



# Partnerships for Enhanced Engagement in Research (PEER) Health

## Request for Applications: Invited Applicants Only\*

**\*This is the second step of a two part application process and applicants should submit an application only if invited to do so.**

Full proposals must be submitted electronically via the PEER Health Web site by February 1, 2013 at 11:59 PM (U.S. Eastern Standard Time). **Do NOT submit a full application unless requested to do so by the National Academies.**

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## I. PROGRAM BACKGROUND

The United States Agency for International Development (USAID) is committed to transforming development through the increased use of science and technology (S&T). In keeping with President Obama's Global Health Initiative (GHI), which leverages the whole of the United States Government (USG) to collaboratively advance global health, USAID would like to enhance its long-time collaboration with the National Institutes of Health (NIH) to achieve USG global health objectives. This includes improving rates of child survival in low and middle income countries by developing interventions that reduce under-five mortality.

The NIH is a world-class research institution that has supported research, training, and capacity building in the developing world for several decades. However, linkages between NIH projects and NIH supported researchers in less developed countries and the local USAID Missions need to be strengthened in order to fully leverage USG research investments, development platforms, and expertise and translate advances in science to health benefits. To accelerate progress in USG global health priority areas, such as ending child preventable deaths, USAID and NIH are collaborating on a new program called Partnerships for Enhanced Engagement in Research (PEER) Health to support collaborative research projects on implementation science.

The U.S. National Academy of Sciences, National Academy of Engineering, Institute of Medicine, and National Research Council—collectively the U.S. National Academies (NAS)—are private, nonprofit institutions that advise the federal government and public on matters of science, technology, and health by establishing committees of experts to address critical technical and policy issues. Throughout a given year, the Academies convene hundreds of conferences, workshops, symposia, and standing committees, which attract the finest minds in academia and the public and private sectors. The National Academies has long-standing relationships with over a hundred foreign scientific academies including those in developing countries. The Division of Policy and Global Affairs at the National Academies has managed several grant research programs including the [Pakistan-US S&T Cooperation Program](#), and the [PEER Science program](#). The programmatic and scientific expertise resident at the National Academies makes this organization an ideal convener for interagency collaboration around research.

Worldwide, under-five mortality has declined from more than 12 million deaths in 1990 to 6.9 million in 2011, yet thousands of children still die every day from preventable diseases. On June 14-15, 2012, the Governments of Ethiopia, India, and the United States, together with UNICEF, convened the [Child Survival Call to Action](#) Summit, mobilizing the world toward one ambitious but simple goal – ending preventable child deaths. Eighty percent of under-five deaths occur in 24 countries. More than 160 countries have signed [A Promise Renewed](#), a pledge to work toward greater child survival.

Accelerating reduction of under-five mortality rates will require implementing innovative country-owned, evidence-based global health and child survival programs that deliver lifesaving interventions and services. In many countries there is an unmet need for implementation science research to inform approaches and investments for public health programming and policymaking. To maximize public health impact, significant progress is needed to deliver interventions more efficiently and effectively, transfer interventions from one setting or population to another, scale interventions to population level impact, and to make better-informed choices between competing interventions. This gap between

research and implementation is impeding success in prevention, care, and treatment programs. Implementation science is intended to facilitate evidence-based decision-making that can inform policy, practice, and improve health outcomes through the delivery of cost-effective programs. High impact implementation science research may require partnerships with and leveraging of in-country implementers and USAID Missions, government agencies, the private sector, and UN partners.

## **NATURE OF USAID-NAS-NIH PEER HEALTH PARTNERSHIP**

PEER Health is a collaborative undertaking between USAID and NIH. The strength of this partnership is the ability to leverage each agency's respective strengths, investments and methodologies. To that end, the *Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)* at the NIH has undertaken the responsibility of conducting a special, independent peer review session for scientific merit and development impact with NIH peer review policy and procedures as a model, including the use of NIH review criteria as described hereafter.

The National Academies, as the implementer, will be awarding the subject grants to selected applicants and will be providing administrative and management services for the PEER Health Program in collaboration with, and on behalf of, USAID. All PEER Health awards will be managed by the National Academies.

As part of their application, each applicant is required to provide written permission for their NIH Summary Statements, which are written reviews for each application, to be shared among the National Academies, USAID, and NIH. All required reports and publications should be submitted to the National Academies, which will share them with USAID and NIH. If the PEER Health NIH-funded collaborator is supported through an NIH extramural program, there will likely be a program officer, assigned to the NIH grant. In such cases, the NIH program officer may benefit from having access to the PEER Health grant application and progress reports, and the PEER Health researcher or principal investigator (PI), is encouraged to provide this information either directly or through their NIH-funded collaborator.

## **II. PROGRAM DESCRIPTION AND OBJECTIVES**

PEER Health is a competitive grants program that supports scientists from [26 eligible countries](#) who are collaborating with NIH supported researchers to develop and advance implementation science projects reflecting the health priorities of eligible countries, USAID missions, and governments. USAID defines **Implementation science** as the "*application of systematic learning, research and evaluation to improve health practice, policy and programs in developing countries*".

The program intends to catalyze high quality, collaborative research projects that will address research-to-practice barriers and constraints while simultaneously building professional capacity and cross-sectoral linkages, particularly between local public health and research institutions and USAID missions. Drawing upon the capacity and investments in global health research at NIH, PEER Health will achieve the following:

- Leverage research capacity developed by the scientific community, including NIH, to accelerate reductions of under-five mortality and to advance a country's strategic health goals as articulated in GHI country strategies and child survival plans through collaborative research partnerships.
- Encourage research to improve the uptake and scale of efficacious health interventions, and to inform and enhance the effectiveness and efficiency of interventions in order to maximize health impact and accelerate reduction in under five mortality.
- Strengthen collaborations among USAID Missions, local researchers, and NIH-affiliated investigators to enhance the impact of research and innovation on public health outcomes and contribute to the evidence-base needed for policy decisions and accelerated progress towards a country's health objectives.
- Strengthen long term in-country research capacity.

This RFA has two focus areas: 1) [Child Survival](#) (with applications accepted from all eligible countries) and 2) Priority health topics in [Indonesia](#), with Mission-specific funds to support the latter.

### **III. FOCUS AREAS**

#### **a. CHILD SURVIVAL**

A range of global initiatives have been directed at improving efficiency, effectiveness, and access to interventions for major childhood diseases. Major deficiencies in financing of health systems and in the availability of appropriately trained health personnel are obstacles to progress, but there are also substantial gaps in knowledge about how to manage, organize, and deliver health care in resource-poor settings. To a significant degree, this is due to the lack of knowledge on how to tackle the barriers and constraints in health systems and how to fill the gaps between the knowledge from biomedical research, clinical trials, and its implementation in the field to deliver cost-effective interventions. Moreover, even when there is sufficient knowledge, the lack of translation of research findings into evidence for health policy is a major obstacle to scaling up interventions.

In response to the Child Survival Call to Action to end preventable child deaths, the PEER Health Program invites researchers to submit proposals that focus on child survival. These proposals should emphasize integrated biomedical, behavioral, social, and public health interventions to accelerate reduction in morbidity and mortality among children under five with an emphasis on the most vulnerable populations, especially those in the poorest quartile, children outside family care, and HIV+ children. Applications focused on reducing neonatal mortality, which accounts for an estimated 40 percent of under-five mortality and lags behind overall reductions in under-five mortality, are particularly encouraged. Other areas of interest in relation to child health include: family planning and reproductive health, pediatric tuberculosis, pandemic influenza and other emerging diseases, neglected tropical diseases and nutrition. Applicants are encouraged to collaborate with partners and propose research projects with a strong potential for large-scale results and broad impact. Optimal partners are those with the greatest potential to influence scale up and impact.

Child survival may be addressed within country specific health strategies based on the [GHI strategic plan](#). GHI target areas include: HIV/AIDS, malaria, tuberculosis, maternal health, child health (and neonatal health), nutrition, family planning, and neglected tropical diseases. All applicants should also refer to the global [Summary Roadmap](#).

More specifically, applications for PEER Health funding should propose implementation research around child survival such as:

1. Innovative health delivery solutions or interventions to reduce child morbidity and mortality that are context-sensitive (situational) and/or cost-effective.
2. Improved methodologies that address specific barriers or constraints for optimizing time-to-effect, sustained coverage, and long-term impact to accelerate reduction in under-five child mortality.
3. Innovative approaches, guidelines, or context specific scenarios for integrating and scaling up effective child health interventions.

The proposed research projects may include utilizing clinical and observational research methods, medical and social epidemiology, health economics, informatics, operational research, marketing and decision analysis, and other related disciplines.

## **b. INDONESIA**

The USG strategy in Indonesia is focused on catalyzing action to accelerate Indonesia's progress toward achievement of [Millennium Development Goals \(MDGs\)](#) 4, 5 and 6; enhancing the use of quality research and evidence in policy and programming; and partnering to address regional and global infectious disease threats. Priority areas for health research should relate to the broad areas of this strategy as described below:

1. **Newborn survival:** While under-five mortality is declining in Indonesia and is on track to meet the MDG 4 goal, newborn mortality has stagnated. The newborn mortality rate is an ever greater percentage of the under-five mortality rate. Proposed research to improve newborn health must respond to national priorities and address key obstacles to reducing newborn mortality due to primary causes – asphyxia, sepsis and pneumonia, low birth weight, and prematurity.

Research should address an aspect of implementation science and can be in any of the following areas: facility-based care, community-based knowledge, behavior and care, scale-up of existing interventions, innovation including innovative technologies, to improve referral from community to health center or between health facilities, or to improve clinical care, including improving the quality of care, and application or adaptation of innovation and/or technologies from other countries to address priority causes in Indonesia. Applications in priority areas of post-neonatal infant survival will also be considered.

2. **Tuberculosis (TB):** Indonesia, a country of more than 245 million people as of 2011, is a high burden TB country. Indonesia ranked fourth globally and eighth for multi-drug resistant (MDR) TB. TB is responsible for 6.3 percent of the total disease burden in Indonesia, compared with 3.2 percent in the Southeast Asian region. There is a need for epidemiological research to better understand drivers of TB transmission in Indonesia (poor nutrition, smoking, diabetes, social drivers, health care

setting, HIV) and to develop cost effective methods and tools for effective contact tracing at the community level.

Drug Resistance (MDR, XDR) is a growing challenge for Indonesia. The [National TB Program](#) (NTP) began a Programmatic Management of Drug-Resistant TB Treatment (PMDT) pilot project in 2009 and this year launched a GenExpert pilot project to increase MDR diagnosis and rapid treatment. There is a need to better understand the transmission of MDR TB in Indonesia, examine the patterns and types of resistance, and improve treatment outcomes. Priority research topics include:

- i. Molecular epidemiology to identify the major points of drug sensitivity transmission.
- ii. Examination of the proportions and types of previously treated people who develop MDR and XDR TB.
- iii. Measurement of reproductive fitness of various drug resistant conferring mutations in Indonesia.
- iv. Evidence based research to determine which high risk populations should be screened for MDR and XDR TB and the optimal method for screening.
- v. Clinical research to investigate treatment regimens and side-effects.
- vi. Examination of risk factors for health workers.

3. **Other areas of interest include:** Maternal and child health; HIV/AIDS; neglected tropical diseases; emerging pandemic threats, pandemic influenza and zoonotic diseases; epidemiology; monitoring, evaluation and survey methodologies; and environmental health. Illustrative examples include:

- i. Research to examine oseltamivir resistance in influenza and transmissibility of H5N1.
- ii. Identification of biomarkers for human response to environmental agents.
- iii. Chronic disease epidemiological trends and modeling of disease burden.
- iv. Evaluation of new infectious diseases diagnostic technologies.

## IV. ELIGIBILITY INFORMATION

### Applicants

Applicants submitting proposals to the PEER Health Program must be citizens of an eligible country affiliated with and permanently based at an academic or government-managed research or healthcare institution in a developing country included on the PEER Health eligible country list (see below). Researchers from non-eligible countries and employees of nongovernmental organizations (NGOs) and/or for-profit firms in PEER Health-eligible countries may participate as co-investigators in projects, using non-PEER Health funding.

Eligibility for PEER Health Principal Investigators	
Eligible Categories (any of the following)	Ineligible Categories (any of the following)
No previous NIH funding	Current NIH Principal Investigators (PI)
Previous or current NIH Trainee	Current NIH Co-PIs
Current financial support from NIH grant or contract (but not a PI or Co- PI)	Employees of NGOs or for-profit firms

Developing country researchers who apply must either be actively engaged or plan to be engaged with an intramural or extramural NIH researcher on their PEER Health project. Applicants should demonstrate how they are leveraging their NIH partner's research capacity that has resulted from previous or current NIH investments. Applicants are encouraged to use their research networks to find a NIH partner.

### **NIH-Supported Partner**

The requirement of having PEER Health applicants partner with an intramural or extramural NIH researcher on PEER Health projects is intended to reflect the rationale of the PEER Health program to leverage USG scientific investments to enhance USG health development goals. NIH extramural collaborators must have an active NIH grant ([all NIH grants except for K and T qualify](#)) at the time of application to PEER Health and demonstrate a successful track record of NIH funding by indicating receipt of at least two NIH grants or NIH funding for the majority of the past 5 years. Ideal collaborators are mid- to senior-level investigators from the intramural or extramural NIH communities. The NIH collaborator is expected to enhance the scientific merit and impact of PEER Health projects through leveraged and applied expertise, skills, methodologies, laboratory access, and synergies with ongoing projects. Although previous collaboration between the applicant and NIH-funded collaborator is acceptable, NIH collaborators are encouraged to enter into new collaborative relationships especially in those countries which could benefit from their topical scientific expertise.

PEER Health applicants are strongly encouraged to demonstrate leveraging existing research and implementation platforms. This may include existing NIH networks, centers, or research capacity such as the [Medical Education Partnerships Initiative](#), local health implementing partners, the private sector, and other research networks, including, but not limited to the [Global Health Policy and Health Systems Research Program](#). USAID Missions may be able to advise on child survival projects that may be leveraged for implementation science projects.

Please review the [Frequently Asked Questions \(FAQs\)](#) section of the program Web site for additional details.

### **Countries invited to submit a full proposal**

Investigators based in these countries from one of the following three categories are invited to submit a full PEER Health:

1. Low-income countries with approved GHI strategic plans;
2. Low and lower middle income countries contributing to 80 percent of under-five mortality in 2011-12; and,
3. Countries with specific USAID Mission contributions to the PEER Health program as listed below.

The complete list of eligible countries is as follows:

Bangladesh	Indonesia	Niger
Burkina Faso	Kenya	Rwanda
Burundi	Liberia	Sierra Leone
Cambodia	Malawi	Somalia
Democratic Republic of Congo	Mali	Tanzania
Ethiopia	Mozambique	Uganda

Guinea

Nepal

Researchers from the following [lower middle income countries](#) (as defined by the World Bank), many of which have excellent scientific capacity, are eligible only if they can demonstrate matching funds from within the country (government, research institutions, private sector, etc.):

Cameroon

Pakistan

India

Philippines

Nigeria

Yemen

## **V. FULL PROPOSAL PREPARATION AND SUBMISSION INSTRUCTIONS**

**Who may apply?** Only invited applicants may submit a full proposal to this RFA. Do NOT submit a full application unless invited to do so by the National Academies. All other individuals are ineligible to apply.

**Electronic Submission Instructions:** All proposals must be submitted electronically via the [PEER Health online application site](#). To apply online, please visit the PEER Health online application site and create an account by entering your name, assigned proposal number, contact information, and information about your organization. After creating your account, please login to the system and click on the “apply” icon visible in the left banner. You can then select the PEER Health program and continue your application. You can save your online application as a draft at any time and resume it later. However, we highly recommend that you first review the required application sections online and prepare your answers accordingly in a separate Word document. Before submitting your application, you can copy and paste each section into the online application. Click the “Submit Form” button when you are ready to submit the application.

**PLEASE READ AND FOLLOW THE INSTRUCTIONS CAREFULLY. Incomplete proposals will not be considered. Zip files are not supported by this online application system. Please use only Microsoft Office, Adobe Portable Document Files (PDF), and JPG files when uploading your documents. Emailed proposals will not be accepted.**

Specific instructions on all sections of the required proposal format are presented below.

**Overview:** When writing the full-proposal, developing country applicants should consider how their research will contribute to the strategic health objectives identified by the USAID Mission in their country. Full proposals must expand on the concepts and methodology presented at the pre-proposal stage. **It is not permissible to change the application focus between the pre-proposal and full proposal stage.** Applicants are encouraged to explore various development resources including USAID Mission, , and GHI country strategies and the overall goals of the [Global Health Initiative](#). In particular, applicants should be mindful that PEER Health will not fund research projects that are not directly linked to development objectives. Reviewers for the NIH reviewer panel will be asked to provide an overall “Impact” score based upon the entire application, reflecting the likelihood of the project to exert a significant impact on child survival or for Indonesian applications, does the application address Indonesian priority health areas.

Research topics proposed under PEER Health must be collaborative in nature. The NIH-supported partner's research should complement the PEER Health proposal. **Only proposals involving a partnership with the PI or Co-PI on an NIH extramural award (i.e., that will be active at the time of application to the PEER Health program) or with an NIH intramural investigator will be considered.** Collaborative projects involving a regional health issue in multiple PEER Health-eligible developing countries are encouraged.

Please carefully review the full text of the program announcement, the instructions below, the review criteria, and the program FAQs for further guidance on each required proposal element.

## **1. General Application Data**

Please answer the first set of questions in the indicated spaces. Enter your assigned proposal number indicated on your invitation to submit a full proposal. All applications must list a NIH-supported collaborator and provide the title and award number of his or her NIH grant. Grants will be made only to institutions, so individuals who have no institutional affiliation or whose institutions are not willing to accept and manage a grant for them are not eligible to apply. Principal investigators may submit only one proposal in any one application cycle of the PEER Health program.

If selected for funding, all developing country institutions must have a DUNS number (available online at <http://fedgov.dnb.com/webform>), but it is not necessary to obtain this number at the time the proposal is submitted.

## **2. Project Abstract**

The abstract should be brief and clearly state the goals and objectives of the project. Please include a description of the problem that the implementation science project will address. This section should include project plans such as study design, implementation partners, study population, expected outcomes, etc. The summary should also explain the role and added value of the collaboration with the NIH partner.

## **3. Description of Scientific Merit and Development Impact**

Please use this section to first discuss the scientific merit and second, the development impacts of your project. In describing these impacts, the specific focus should be on how the project addresses challenges in the reduction of under-five mortality as outlined in the RFA or for Indonesian applications, how the application addresses Indonesian priority health areas.

## **4. Scored Review Criteria Sections**

Applicants should understand that reviewers will be asked to provide an overall "Impact" score based upon the entire application and the likelihood of the project to exert a sustained influence on child survival or for Indonesian applications, does the application address Indonesian priority health areas.

Please address each section of the five review criteria below concisely (within the character limit as provided in the online application). If needed, you may also upload figures and/or tables as an annex at the end of this application. Please reference each figure in the text. Incomplete proposals and those not submitted in the required format will not be considered.

#### **4.1. Significance**

##### **a. Background and Rationale**

Explain how the proposed project is related to the country's health need and the USAID Mission's health priorities. Describe what important problem or critical barrier in the implementation of USAID health programs is being addressed with the proposed project.

##### **b. Project Scope, Objectives, and Potential Impact**

Please state clearly how the implementation problem related to the country's reduction in under-five mortality and/or other strategic health priorities will be addressed and how the proposed goals will be achieved. Then describe the anticipated potential scientific and development impact: How will the proposed project influence current USAID and/or country programmatic practices? How will the project aims impact the sustainable health of the country's population? How will scientific knowledge, technical capability, implementation and/or clinical practice be improved?

#### **4.2. Investigator(s)**

##### **a. Prior Experience and Relevant Capabilities of Principal Investigator**

Briefly explain the qualifications of the principal investigator as they relate to the proposed project and illustrate how the project will build upon existing expertise.

##### **b. Contributions of the NIH Partner**

Explain in detail the role the NIH- collaborator will have in the proposed project, and how it relates to his or her expertise and/or existing NIH-funded award. Explain why this collaboration is appropriate for the developing country PI and NIH researcher. Explain how the participation of the NIH-supported collaborator enhances the proposed project. How is the NIH researcher involved in the overall program goal of promoting capacity building in the developing countries while building on existing investments of NIH support?

##### **c. Description of Senior/Key Personnel**

Applicants must provide for each Senior/Key Personnel staff member background information within the [Senior/Key Personnel form](#) and a [biosketch in the standardized format provided](#).

[Instructions for completing the forms](#) and a [sample biosketch](#) are included. Senior/Key Personnel are defined as all individuals who contribute in a substantive, meaningful way to the scientific development or execution of the project, whether or not salaries are requested. Consultants and those with a post-doctoral role should be included if they meet this definition, as well as any other significant contributors. Reviewers will use these pages to address the "Investigator" review criterion. Please save this information in a single file (using the format provided) and attach to your submission..

#### **4.3. Innovation**

Describe any novel concepts, approaches, methods, tools, or technologies to be applied in the proposed activity and how the overall approach is innovative. Innovation can include: 1) potential to change existing paradigms or programmatic practice; or address an innovative hypothesis or critical barrier to success of child health interventions or policies; 2) incorporation of new approaches to answer questions related to program design and scientific advances in program implementation of child health interventions; 3) adding significantly to the knowledge base related to child health and/or maternal/child care.

#### **4.4. Approach**

##### **a. Research Plan**

Describe the overall project design, highlighting the research aims, objectives and clear, testable hypotheses. The study design must be described and justified with an adequate description of the target population and a statistical analysis plan. The overall design should be adequate to answer the primary study objectives. Anticipated strengths and limitations of the proposed design (particularly feasibility of the project to reach completion) and any high-risk aspects of the proposed research should be articulated. Discuss the potential difficulties and limitations of the proposed procedures.

**b. Data Dissemination & Utilization Plan**

Include a clear and detailed plan describing how the research findings will be disseminated and utilized. The plan should discuss the global application(s) of the research findings, and activities to promote the dissemination and utilization research findings at the local, national, and global levels. The plan should articulate how the research findings will be disseminated to key stakeholders, and utilized to improve host country policies and programs.

**c. Collaboration Plan**

Provide details on how the project teams intend to collaborate with the existing health system and other relevant in-country organizations and USAID Missions, and keep in line with the country's health priorities. As applicable, specify plans for promoting the participation of women and youth in any of the proposed activities.

**d. Timeline**

Provide a list of major project activities and milestones along with the estimated time required to complete each. (If your timeline is in a spreadsheet or graphical format, you may upload it instead of entering the text in the text box provided in the online application).

#### **4.5. Environment**

**a. Local Environment.** Describe briefly how the project will benefit from unique features of the local environment, subject populations, and collaborative arrangements. Explain how the proposed work may fit into regional health plans, projects funded by USAID, and/or other sources within the existing health system.

**b. How will the environment contribute to the success of the project?**

### **5. Additional Review Criteria Sections**

If your project involves human subjects, animals, or biohazards please describe plans for addressing these aspects, including minimizing potential risks and proper storage and disposal. If your program does not involve any of the below mentioned aspects, please add "not applicable" in the appropriate online application textboxes.

#### **5.1. Protection for Human Subjects**

**a.** The PEER Health Principal Investigator and recipient organization are responsible for safeguarding the rights and welfare of human subjects involved in research under this award, and must comply with 45 CFR Part 46 <http://www.hhs.gov/ohrp/humansubjects/index.html>.

Please use the [Targeted/Planned Enrollment Table](#) to provide information about study participants in Section 7.7. Applicants will need to address several areas to enable reviewers to assess the adequacy of human subject protections: 1) risks to subjects, 2) adequacy of protections of risks, 3) potential benefits to subjects and others, 4) importance of the knowledge to be gained, 5) data safety and monitoring. Please see NIH application instructions, Part II Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan ([http://grants.nih.gov/grants/funding/424/SF424\\_RR\\_Guide\\_General\\_Adobe\\_VerB.pdf](http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_Adobe_VerB.pdf)).

**b.** For clinical trials, data safety and monitoring plans should be described by the PEER Health applicants and comply with guidance provided by NIH [http://grants.nih.gov/grants/policy/hs/data\\_safety.htm](http://grants.nih.gov/grants/policy/hs/data_safety.htm). A Data and Safety Monitoring Board (DSMB) refers to a committee of independent experts (not affiliated with the trial, or institutions involved in the trial), that periodically reviews the conduct and results of the trial and recommends continuation without change, continuation with change, or termination of the trial. Clinical trials that most often require DSMB oversight are randomized, multi-center trials that are large Phase II or Phase III trials, or are Phase IV trials. The level of monitoring should be commensurate with the level of risk. NIH policy requires data and safety monitoring plans for clinical trials to be submitted at the time of the application.

**c.** PEER Health applicants proposing a clinical trial will either provide a US Federal-Wide Assurance (FWA) which designates an Office of Human Research Protection (OHRP) registered Institutional Review Board (IRB) at the time of application or seek a FWA within 30 days of receiving a PEER Health award. The Web page for electronic submission of new IRB registrations and FWAs, or update/renewal of existing registrations can be found at <http://ohrp.cit.nih.gov/efile/Default.aspx>. Please provide your institution's FWA number and the name of the registered IRB that you will use for PEER Health. If your institution does not have an FWA, you will need to obtain the FWA before an award can be made. Plans for Institutional Review Board approval of your future PEER Health protocol should also be described. Note: within the first 30 days of award notification, PEER Health recipients are expected to develop and submit the study protocol and obtain a US Federal-Wide Assurance (FWA). Applicants should include this step in their timeline (see 4.d).

**d.** For help with human subject issues, PEER Health applicants are encouraged to collaborate with their NIH partner on protection of human subject requirements should assistance be needed. In addition to the OHRP website <http://www.hhs.gov/ohrp/>, the Department for Health and Human Services decision trees for human subjects may be helpful to PEER Health applicants: <http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html>.

## **5.2. Vertebrate Animals**

Recipients of PEER grants must assure the humane treatment of animals involved in the research. Recipients of PEER Health grants must have an Office of Laboratory Animal Welfare (OLAW) approved Animal Welfare Assurance before carrying out any activities involving live vertebrate animals. Institutions outside the United States that receive PEER Health grants are to use the Animal Welfare Assurance for Foreign Institutions (Foreign Assurance). All entities proposing to conduct research, research training, and/or biological testing activities involving live, vertebrate animals supported by a PEER Health grant must have a Foreign Assurance in place prior to beginning the activity.

For additional application instructions related to vertebrate animals protections, please refer to Part III-20, Section 2.2, Vertebrate Animals, in the DHHS SF424 (R&R) Application Guide for NIH and Other PHS Agencies.

The PEER Health applicant will collaborate with NIH supported researchers. As such, the Institutional Animal Care and Use Committee (IACUC) of the NIH Institute/Center (I/C) supporting the NIH researcher must review and approve the proposed animal activity for intramural investigators, and the collaborating institution's IACUC must review and approve the proposed animal activity for extramural investigators. Only activities that do not involve live vertebrate animals may be conducted at any performance site until OLAW has approved a

Foreign Assurance for that site, and the IACUC of the collaborating NIH I/C or has reviewed and approved the activity. The PEER Health grants manager will ensure that the Foreign Assurance, IACUC approval, and the Vertebrate Animal Section of the grant application are in place prior to allowing release of funds for any animal activity. For additional guidance, please refer to the [Worksheet for Review of the Vertebrate Animal Section \(VAS\).](#)

### **5.3. Biohazards**

Applicants are responsible for describing whether the proposed research will include any potentially hazardous materials and/or procedures and any protections in this regard. During the application review, reviewers will assess whether these materials or procedures pose risks of harm to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

## **6. Additional Review Considerations**

### **6.1. Select Agent Awards to Foreign Institutions and International Organizations**

Foreign Institutions and International Organizations who conduct research involving select agents (see 42 CFR Part 73 for the select agent list; and 7 CFR Part 331 and 9 CFR Part 121 for the relevant animal and plant pathogens) must provide information satisfactory to the NIH that a process equivalent to that described in 42 CFR Part 73 for U.S. institutions is in place and will be administered on behalf of all select agent work sponsored by NIH funds before using these funds for any work directly involving select agents. Grantees should address the following key elements appropriate for their institutions: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the select agents, and any applicable laws, regulations and policies equivalent to 42 CFR Part 73. If this work will not, in fact, involve select agents (e.g. excluded strains), and you provide documentation satisfactory to the NIH that your work does not now nor will it in the future (i.e. throughout the life of the award) involve select agents, no further action will be necessary.

### **6.2. Resource Sharing Plans**

One purpose of PEER Health is to leverage research investments made by the NIH in PEER Health countries to advance knowledge of implementation science for child survival. To this end, applicants should articulate how they are leveraging the NIH partner research to advance their PEER Health project.

### **6.3. Project Budget**

#### **a. Proposed Budget Total (in US \$)**

The total requested budget from PEER Health cannot exceed \$150,000 per year for a maximum of three years, i.e., total requested budget will not exceed \$450,000.

#### **b. Budget Form**

Provide an itemized budget for the project using the [budget form](#) provided. Projects may last no more than three years, and proposals for multi-year projects must provide budgets separately detailing the expected costs for each year. Value for the investment will be an important consideration in proposal evaluation and selection, so all costs should be reasonable and necessary. If your project involves more than one developing country institution (with the lead institution located in a PEER Health eligible country), please prepare a separate budget table for each, so that it is clear what funds are requested for each institution.

### **c. Budget Request Justification**

USAID is a development agency and is seeking development outcomes through accelerated reduction of under-five mortality. As such, applicants should keep in mind that PEER Health supports the GHI principles by promoting country ownership, increasing impact through smart collaborations and integration to enhance health impacts through sustainability. Therefore PEER Health budgets should reflect these principles and, where possible, leverage and facilitate sustainable scientific capacity that is developed and supported, by both the partner country government and the NIH.

#### **i. Personnel Costs**

It is anticipated that the PI's institution will provide salary and benefit support for the PI and other essential research personnel on the project. However, if the research project cannot be effectively conducted without additional personnel/salary support for the PI, a reasonable amount of PI salary support may be allowed in the budget. The PI requesting salary support must ensure that the support letter from his/her institution (see details in section 7.6 below) articulates how the institution will support the research project, specifically including a brief plan for sustaining future personnel costs for the PI and relevant personnel to continue this research after completion of the PEER Health grant. Costs for support for other researchers and technical personnel are allowable, as are stipends for students involved in the project and should also be justified in project budgets and include a list of positions to be supported, a brief explanation of the respective roles, and the percentage of time that would be allocated for each position to the project.

#### **ii. Equipment Costs**

For the purposes of this RFA, equipment is defined as both durable items that will last through the project period and consumables. Where possible, projects should leverage existing durable equipment. Requests for durable equipment should be justified in terms of its importance to successfully completing the PEER Health research project and include plans for maintenance during and beyond the project period.

#### **iii. Travel Costs**

Provide the number, duration, location, and purpose for any project-related trips for which funds are requested, along with the titles or positions of the travelers.

International air travel must be by U.S. air carriers to the maximum extent such that service is available as required under the Fly America Act, so applicants should estimate their air travel budgets accordingly. First or business-class travel costs are not allowable.

If visits to the United States are planned, applicants should include in their travel budgets an extra \$100 for each visit to cover the cost of the medical examination that will be required as part of the visa application process.

#### **iv. Indirect Costs**

If requested, indirect costs (costs supporting overall institutional operations and management) should be kept to a minimum and must be fully explained and justified, with details provided on what specific institutional infrastructure elements or support services are covered.

#### **v. Matching Funds**

Researchers from Cameroon, India, Nigeria, Pakistan, the Philippines, and Yemen must demonstrate monetary matching funds from within the country. These funds can come from the applicant's research institution or from government agencies, the private sector, or any other source. Matching funds need to be provided in monetary form, but do not need to be at the 1:1 matching level.

- vi. Contingency costs** are not allowable.
- vii. PIs can partner with local NGOs** on the implementation side of the proposed project.

These NGOs may receive limited and only well justified funding. Funding of non-local NGOs is not an allowable cost.

#### **viii. Other Contributions**

**Institutional Support.** The institutional support letter must be submitted with the application (see details in section 7.6) and must itemize what support is currently in place at the PI's institution, if any, e.g., salary, lab space, equipment and other resources.

**Other Funding and Other Collaborating Institutions.** List the source and amount of any other funds that you have received or applied for from other sources to support this project, including any support received directly from USAID. If your project involves other institutions besides your own and that of your NIH-supported collaborator, please list them, briefly describe the roles they will play in the project, and indicate whether they will support their costs with their own resources or with funds requested in your PEER Health project budget.

## **7. Required Attachments**

In addition to the completed online application, please also upload the following items in your proposal submission (your application will not be complete and cannot be submitted without these attachments):

### **7.1. Annex**

If necessary, please include your figures and diagrams in a single document annex and refer to them in your project description (for example Figure 1 in Annex, etc.). Please do not exceed five figures/tables combined and do not include an additional project narrative to this document.

### **7.2. Curriculum Vitae (Developing Country PI)**

Please upload the principal investigator's brief curriculum vitae (CV), which should be no more than two pages in length and include citations for no more than ten recent relevant publications or patents. If the project includes more than one developing country institution (including local NGOs), please also include a CV for the key project participant at each institution. Please do not submit electronic copies of publications or other background materials, as they will not be forwarded to reviewers. All the CVs must be uploaded in one single PDF file.

### **7.3. Curriculum Vitae (NIH-supported collaborator)**

Please upload your NIH partner's brief CV, which should be no more than two pages in length and include citations for no more than ten recent relevant publications or patents. Please do not submit electronic copies of publications or other background materials, as they will not be forwarded to reviewers.

### **7.4. NIH Award Abstract**

Please upload a copy of the abstract of your NIH collaborator's eligible award(s).

### **7.5. Letter of support from NIH-supported collaborator**

The letter must be written on official institutional letterhead and must list the title and award number of the collaborator's active NIH grant. It must provide details on how the proposed project relates to this NIH grant and explain the NIH-supported collaborator's expected role in the project and the level of integration of the proposed project with the specific area of research. **The letter must be signed by the NIH-supported collaborator.** Please do not submit the same support letter used for your pre-proposal.

### **7.6. Letter of Support from an Official at the PI's Institution**

**This letter must be written and signed by an official at the principal investigator's institution who is legally authorized to make commitments on the institution's behalf.** If your project involves more than one developing country institution, please submit a separate support letter from each institution. The letter must be written on official institutional letterhead and must include the following elements:

- Confirmation that the institution supports the participation of its staff in the proposed project is willing and able to receive and administer any grant funds awarded, and is permitted under local regulations to receive grant funds from a foreign sponsor.
- A brief description of the institution's structures and practices for project management and financial oversight, as well as a description of the process by which the institution can receive grant funds from a foreign sponsor.
- A brief description of resources that the institution can make available to facilitate the project, whether in cash or in kind, if any. For example, by paying the salary of the principal investigator or other staff for the time he or she works on the project, providing substitute instructors to cover the principal investigator's teaching duties so he or she is free to work on the project, or providing laboratory or office space, access to equipment, or office support staff.
- Examples of other grants your institution has received from foreign sponsors (if any), including the project title, foreign sponsoring organization's name, funded amount, dates, and name and e-mail of contact person at the foreign sponsoring organization.

### **7.7. Targeted/Planned Enrollment Table**

Please use the [Targeted/Planned Enrollment Table](#) to describe study participants. Please include the study title. The "Total Planned Enrollment" refers to the number of subjects that are expected to be enrolled in the study.

## **8. Permission and Consultation**

Please indicate that your institution gives permission to USAID and NIH to share your review summary statement with the National Academies, in order to facilitate the processing of your application.

## **VI. FULL PROPOSAL REVIEW PROCESS**

The *Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)* at NIH will convene a special review panel that will evaluate proposals for scientific and technical merit and development impact using the PEER Health review criteria stated below. Because NICHD is only organizing the review of these proposals and will not be participating in the grants management of the PEER Health program, the [NIH Peer Review Policy](#) will be used only as a model. Thus, certain NIH review

procedures do not apply, including the ability to appeal. All funding decisions will be final when awardees receive notification.

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

- Undergo a selection process in which only those applications deemed to have the highest scientific and technical merit, development impact, and relevance to USAID's global and country-specific programmatic interests or country-specific GHI strategies will be discussed and assigned an overall impact/priority score.
- Receive a written critique.
- Compete for available funds with funding decisions based on 1) Scientific and technical merit and development impact of the proposed project as determined by scientific peer review; 2) Availability of funds, and 3) Relevance of the proposed project to USAID's global and country-specific programmatic interests or country-specific GHI strategies.

## **VII. FULL PROPOSAL REVIEW CRITERIA**

All full-proposals will be evaluated based on the following criteria:

### **Overall Impact**

Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to address an important problem or barrier in the implementation of child survival programs that target accelerated reduction of under-five mortality. Or in the case of applications from Indonesia, overall impact or priority score will reflect responsiveness to priority health areas specified in this PEER Health RFA to support the Indonesian focus on catalyzing action to accelerate Indonesia's progress toward achievement of Millennium Development Goals (MDGs) 4, 5 and 6; enhancing the use of quality research and evidence in policy and programming; and partnering to address regional and global infectious disease threats.

### **Scored Review Criteria**

Reviewers will consider each of the five review criteria below in the determination of scientific and technical merit, and assign 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.

1. **Significance:** Does the project address an important implementation science challenge for reducing under-five child mortality, child survival in at least one of the research priority areas outlined in the Child Survival section of this RFA? For Indonesian applications, does the application address Indonesian priority health areas? If the aims of the project are achieved, (1) how will scientific knowledge, technical capability, implementation and/or clinical practice be improved; (2) how will current USAID or partner country programmatic practices be influenced; and (3) how will they impact the health of the population?
2. **Investigator:** Are the PI(s) and NIH-supported partner qualified to achieve the research goals of the project by having the relevant education, experience, training and/or accomplishments? If the project is collaborative (multi-PIs or co-investigators) do the investigators have complementary and integrated expertise? Will the participation of the NIH-supported collaborator enhance the proposed project? Does it appear that both sides are committed to working together and have a clear plan for how that collaboration will be

carried out? How will the research, expertise, and/or resources of the NIH investigator be leveraged in the PEER Health project?

3. **Innovation:** Does the proposal challenge and seek to shift current practice paradigms by researching novel approaches or methodologies, instrumentation, or interventions? Does the project challenge existing paradigms or programmatic practice; or address an innovative hypothesis or critical barrier to success of child health interventions or policies? Does the project incorporate new approaches or implementation science methods to answer questions related to program design and incorporation of scientific advances in program implementation of child health interventions? Will answering the research question add significantly to the knowledge base related to child health and/or maternal/child care?
4. **Approach:** Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Does the proposal discuss demonstrable or planned collaboration with USAID missions and/or programs in-country to conduct the research and implement the results? Does the proposal include a data dissemination and utilization plan including a description of activities to promote the uptake of research findings? Does the plan discuss the application(s) of the research findings and how the research findings will be disseminated to key stakeholders, utilized to improve child health policies and programs, and how these activities will be achieved within the study timeline?
5. **Environment:** Will the project benefit from unique features of the local environment, subject populations (including but not limited to women, children, and marginalized groups), or collaborative arrangements (including but not limited to NGO's that implement health programs)? Will there be other networks or resources leveraged to complete the project and how integral are they to the research plan? Will the project strengthen research capacity in-country by involving a broader group of students and local researchers? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed?

### **Additional Review Criteria**

Reviewers will also evaluate the following items as part of the overall impact/priority score.

1. **Appropriate Representation:** Reviewers will evaluate how well the proposal describes the participation of women, racial/ethnic minorities, other marginalized populations, and persons with disabilities in the planning, organization, and implementation of the proposed project.
2. **Protections for Human Subjects:** For research that involves human subjects but does not involve one of the [categories of research that are exempted under 25 CFR Part 225](#), 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 research that are exempt under 25 CFR Part 225, 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](#).

3. **Inclusion of Women, Minorities, and Children:** When the proposed project involves clinical research, the committee will evaluate the proposed plans for considering the 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](#).
4. **Vertebrate Animals:** When the proposed project involves vertebrate animals, reviewers will evaluate the proposed plans to assure the humane treatment of animals involved in the research. The applicant must agree to comply with the PHS Policy or provide evidence that acceptable standards for the humane care and use of the animals in the PHS-conducted or supported activities will be met. Reviewers will bring any concerns to the attention of the Scientific Review Officer. For additional guidance, please refer to the [Worksheet for Review of the Vertebrate Animal Section \(VAS\)](#).
5. **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. Reviewers will bring any concerns to the attention of the Scientific Review Officer.

## **Additional Review Considerations**

Reviewers will also consider the following items, as part of the overall impact/priority score.

1. **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).
2. **Resource Sharing Plans:** What percentage of the PI's budget come from leveraging or cost sharing from NIH networks and other non-NIH resources?
3. **Budget and Period of Support:** Is the project budget requested reasonable? If sub-awards are requested to other institutions besides the PI's, are they consistent with the PEER Health project goals? If the sub awardees are NIH-supported or located in countries ineligible for Health funding, is the requested amount reasonable and critical to the success of the PEER Health project? Please note recommendations where decreasing or eliminating specific budget items is possible due to financial constraints.

**Required Attachments:** Must be properly submitted and will be considered during the review.

## **VIII. AWARD INFORMATION**

The number of awards is subject to the availability of funds. The release of each annual funding increment is contingent on the project meeting annual financial, collaborative and technical reporting requirements.

Upon receipt of a PEER Health award, developing country PIs will be expected to meet with USAID health officers, Mission staff, and NIH collaborators to review the research project and discuss how the proposed project aligns with Mission goals.

PEER Health applicants are not required to include a protocol when they first submit their grant application. However, following the completion of the NICHD scientific peer review session, all successful PEER Health Principal Investigators (PIs) must submit their PEER Health protocols for review and approval by the PEER Health Protocol Review Committee (PRC). Following protocol approval by the PRC, PIs must submit their protocol to their IRB for approval. No funding will be provided in the absence of a FWA and IRB approval.

If NIH funding is directly or indirectly used, publications resulting from the PEER Health Program may need to comply with the NIH Public Access Policy (Division G, Title II, Section 218 of PL 110-161; Consolidated Appropriations Act, 2008) in a manner consistent with copyright law. This Policy requires that investigators funded by NIH submit or have submitted for them to the National Library of Medicine's PubMed Central (<http://www.ncbi.nlm.nih.gov/pmc/>), an electronic version of their final peer-reviewed manuscripts upon acceptance for publication. Under the policy, manuscripts must be made publicly available no later than 12 months after the official date of publication in an effort to help advance science and improve human health.

**Applicants who have questions after reviewing the materials on the [PEER Health Web site](#) are encouraged to contact PEER Health staff by e-mail at [peerhealth@nas.edu](mailto:peerhealth@nas.edu).**

PEER Health is implemented by

**THE NATIONAL ACADEMIES**  
*Advisers to the Nation on Science, Engineering, and Medicine*