

AIDS INTERNATIONAL TRAINING AND RESEARCH PROGRAM

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Fogarty International Center (FIC)

(<http://www.nih.gov/fic>)

National Cancer Institute (NCI)

(<http://www.nci.nih.gov>)

National Heart, Lung and Blood Institute (NHLBI)

(<http://www.nhlbi.nih.gov>)

National Institute of Allergy and Infectious Diseases (NIAID)

(<http://www.niaid.nih.gov/>)

National Institute of Dental and Craniofacial Research (NIDCR)

(<http://www.nidcr.nih.gov>)

National Institute of Mental Health (NIMH)

(<http://www.nimh.nih.gov/>)

National Institute of Nursing Research (NINR)

(<http://www.nih.gov/ninr/>)

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

(<http://www.niaaa.nih.gov/>)

National Institute on Drug Abuse (NIDA)

(<http://www.nida.nih.gov/>)

Office of AIDS Research (OAR)

(<http://www.nih.gov/od/oar/index.htm>)

Office of Research on Women's Health (ORWH)

(<http://www4.od.nih.gov/orwh/>)

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PURPOSE OF THIS PA

The purpose of this announcement is to invite applications from eligible institutions for innovative, collaborative training programs that would contribute to the long-term goal of building sustainable research capacity in HIV/AIDS and HIV-related conditions at developing country institutions. These research-training programs will strengthen scientific knowledge and skills to enhance prevention of and treatment and care for HIV/AIDS and HIV-related conditions in developing countries.

The Fogarty International Center (FIC), together with partner Institutes and Offices from the National Institutes of Health (NIH), has supported long-term research capacity-strengthening efforts in developing country institutions for the past 15 years through a series of competing five-year awards solicited through requests for applications (RFAs) for the AIDS International Training and Research Program (AITRP). At this time, the Fogarty International Center (FIC) with its partners, the National Cancer Institute (NCI), the National Institute of Allergy and Infectious Diseases (NIAID), the National Heart, Lung and Blood Institute (NHLBI), the National Institute of Dental and Craniofacial Research (NIDCR), the National Institute of Mental Health (NIMH), the National Institute of Nursing Research (NINR), the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institute on Drug Abuse (NIDA), the Office of AIDS Research (OAR), and the Office of Research on Women's Health (ORWH), will solicit new and competing renewal applications and competing supplement applications to existing grants for AITRP under this program announcement.

PROGRAM OBJECTIVES

Background:

As the global HIV/AIDS epidemic enters its third decade, the toll it has taken on individuals' lives is felt around the world. While currently, the affected populations are primarily in sub-Saharan Africa, HIV epidemics in China, India, other south Asian countries, Russia and the Newly Independent States are increasing. Progress to identify interventions to prevent the transmission of the infection through sexual contact, from mother to child, and through needle use has been made, but additional interventions to prevent transmission are needed if we expect to stem the tide of the epidemic. Effective interventions to prevent the transmission of HIV and other pathogens through unsafe blood and the inappropriate use of transfusion, such as appropriate programs for the recruitment and retention of volunteer donors; effective surveillance for established and emerging potential pathogens, and strategies to promote the rationale use of blood, continue to be needed and promoted.

As attention turns toward integration and expansion of care and treatment of HIV and HIV-related conditions into existing prevention programs, identification of effective interventions will be crucial to a country's ability to respond adequately. The capacity to conduct integrated prevention and care research across the full range of conditions and issues that relate to care of adult and pediatric patients with HIV/AIDS (e.g., opportunistic infections, HIV malignancies, neurological and mental health consequences,

behavioral issues, issues related to mother to child transmission, hematological and cardiovascular conditions, blood safety issues, pulmonary manifestations, ophthalmologic manifestations, gastrointestinal conditions, drug and alcohol usage, sex/gender-related science and issues, and oral health manifestations) need to be strengthened and expanded in developing countries. In addition to the identification of effective interventions, the ability to evaluate the economic and social impacts of these interventions will be crucial to guide policy makers as they develop policies and programs to address the HIV/AIDS epidemic in their countries.

This program will increase research training across the span of biomedical, behavioral and social sciences, clinical science, epidemiology, biostatistics, and public health practice. The research-training program should continue to emphasize prevention research and expand to include research to identify appropriate interventions to provide care to those adults and children infected with HIV. It should involve a wide range of professionals (e.g. nurses, midwives, physicians, dentists, health care administrators and public health workers), and should be multidisciplinary, including training across the span of sciences and disciplines listed above.

Research Training Objectives

Research-training programs should provide a variety of short-, medium- and long-term training opportunities for participants from developing country institution(s) within the context of ongoing research collaborations. Applications should present an assessment of the specific needs for HIV/AIDS and HIV-related research training at their collaborating developing country institution(s) and a proposed training plan to address those needs during the course of a five-year award. It is expected that each research-training program award supported will:

- o Increase the expertise of trainees in relevant biomedical, behavioral, laboratory, clinical, epidemiological and/or social science research;
- o Fill gaps and strengthen the sustainability of HIV/AIDS and HIV-related research within developing country institution(s);
- o Expand and equalize collaborative scientific research interactions between developing country scientists and U.S. or potentially other developed country researchers;
- o Provide data for evidence-based decision-making related to HIV/AIDS and HIV-related conditions with respect to prevention, care and treatment policies in the host developing country;
- o Take advantage of other sources of research and training support in the foreign country;
- o Actively work with collaborating country institutions and government officials within the collaborating country to provide opportunities and positions for all returning trainees to maximize the use of the knowledge and skills they acquired during their training; and
- o Strengthen the capacity of developing country institutions to compete for current and future NIH and non-NIH research and other grants designed for foreign institutions.

Existing and re-competing AITRP applications may include applications for competing supplements for up to the numbers of years of the existing or re-

competing parent grant for the following purposes:

- o Expanding their training programs geographically to institutions without existing AITRP collaborations in India or China;
- o Expanding their training programs geographically to institutions with which they have existing or the potential for strong AITRP collaborations;
- o Expanding their training programs in their emphasis country(ies) to take advantage of existing Centers for AIDS Research (CFAR), AIDS Clinical Trials Group (ACTG), and Pediatric AIDS Clinical Trials Group (PACTG) grants at their institution;
- o Expanding their training program to respond to existing needs or opportunities related to the research areas of co-sponsoring NIH Institutes, Centers or Offices;
- o Supporting U.S. graduate or medical students and postdoctoral fellows for research training at the collaborating developing country institution.

Beginning with awards funded under this PA, grantees may submit competing supplement applications for up to three years of support for advanced in-country re-entry support to establish independent research projects at the developing country institution for developing country participants who have completed substantial medium-and long-term research training. Eligibility for these supplements will be limited to trainees who have received a degree or advanced skill training for at least six months continuous duration through the AITRP program submitting the competing supplement application. See Supplemental Instructions for additional instruction for competing supplement applications for this purpose. The competing supplement application process also may be used for degree-required and mentored trainee research projects which are not part of an existing NIH research award and which require additional independent peer review.

Training may occur in either the U.S. or developing country institution. However, applicants are strongly encouraged to provide support and mentoring for trainees to conduct the research related to their training in the host developing country to the greatest extent possible. Applicants should include plans that demonstrate the increasing transfer of appropriate training options and responsibilities to the developing country institution during the course of the five-year award.

Additional support for research training to support specific NIH initiatives (HIV Vaccine Trials Network (HVTN), HIV Prevention Trials Network (HPTN), NIMH Popular Opinion Leader (POL) network, and Comprehensive International Program of Research on AIDS (CIPRA)) will be made administratively, as needed, based upon the peer-reviewed grants for these initiatives.

MECHANISM OF SUPPORT

This PA will use the NIH (D43) international research training award mechanism. As an applicant, you will be solely responsible for planning, directing, and executing the proposed project. An applicant for an AITRP award may request a project period of up to five years and a budget for total costs (including eight percent facilities and administrative (F & A) costs) according to the following guidelines:

- o For re-competing programs entering their sixteenth year of funding- \$1

million for base amount each year and up to \$100,000 for each competing supplement for a maximum request of \$1.3 million total costs for any year;

- o For re-competing programs entering their eleventh year of funding- \$750,000 for base amount each year and up to \$100,000 for each competing supplement for a maximum request of \$1 million total costs for any year;
- o For re-competing programs entering their sixth year of funding- \$500,000 for base amount each year and up to \$100,000 for each competing supplement for a maximum request of \$650,000 total costs for any year;
- o For new programs, \$300,000 for base amount each year only.
- o For competing supplements to existing AITRP grants for advanced in-country research support - up to three years of \$35,000 maximum total cost annual funding per supplemental application;
- o For competing supplements to existing AITRP grants for degree-required and mentored trainee research projects support - up to two years of \$25,000 maximum total cost annual funding per supplemental application;
- o For competing supplements to existing AITRP grants for expansion of research training support to new collaborating institutions - up to \$100,000 for a competing supplement application in each country for a maximum request of \$200,000 total costs.

ELIGIBLE INSTITUTIONS

Eligible institutions are U.S. (or pre-approved non-U.S. developed country) nonprofit, public or private institutions with HIV/AIDS and HIV-related research collaborations with institutions in the developing countries listed below. A non-U.S. developed country applicant must provide documentation that their government or institution is willing to support at least 50 percent of the requested budget per year for the full award period. FIC will provide up to 50 percent of the total costs for a non-U.S. developed country applicant.

Developing countries include the low- and middle-income countries in the following regions: Africa, Asia (except Japan, Singapore, South Korea and Taiwan), Central and Eastern Europe (Hungary, Poland, the Czech and Slovak Republics, Romania, Bulgaria, Albania, Turkey and the countries of the former Yugoslavia), Russia and the Newly Independent States of the former Soviet Union, Latin America and the Caribbean, the Middle East (except Israel), and the Pacific Ocean Islands (except Australia and New Zealand).

Only one application for a base award may be submitted from an institution. Only one base award will be made to an institution at any given time. More than one competing supplement application may be submitted by an institution applying for a re-competing base award or with an existing AITRP grant, as long as the budgets do not exceed the funding limits for total costs described above.

INDIVIDUALS ELIGIBLE TO BECOME PRINCIPAL INVESTIGATORS

Any individual from an eligible institution with the skills, knowledge, and resources necessary to carry out the proposed international HIV/AIDS and HIV-related research training is invited to work with their institution to develop an application for support. U.S. (or pre-approved non-U.S.)

applicants must apply with developing country institution(s) with whom they have a demonstrable history of HIV/AIDS and HIV-related research collaboration.

Applicants must have a strong HIV/AIDS and HIV-related research and research-training program and the requisite faculty and facilities to carry out the proposed training activities. The principal investigator and/or faculty at the applicant institution listed as key personnel must be designated as the principal investigator of at least one active (with at least 18 months of support remaining at the time of application) HIV/AIDS or HIV-related research award, directly relevant to the research-training proposed, funded by the NIH or other national or international organization. Priority will be given to applicants associated with NIH direct research grants to the proposed collaborating developing country institution(s) or with research grants with foreign components at the collaborating developing country institution(s). Applicants should explain in detail how their relevant research grant support and activities are related to the proposed training plan. Applicants need to document this existing research support in their application.

Women and individuals from underrepresented racial and ethnic groups, as well as individuals with disabilities, are always encouraged to apply for NIH programs.

SPECIAL REQUIREMENTS

1. Applications submitted in response to this announcement should describe the specific linkages that they can leverage to strengthen the capacity of the foreign institutions to collaborate with the National Institutes of Health (NIH), other United States Government (USG) agencies, and other international efforts by governments, international agencies, non-governmental organizations, foundations, faith-based organizations and other groups in their efforts to respond to this global health crisis. Letters of support and collaboration from awardees funded by these organizations are encouraged.
2. Letters of support from foreign collaborators, foreign institutions, and developing country(ies) officials are required. Letters of support from foreign institutions and governments should indicate support of trainees in the form of a position, time dedicated to research, laboratory space, financial support, etc. when they return. Letters from groups with whom the applicant expects to collaborate are encouraged.
3. Re-competing AITRP applicants should include a description of the activities of previous and current AITRP awards and include:
 - o a description of the relevance of the research and public health training to the country's(ies') needs and priorities;
 - o a description of how the AITRP grant has increased the research and public health capacity of the developing country institution(s);
 - o a description of how the applicant has been able to leverage other NIH or non-NIH programs opportunities in the country(ies);
 - o the number of trainees by type of training for each collaborating country;

- o a list of publications in peer-reviewed journals in which a former or current trainee is listed as first author and which was supported through the AITRP grant as evidenced by acknowledgement of FIC in the publication;
- o a description of how the program addressed the recruitment and support for women and socially disadvantaged groups within the population of the country(ies);
- o the percentage of long-term trainees (one year or more) who returned to the country following the completion of their training;
- o a description of the strategies used by the program to maximize the number of trainees who return to their country of origin upon completing their training.

4. Trainee research projects encompass research included as part of a degree-directed training program, research undertaken as part of a mentored training experience or research supported as advanced in-country research for a completing trainee. Trainee research projects may be part of existing faculty research grants from NIH or other research support agencies. Degree-required and mentored trainee research projects that have not been part of scientifically peer reviewed faculty research grants must be reviewed by the proposed training advisory group (see below), and may be required to be peer-reviewed as a competing supplement to an AITRP award. All advanced in-country research must be peer reviewed as a competing supplement to an existing AITRP grant, or separately as an application to the FIC Global Health Research Initiative Program for New Foreign Investigators (GRIP) Program or to the Fogarty International Research Collaboration Award for HIV/AIDS (AIDS FIRCA) program (<http://www.nih.gov/fic/programs/aidsfirc.html>). All training-related research must meet all USG regulations for animal welfare and protection of human subjects and receive approval from the Institutional Review Board or Ethics Committee at the US institution to which the AITRP award is made and the collaborating country institution.

WHERE TO SEND INQUIRIES

We encourage your inquiries concerning this PA and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues.

- o Direct your questions about scientific/research training issues to:

Jeanne McDermott
Division of International Training and Research
Fogarty International Center
National Institutes of Health
Building 31 Room B2C39
Bethesda, MD 20892
Telephone: (301) 496-1492
FAX: (301) 402-0779
Email: mcdermoj@mail.nih.gov

- o Direct your questions about peer review issues to:

Elliot Postow
Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 4160
Bethesda, MD 20892
Telephone: 301 435-0911
FAX: 301-490-2327
Email: postowe@csr.nih.gov

o Direct your questions about financial or grants management matters to:

Bruce Butrum
Grants Management Officer
Fogarty International Center
National Institutes of Health
Building 31, Room B2C29
Bethesda, MD 20892
Telephone: (301) 451-6830
FAX: (301) 594-1211
Email: butrumb@mail.nih.gov

LETTER OF INTENT

Prospective applicants are asked to submit a letter of intent that includes the following information:

- o Descriptive title of the proposed research or research training
- o Name, address, and telephone number of the Principal Investigator
- o Names of other key personnel
- o Participating institutions
- o Number and title of this PA

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

The letter of intent is to be sent by the date listed at the beginning of this document. The letter of intent should be sent to:

Jeanne McDermott CNM MPH Ph.D.
Division of International Training and Research
Fogarty International Center
National Institutes of Health
Building 31 Room B2C39
Bethesda, MD 20892
Telephone: (301) 496-1492
FAX: (301) 402-0779
Email: mcdermoj@mail.nih.gov

SUBMITTING AN APPLICATION

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/2001). The PHS 398 is available at <http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov. Use the Institutional NRSA budget page of the PHS 398 research grant application instructions and forms for the budgets for research training applications. Each competing supplement should be submitted as a separate application.

SUPPLEMENTAL INSTRUCTIONS FOR RESEARCH TRAINING APPLICATIONS

The research training application (25-page limit) should include:

1. A needs assessment that details the specific scientific and research support (e.g. the use of scientific literature, scientific presentations, grant writing, bioinformatics, bioethics, good clinical practice, biosafety, data management, research administration and the management of intellectual property) needs at each of the developing country institutions included in the application;
2. A description of the training plan proposed to address the needs assessment. The training plan should include:
 - o the goals, objectives and plan for meeting the objectives for the training program;
 - o a description of how the proposed program will address the research needs and health priorities defined by the country;
 - o a description of the types and mix of training proposed. Applicants may propose a variety of research training options (long-, medium-, and short-term, degree related or non-degree, and short courses/workshops). Long-term research training includes studies leading to an advanced degree or a mentored post-advanced degree experience related to HIV/AIDS and HIV-related research. Medium- and short-term training of up to several months may include specific research methods or other laboratory, clinical, or field skills related to HIV/AIDS and HIV-related research. Courses for English as a second language, if necessary, are permitted. Training may occur in either the U.S. or developing country institution. However, applicants are strongly encouraged to provide support and mentoring for trainees to conduct the research related to their training in the host developing country to the greatest extent possible. Applicants should include plans that demonstrate the increasing transfer of appropriate training options and responsibilities to the developing country institution during the course of the five-year award;
 - o a description of the program for Training in Responsible Conduct of Research - Applicants are required to provide all medium- and long-term trainees with training in the responsible conduct of research. For more information on this provision, see the NIH Guide for Grant and Contracts (volume 21, number 43 - <http://grants.nih.gov/grants/guide/notice-files/not92-236.html>);
 - o a plan for recruitment, selection and evaluation of trainees, and a plan for post-training integration into the collaborating developing country institution's HIV/AIDS and HIV-related research. Training may be offered to a wide range of developing country scientists, technical staff,

administrators, clinicians and health professionals, public health professionals and social scientists to build a critical mass of researchers and support staff with the combined expertise and skills to conduct independent HIV/AIDS and HIV-related research. Applicants are strongly encouraged to consider women and members of minority or socially disadvantaged populations in the collaborating developing country in the selection of trainees;

o a description of the background of the research and training collaborations of the institutions, the principal investigators and of the faculty proposed to be the research-training partners, a description of the organizational structure at each institution that will be available for the proposed training program, and a description of the current and future research that will serve as the research base for the proposed training program at each proposed foreign institution;

3. A description of a Training Advisory Group which is composed of expert U.S. and developing country faculty who are not directly involved in mentoring trainees and which should be established to assist in trainee selection, scientific review of trainee projects, and evaluation of trainee and training program progress. Applicants should describe the composition and expertise of the proposed training advisory group, the responsibilities of the group and the processes for it to accomplish its responsibilities, including a detailed description of the procedures for scientific review of training-related research.

Re-competing research training applications should also include a description of the past experience of the grantee in AITRP (ten-page limit). See SPECIAL REQUIREMENTS 3.

Budget Preparation for Research Training Applications

Use the Institutional NRSA budget page of the PHS 398 research grant application instructions and forms for the budgets for research training applications. Applicants should develop a budget that reflects the resources necessary to implement the components of the comprehensive developing country training plan included in their application. The budget should include costs to support the proposed research-training plan.

All expenses related to trainee participation in the program should be itemized on the PHS Form 398 (NRSA substitute budget pages 4 & 5) in the appropriate categories. All expenses related to faculty participation in the program should be itemized on the PHS Form 398 (budget form pages 4 and 5) in the appropriate categories. The total direct costs of the trainee participation budget should be identified on PHS Form 398 (budget form pages 4 and 5) in the "Other" category. The combining of the budgets will allow reviewers and FIC staff to review a composite budget of all costs.

Requested Salary Support

The salary for the Principal Investigator and other training faculty and administrative staff must be commensurate with the salary structure and benefits at the applicant institution.

Trainees' Stipends

Trainees may be paid a stipend comparable to their professional experience in accordance with NRSA levels or grantee institutional policies while involved in long-term training at the grantee institution. Current NRSA stipend levels are described on the web site <http://grants.nih.gov/training/nrsa.htm>.

Tuition, Fees and Insurance for Trainees

Funds for tuition, academic fees and self-only or family medical insurance may be requested. Programs are encouraged to seek cost-sharing arrangements with the grantee institutions in order to provide reduced tuition for long-term trainees and tuition-free short courses.

Network Meetings

Funds to support the attendance of the Principal Investigator and two to three other people (foreign collaborators, faculty, administrators or trainees) to attend an annual network meeting.

In-Country Activities

Before any funds can be expended for in-country trainee research project activities under this award, the grantee institution must document a collaborative research arrangement between the U.S. and foreign country institutions. This can be documented through an endorsement from the Minister of Health or other appropriate foreign government official as well as from the collaborating institutions.

SUPPLEMENTAL INSTRUCTIONS FOR COMPETING SUPPLEMENTS FOR TRAINEE RESEARCH PROJECTS SUPPORT

The total direct costs must be requested in accordance with the program guidelines and the modifications made to the standard PHS 398 application instructions described below.

The research plan included in the supplement application should answer these questions:

- 1) What does the current or former trainee intend to do?
- 2) Why is the work important?
- 3) What has already been done?
- 4) How is the current or former trainee going to do the work?
- 5) What form of mentoring will be available to help guide the proposed work?

It should provide the information needed to evaluate the application, using the Review Criteria for Competing Supplement Applications for Trainee Research Projects Support.

In addition, applications for advanced in-country research project support should include:

- o date that the current or former trainee has returned or expects to return to their home country;
- o a letter from the U.S. host institution, outlining the nature of the future collaborative relationship, and how the program supported, and/or will support, a continued collaboration with the investigator, using all appropriate resources;
- o a letter of support from the developing country institution to which the

trainee is returning or has returned;

- o a description of the training the current or former trainee investigator received under the AITRP program, including dates of training; and
- o two letters of reference relating to the abilities of the current or former trainee investigator, specifically indicating the ability to become a leader in scientific pursuits.

Under Personnel, list all project personnel, including their names, percent of effort, and roles on the project. For advanced in-country research projects, the current or former trainee is expected to devote at least 50 percent of his/her total effort to this project and may only request support of up to 50 percent of his/her effort on this project. Salary requests of collaborating developing country personnel should be commensurate with the salary structure at the collaborating developing country institution. For degree-required and mentored trainee research projects, 100 percent of the stipend for a trainee may be requested.

Checklist: This page should be completed and submitted with the application. Applications can request facilities and administrative (F&A) costs up to a maximum of eight percent. Please see the web site <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-028.html> for more information on the allowability of F&A costs for foreign and international organizations.

SENDING AN APPLICATION TO THE NIH: Submit a signed, typewritten original of the application, including the checklist, and five signed photocopies in one package to:

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710
Bethesda, MD 20817 (for express/courier service)

APPLICATION PROCESSING: Applications must be received by the application receipt date listed in the heading of this PA. If an application is received after that date, it will be returned to the applicant without review. The Center for Scientific Review (CSR) will not accept any application in response to this PA that is essentially the same as one currently pending initial review unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of a substantial revision of an application already reviewed, but such application must include an introduction addressing the previous reviewers' comments.

PEER REVIEW PROCESS

Upon receipt, applications will be reviewed for completeness by the CSR, and responsiveness by the FIC and the co-sponsoring NIH Institutes, Centers and Offices. Incomplete and/or non-responsive applications will be returned to the applicant.

Applications will be evaluated for scientific and technical merit by an appropriate scientific review group convened by the CSR, in accordance with the standard NIH peer review procedures (<http://www.csr.nih.gov/refrev.htm>) with the review criteria stated below. As part of the initial merit review, all applications will receive a written critique, and will be discussed, assigned a priority score, and receive a second level review by the FIC Advisory Board, and possibly by the Advisory Boards or Councils of the co-sponsoring NIH Institutes, Centers and Offices.

REVIEW CRITERIA

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In the written comments, reviewers will be asked to discuss the following aspects of your application in order to judge the likelihood that the proposed training or research will have a substantial impact on the pursuit of these goals:

- o Significance
- o Approach
- o Innovation
- o Investigator
- o Environment

The scientific review group will address and consider each of these criteria in assigning your application's overall score, weighting them as appropriate for each application. Your application does not need to be strong in all categories to be judged likely to have major scientific training impact and thus deserve a meritorious priority score. For example, you may propose to carry out important research training that, by its nature, is not innovative but is essential to move a field forward.

Review Criteria for Applications for Research Training

Significance

- o The expected contribution of the research-training program described in the application to fill the identified gaps in HIV/AIDS and HIV-related research expertise at the developing country institution(s).
- o The expected ability of the proposed training plan to strengthen multidisciplinary approaches (biomedical, behavioral, social, and cultural) to research and public health in the country(ies).
- o The expected potential of the developing country institution(s) to achieve independent and sustainable laboratory, clinical or public health HIV/AIDS and HIV-related research capacity through the proposed training efforts.

Approach

- o The adequacy of the research training plan to achieve the proposed training objectives including:
 - a) The adequacy of the proposed mix of long-, medium- and short-term training to achieve the goals of this PA;
 - b) The ability of the trainee recruiting and selection process to capture the most qualified individuals and to include an adequate representation of

men, women and ethnic minorities or socially disadvantaged population groups among the developing country trainees;

c) The adequacy of the process for matching trainees to appropriate mentors that will promote acquisition of research skills and development of research projects to fill recognized gaps in expertise at the developing country institution(s);

d) The adequacy of the plan to provide adequate training in sustainable research enhancing areas such as laboratory safety, responsible conduct of research, technical and grant writing, statistical methods, good clinical practice, medical informatics, English as a second language (if necessary), etc;

e) The expected ability of the plan to maximize the return and integration of trainees into HIV/AIDS and HIV-related research at the developing country institution(s) to build sustainable research capacity;

f) The adequacy of the method to monitor the long-term impact of the HIV/AIDS and HIV-related research training experience on the subsequent careers of the trainees, the HIV/AIDS and HIV-related research capacity at the developing country institution(s), and public health in the developing country(ies); and

g) The capability of the system for the scientific peer review of training-related research by the Training Advisory Group.

Innovation

o The ability of the proposed training program to take advantage of the foreign institution's research infrastructure and of previous and current investments and support from FIC, NIH or other organizations.

o The identification of innovative strategies for trainees to become actively involved in multidisciplinary HIV/AIDS and HIV-related research studies or intervention trials relevant to national health priorities conducted at the developing country institution(s).

o The innovation in training strategies to produce a critical mass of independent HIV-AIDS and HIV-related researchers and sustainable research training by trainees at the developing country institution(s) at the end of the program.

Investigators

o The qualifications of the Principal Investigator and foreign collaborator(s) to lead the identified faculty to participate as mentors in the proposed research training program.

o The adequacy of the ongoing collaboration between the investigators and the institutions named in the applicant to provide a suitable framework in which the proposed training will occur.

o The adequacy of research support for the investigators named in the application.

o The extent and effectiveness of previous research training efforts made by the applicant in the proposed developing countries.

o For re-competing applications, the success of the applicant in strengthening the research capacity of the developing country institutions, as requested in number 3 under SPECIAL REQUIREMENTS.

Environment

o The adequacy of the HIV/AIDS and HIV-related teaching and research

facilities and other resources related to the overall training environment at the applicant and developing country institutions.

- o The strength of the U.S. and developing country institutional commitments to the proposed HIV/AIDS and HIV-related research training program, including research support at each developing country institution included in the application. See letters of support as requested in number 2 under SPECIAL REQUIREMENTS.

Review Criteria for Competing Supplement Applications for Trainee Research Projects

Significance

- o The importance and priority of the problem that the study will address in the home country.
- o The ability of the results of the study to advance scientific knowledge and to enhance the research career of the trainee.
- o The expected effect of these studies on the concepts or methods that drive this field.

Approach

- o The development, integration and appropriateness of the conceptual framework, design, methods, and analyses.
- o The identification of potential problem areas and alternatives to address these problems.

Innovation

- o The application of novel concepts, approaches or methods.
- o The originality and innovation of the aims.
- o The expected ability of the project to develop new methodologies or technologies or establish a new paradigm.

Investigator

- o The appropriateness of the training of the investigator to carryout the project successfully.
- o The appropriateness of the project to the experience level of the trainee investigator and other researchers (if any).
- o The contribution of the project to the trainee investigator's career development.
- o The strength of commitment for the trainee investigator demonstrated in the letters of support.

Environment

- o The ability of the in-country scientific environment to contribute to the probability of success.
- o The ability of the proposed project to take advantage of unique features of the scientific environment or employ useful collaborative arrangements.

In addition, for advanced in-country research projects, there must be:

- o Evidence of institutional support and a convincing commitment by the home institution to support the investigator (e.g. to provide a research/academic appointment and partial salary support), and
- o Evidence of continuing commitment of the U.S. collaborating institution to

further develop the career and research interests of the trainee investigator

ADDITIONAL REVIEW CRITERIA: In addition to the above criteria, your application will also be reviewed with respect to the following:

PROTECTIONS: The adequacy of the proposed protections for humans, animals, or the environment, to the extent they may be adversely affected by the project proposed in the application.

INCLUSION: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated. (See Inclusion Criteria included in the section on Federal Citations, below.)

DATA SHARING: The adequacy of the proposed plan to share data.

BUDGET: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research.

AWARD CRITERIA

Applications submitted in response to a PA will compete for available funds with all other recommended applications. The following will be considered in making funding decisions:

- o Scientific merit of the proposed project as determined by peer review;
- o Availability of funds;
- o Relevance to program priorities of FIC and co-sponsoring organizations;
- o Contribution to other FIC- and NIH-funded activities; and
- o For competing research training supplements, the extent to which applicants devote a portion of their base budgets to activities requested in the competing supplement application

REQUIRED FEDERAL CITATIONS

MONITORING PLAN AND DATA SAFETY AND MONITORING BOARD: Research components involving Phase I and II clinical trials must include provisions for assessment of patient eligibility and status, rigorous data management, quality assurance, and auditing procedures. In addition, it is NIH policy that all clinical trials require data and safety monitoring, with the method and degree of monitoring being commensurate with the risks (NIH Policy for Data Safety and Monitoring, NIH Guide for Grants and Contracts, June 12, 1998: <http://grants.nih.gov/grants/guide/notice-files/not98-084.html>).

INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH: It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing clinical research should read the AMENDMENT "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>); a complete copy of the updated Guidelines are available at

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups, if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS: The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects that is available at <http://grants.nih.gov/grants/funding/children/children.htm>.

REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS: NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for research involving human subjects. You will find this policy announcement in the NIH Guide for Grants and Contracts Announcement, dated June 5, 2000, at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

HUMAN EMBRYONIC STEM CELLS (hESC): Criteria for federal funding of research on hESCs can be found at http://grants.nih.gov/grants/stem_cells.htm and at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html>. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (see <http://escr.nih.gov>). It is the responsibility of the applicant to provide the official NIH identifier(s) for the hESC line(s) to be used in the proposed research. Applications that do not provide this information will be returned without review.

PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT: The Office of Management and Budget (OMB) Circular A-110 has been revised to

provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm.

Applicants may wish to place data collected under this PA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

URLS IN NIH GRANT APPLICATIONS OR APPENDICES: All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

HEALTHY PEOPLE 2010: The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This PA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at <http://www.health.gov/healthypeople>

AUTHORITY AND REGULATIONS: This program is described in the Catalog of Federal Domestic Assistance No. 93.989, and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under authorization of the Public Health Service Act, as amended (42 USC 241 and 287b) and administered under Public Health Service (PHS) grants policies described at <http://grants.nih.gov/grants/policy/policy.htm> and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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