research (RCR). Taking into account the level of experience of the applicant, including any prior instruction or participation in RCR as appropriate for the applicant's career stage, the reviewers will evaluate the adequacy of the proposed RCR training in relation to the following five required components: 1) *Format* - the required format of instruction, i.e., face-to-face lectures, coursework, and/or real-time discussion groups (a plan with only on-line instruction is not acceptable); 2) *Subject Matter* - the breadth of subject matter, e.g., conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics; 3) *Faculty Participation* - the role of the mentor(s) and other faculty involvement in the fellow's instruction; 4) *Duration of Instruction* - the number of contact hours of instruction (at least eight contact hours are required); and 5) *Frequency of Instruction* - instruction must occur during each career stage and at least once every four years. Plans and past record will be rated as *ACCEPTABLE* or *UNACCEPTABLE*, and the summary statement will provide the consensus of the review committee. See also: [NOT-OD-10-019 \(http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html\)](http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html).

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 \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11151\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11151); (2) [Sharing Model Organisms \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11152\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11152); and (3) Genomic Data Sharing Plan.

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), in accordance with [NIH peer review policy and procedures \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11154\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11154), using the stated [review criteria](#). Assignment to a Scientific Review Group 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 score.
- Will receive a written critique.

Applications will be assigned to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications. Following initial peer review, recommended applications will receive a second level of review by the FIC Advisory 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.
- Geographic balance considerations.
- Relevance to the interests of co-funding organizations.
- Potential to contribute other NIH and U.S. government supported research initiatives in LMICs.

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 \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123).

Information regarding the disposition of applications is available in the [NIH Grants Policy Statement \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11156\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11156).

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 \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11157\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11157).

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

Awardees must comply with any funding restrictions described in [Section IV.5. Funding Restrictions](#). Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this FOA will be subject to terms and conditions found on the [Award Conditions and Information for NIH Grants \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11158\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11158) website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the [NIH Grants Policy Statement \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120) 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 \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11157\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11157) and [Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11159\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11159). More information is provided at [Award Conditions and Information for NIH Grants \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11158\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11158). More specifically, for K Awards, visit the [Research Career Development \("K"\) Awardees section of the NIH Grants Policy Statement \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=51164\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=51164).

3. Reporting

When multiple years are involved, awardees will be required to submit the Research Performance Progress Report (RPPR) annually and financial statements as required in the [NIH Grants Policy Statement \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120). The Supplemental Instructions for Individual Career Development (K) RPPRs must be followed. Both primary (U.S. and LMIC) mentors' reports must include an annual evaluation statement of the candidate's progress.

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 \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11161\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11161).

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 \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11170\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11170) on all subawards over \$25,000. See the [NIH Grants Policy Statement \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11171\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11171) for additional information on this reporting requirement.

4. Evaluation

In carrying out its stewardship of human resource-related programs, the NIH may request information essential to an assessment of the effectiveness of this program from databases and from participants themselves. Participants may be contacted after the completion of this award for periodic updates on various aspects of their employment history, publications, support from research grants or contracts, honors and awards, professional activities, and other information helpful in evaluating the impact of the program.

Section VII. Agency Contacts

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

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons registration, submitting and tracking an application, documenting system problems that threaten submission by the due date, post submission issues)

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

Finding Help Online: <http://grants.nih.gov/support/index.html>

([https://mail.nih.gov/owa/oeopsharepoint@od.nih.gov/redirect.aspx?](https://mail.nih.gov/owa/oeopsharepoint@od.nih.gov/redirect.aspx?C=SBSsznBBxkKkui2PqwIuddhr2H8h69AIPxQw4G9TysH6AqY28OipjFX-)

[C=SBSsznBBxkKkui2PqwIuddhr2H8h69AIPxQw4G9TysH6AqY28OipjFX-](https://mail.nih.gov/owa/oeopsharepoint@od.nih.gov/redirect.aspx?C=SBSsznBBxkKkui2PqwIuddhr2H8h69AIPxQw4G9TysH6AqY28OipjFX-)

[oaEAUilxzeJdLQFNqVE.&URL=http%3a%2f%2fgrants.nih.gov%2fsupport%2findex.html](https://mail.nih.gov/owa/oeopsharepoint@od.nih.gov/redirect.aspx?C=SBSsznBBxkKkui2PqwIuddhr2H8h69AIPxQw4G9TysH6AqY28OipjFX-))

Email: commons@od.nih.gov (<mailto:commons@od.nih.gov>)

[Grants.gov Customer Support](http://www.grants.gov/contactus/contactus.jsp) (<http://www.grants.gov/contactus/contactus.jsp>) (Questions regarding Grants.gov registration and submission, downloading forms and application packages)

Contact Center Telephone: 800-518-4726

Web ticketing system: <https://grants-portal.psc.gov/ContactUs.aspx> (<https://grants-portal.psc.gov/ContactUs.aspx>)

Email: support@grants.gov (<mailto:support@grants.gov>)

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

Email: GrantsInfo@nih.gov (<mailto:GrantsInfo@nih.gov>) (preferred method of contact)

Telephone: 301-435-0714

Scientific/Research Contact(s)

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National Institute of Mental Health ([NIMH](http://www.nimh.nih.gov/) (<http://www.nimh.nih.gov/>))

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Email: lprice@mail.nih.gov (<mailto:lprice@mail.nih.gov>)

Lynn King, Ph.D.

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For inquiries related to the career development aspects, contact:
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Email: [lims@mail.nih.gov \(mailto:lims@mail.nih.gov\)](mailto:lims@mail.nih.gov)

For inquiries related to the HIV and AIDS Malignancy research aspects, contact:
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For inquiries related to broader global health research aspects, contact:
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Peer Review Contact(s)

Hilary D. Sigmon, Ph.D.
Center for Scientific Review (CSR)
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Financial/Grants Management Contact(s)

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Section VIII. Other Information

Recently issued trans-NIH [policy notices \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11163\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11163) may affect your application submission. A full list of policy notices published by NIH is provided in the [NIH Guide for Grants and Contracts \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11164\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11164). All awards are subject to the terms and conditions, cost principles, and other considerations described in the [NIH Grants Policy Statement \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

Authority and Regulations

Awards are made under the authorization of Sections 301, 307, and 405 of the Public Health Service Act as amended (42 USC 241, 284, and 287(b)) and under Federal Regulations 42 CFR Part 52 and 45 CFR Parts 74 and 92

[Weekly TOC for this Announcement \(/grants/guide/WeeklyIndex.cfm?07-10-15\)](/grants/guide/WeeklyIndex.cfm?07-10-15)

[NIH Funding Opportunities and Notices \(/grants/guide/index.html\)](/grants/guide/index.html)

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National Institutes of Health (</grants/oer.htm>)
Office of Extramural Research



<http://www.hhs.gov>) Department of Health
and Human Services (HHS)



<http://www.usa.gov/>)

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