

FOGARTY INTERNATIONAL RESEARCH COLLABORATION AWARD FOR HIV-AIDS (AIDS FIRCA)

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Fogarty International Center (FIC)

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

National Institute of Child Health and Human Development (NICHD)

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

National Institute of Dental and Craniofacial Research (NIDCR)

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

National Institute on Mental Health (NIMH)

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

Application Receipt Dates: January 2, May 1, September 1

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PURPOSE OF THIS PA

The Fogarty International Research Collaboration Award for HIV-AIDS (AIDS FIRCA) facilitates collaborative research between U.S. scientists supported by the National Institutes of Health (NIH) and foreign scientists through small individual research grants.

The AIDS FIRCA will extend and enhance the research interests of both the U.S. scientist and the collaborating foreign scientist, and will help to increase the research capacity of the foreign scientist and institution. Awards are made to the U.S. applicant institution to support a collaborative research project that will be carried out mainly at the foreign collaborator's research site. Support is available for research related to human immunodeficiency virus (HIV), acquired immunodeficiency syndrome (AIDS), and for research among HIV-infected persons of conditions that disproportionately affect such individuals.

Total direct costs of \$32,000 per year is available for up to three years to help cover purchase of supplies, small equipment for developing countries, technical assistance at the foreign collaborator's laboratory or research site, a small salary or consultant fee for the foreign investigator, and travel for the U.S. and foreign collaborators and their research associates, as justified by the needs of the collaborative research. For the purpose of this program, developing countries eligible to use AIDS FIRCA funds for equipment are considered to include those 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 independent countries of the former Soviet Union, Latin America, the Middle

East, and the Pacific Ocean Islands (except Australia and New Zealand).

All areas of research related to HIV infection and AIDS are eligible for consideration. Eligible topics are those contained in the NIH plan for HIV-related research which is available at the Office of AIDS Research (OAR) website <http://www.nih.gov/od/oar/index.htm>. Investigators working on topics not related to HIV, AIDS or related illnesses among HIV-infected persons should apply for a Fogarty International Research Collaboration Award (FIRCA). See the FIRCA announcement in the NIH Guide (<http://grants.nih.gov/grants/guide/pa-files/PA-02-057.html>) and at the FIC website (<http://www.nih.gov/fic/programs/firca.html>)

RESEARCH OBJECTIVES

An important role of the FIC is to foster discovery and reduce global health disparities through the support of international cooperation across the continuum of basic, clinical and applied biomedical, behavioral and health sciences. The opportunity to collaborate internationally provides a means of access to new information and perspectives, innovative concepts and methods, emerging research technologies, and unique populations and environments important for addressing global health problems.

The main objectives of the AIDS FIRCA program are: 1) to support collaborative HIV/AIDS-related efforts between U.S. and foreign scientists on research of high scientific merit and mutual interest and benefit, and 2) to help build research capabilities at the foreign site, if the site is in a developing country, and foster further sustained and productive research and research collaborations at the foreign site.

MECHANISM OF SUPPORT

The AIDS FIRCA will use the NIH small research project grant (R03) mechanism. One module of \$32,000 direct costs per year for up to three years may be requested. As an applicant, you and your foreign collaborator will be solely responsible for planning, directing, and executing the proposed project.

This PA uses just-in-time concepts. The just-in-time concept allows applicants to submit certain information only when there is a possibility for an award. It also uses the modular budgeting format (see <http://grants.nih.gov/grants/funding/modular/modular.htm>). The modular grant concept establishes a specific module in which direct costs (in this case, \$32,000) may be requested. Only limited budgetary information is required under this approach. It is anticipated that these changes will reduce the administrative burden for the applicants, reviewers and NIH staff.

Continuation of the AIDS FIRCA project depends upon satisfactory research progress and availability of funds. The AIDS FIRCA grant will remain active if the "parent grant" (see Special Requirements for more detail about "parent grants") expires and is not renewed during the AIDS FIRCA project period.

ELIGIBLE INSTITUTIONS

Only domestic U.S. organizations are eligible to apply. You may submit (an) application(s) if your institution has any of the following characteristics:

- o For-profit and non-profit organizations
- o Public or private institutions, such as universities, colleges, hospitals (including Veteran's Administration hospitals), and laboratories
- o Units of State and local governments
- o Faith-based organizations

Note: Applicants should check

<http://www.nih.gov/fic/regional/CountryInstructions.html> for special

considerations relative to some potential collaborating countries.

INDIVIDUALS ELIGIBLE TO BECOME PRINCIPAL INVESTIGATORS

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research and who meets the other eligibility requirements below is invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups, women and individuals with disabilities are always encouraged to apply for NIH programs.

The U.S. scientist, who must have current NIH-funded research ("parent grant"), will apply as Principal Investigator, with a colleague from a laboratory or research site in an eligible country. Occasionally, scientific opportunities may arise that warrant a formal collaborative effort between the U.S. investigator and individuals from more than one country. Such applications may be considered only after consultation with and pre-approval by the FIC AIDS FIRCA Program Officer.

The foreign collaborator must hold a position at an eligible public or private non-profit institution that will allow him or her adequate time and provide appropriate facilities to conduct the proposed research.

SPECIAL REQUIREMENTS

- o The U.S. applicant must be Principal Investigator or project director on a NIH research project grant (referred to as the "parent grant") that will be active and funded at the start of the proposed AIDS FIRCA budget period. Eligible mechanisms are the R01, P01, or U01. Principal Investigators of subprojects of a program project (P01) or Cooperative Agreement (U01 and U19) are eligible. Other R, P and U mechanisms, and significant subprojects within these mechanisms, will be considered on a case by case basis after consultation with and pre-approval by the FIC AIDS FIRCA Program Officer. Under exceptional circumstances some research contracts (N01 series) may be eligible "parent" funding for the AIDS-FIRCA. Among the mechanisms not accepted as "parent grants" are training grants and other research contracts, Center Core Grants (P30), Small Business Innovative Research Awards (R43), STTR (R44) and Shannon Awards (R55). AIDS FIRCA applications linked to international HIV-AIDS research initiatives of other NIH Institutes and Centers and which meet the basic criteria of the program are particularly encouraged. Examples include applications linked to research awards that meet the "parent grant" eligibility requirement under programs related to AIDS from the National Institute of Allergy and Infectious Diseases, (in particular U and P mechanisms of the Comprehensive International Program of Research on AIDS, the HIV Vaccine Trials Network, the HIV Prevention Trials Network); National Institute of Child Health and Human Development; National Institute of Mental Health; National Cancer Institute; National Institute on Drug Abuse; National Institute on Alcohol Abuse and Alcoholism; and the National Institute on Dental and Craniofacial Research.

- o The "parent grant" must have a minimum of 12 months of funding, which may include a no-cost extension, remaining at the time of the application deadline to be eligible to apply for AIDS FIRCA funding.

- o The AIDS FIRCA research proposal may be an extension or a new direction of the "parent grant." However, the proposed research must not overlap with research already supported by the U.S. investigator's "parent grant" or by other sources. If the proposal is for work that is not an obvious extension of the "parent grant," the research must be clearly within the expertise and field of interest of both the U.S. and foreign collaborators, as indicated by the general area of science in the "parent grant" and other research support and published work. Such research should ideally make use of the comparative strengths of the U.S. and foreign investigators. Special consideration may

be given to proposed research which addresses significant global health problems, particularly those of high relevance to the foreign country or region, and to research that makes use of unique or special resources, circumstances or environment of the foreign site.

- o There is no limit to the number of distinct AIDS FIRCA grants an applicant may be awarded over time and applicants may already be AIDS FIRCA grantees at the time of application. However, only one AIDS FIRCA application may be submitted by the same U.S. investigator per review cycle.

- o Applicants may apply for only one competitive renewal for an additional three years of a given AIDS FIRCA award, providing the above-mentioned criteria are satisfied at the time of application for the renewal. Current grantees may want to consider whether their collaboration has developed to the point where they can submit an R01 research grant application.

- o The research under the AIDS FIRCA award is to occur mainly at the foreign site and the major portion of the funds and items purchased must be used at the foreign site to support this research.

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, administrative and financial/grants management issues.

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

Jeanne McDermott, C.N.M., M.P.H., Ph.D.
Division of International Training and Research
Fogarty International Center
Building 31, Room B2C39
31 Center Drive, MSC 2220
Bethesda, MD 20892-2220
Telephone: 301-496-1653
Fax: 301-402-0779
Email: mcdermoj@mail.nih.gov

Jennifer S. Read, M.D., M.S., M.P.H.
Pediatric, Adolescent and Maternal AIDS Branch
National Institute of Child Health and Human Development
National Institutes of Health
Executive Building, Room 4B11F
6100 Executive Boulevard, MSC 7510
Bethesda, MD 20892-7510
Telephone: 301-435-6872
Fax: 301-496-8678
Email: jr92o@nih.gov

Dr. Willo Pequegnat
Chief, Prevention & Translational Research Program
Division of Mental Disorders, Behavioral Research and AIDS
National Institute of Mental Health
6001 Executive Blvd., Room 6205, MSC 9619
Bethesda, MD 20892-9619
Telephone: 301-443-6100
Fax: 301-443-9719
Email: wpequegn@mail.nih.gov

Direct your questions about general administrative issues to:

Ms. Janice Solomon

Program Specialist
Fogarty International Center
Building 31, Room B2C39
31 Center Drive, MSC 2220
Bethesda, MD 20892-2220
Telephone: 301-496-1653
Fax: 301-402-0779
Email: solomonj@mail.nih.gov

Direct your questions about financial or grants management issues to:

Mr. Randolph Williams
Grants Management Specialist
Fogarty International Center
Building 31, Room B2C29
31 Center Drive, MSC 2220
Bethesda, MD 20892-2220
Telephone: 301-496-5710
Fax: 301-594-1211
Email: willrand@mail.nih.gov

SUBMITTING AN APPLICATION

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/2001) along with the supplemental instructions below. 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. Additional important information and clarifications may be found under the Frequently Asked Questions section of the FIC AIDS FIRCA website (<http://www.nih.gov/fic/programs/fircin2.html>).

SUPPLEMENTAL INSTRUCTIONS

Under the Description Section:

Please include the name of the foreign country and institution, the foreign collaborator and the "parent grant" number in your description. (e.g., "This research will be done primarily in Peru at Lima University in collaboration with Jorge Smith as an extension of NIH grant # R01AI98765.")

Performance Site Section:

Provide the full name, address at the foreign institution, phone, and Email of the foreign collaborator where the research will be performed. Also provide the full number of the NIH "parent grant" and the dates of the award (e.g., R01AI98765-01; 9/30/2000 - 9/29/2003).

Research Plan - special instructions:

Follow the instructions for the PHS 398 except as described below (and note that the research plan must not exceed ten pages for sections a-d):

Foreword:

Original AIDS FIRCA applications should have a one-page foreword in which you describe the nature of the proposed collaboration, and discuss any relevant previous collaborative arrangement(s). In cases where the Principal Investigator has previously served as a mentor to the foreign collaborator, address the independence of the foreign collaborator in regards to the proposed AIDS FIRCA research. In particular, address respective contributions to the preparation of the research proposal.

Specific Aims:

List the specific aims of the "parent grant" exactly as written in the "parent grant." If these are longer than one page, you may summarize them and indicate that you have done so. If the AIDS FIRCA is more closely

related to another funded (but not AIDS FIRCA-eligible) grant, please be sure to give the specific aims of that grant here also. Then, list the specific aims of the AIDS FIRCA proposal. Finally, discuss how the specific aims of the AIDS FIRCA relate to the aim(s) of the "parent grant," and other relevant grants, if applicable.

Research Design and Methods:

Follow the instructions described in PHS Form 398 instructions. However, at the end of this section, outline the proposed contributions of the U.S. Principal Investigator and the foreign collaborator to the study. Describe exactly where and when each aspect of the work will be carried out and by whom. This will allow reviewers to assess the contributions of each laboratory or research site and predict the likelihood for success.

Collaborator Assurance:

Attach a letter (on institutional letterhead) from the foreign collaborator confirming his/her role in the project. Also, provide a statement confirming the foreign collaborating organization's willingness to comply with all pertinent U.S. Federal regulations and policies. For example, the institution must be willing to support the collaboration with time and resources for the foreign collaborator, to provide necessary documentation to the U.S. institution for tracking expenditures and human subjects population tracking, and provide necessary documentation to the Office of Human Research Protection (OHRP) for human involvement and to the Office of Laboratory Animal Welfare (OLAW) for animal involvement, if necessary. The letter must be cosigned by the Head of a Department, Dean, or other academic official.

SPECIFIC INSTRUCTIONS FOR MODULAR GRANT APPLICATIONS: Section C, item 3, of the research grant application instructions for the PHS 398 (rev. 5/2001) at <http://grants.nih.gov/grants/funding/phs398/phs398.html> includes step-by-step guidance for preparing modular grants. Additional information on modular grants is available at <http://grants.nih.gov/grants/funding/modular/modular.htm>. Follow the modular grant directions, except that AIDS FIRCA applications must be submitted as one module of \$32,000 in direct costs. The modular grant format simplifies the preparation of the budget in these applications by limiting the level of budgetary detail.

Budgetary Restrictions:

Applications will be submitted using the modular grant process but AIDS FIRCA grants will have the following budget restrictions that must be considered in the development of the modular budget:

- 1) Travel funds for the Principal Investigator, foreign collaborator, or colleagues to visit the research sites must not exceed \$7,000 annually.
- 2) Travel funds for the foreign collaborator to attend scientific conferences must not exceed \$2,000 annually.
- 3) Consultant fees for the foreign collaborator(s) must not exceed a total of \$5,000 annually.
- 4) Salary for the Principal Investigator, or any other staff at the U.S. site, is not allowed.
- 5) Equipment costs may be included for research conducted in countries included 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 independent countries of the former Soviet Union, Latin America, the Middle East, and the Pacific Ocean Islands (except Australia and New Zealand).

Checklist:

Facilities and Administrative costs: Facilities and Administrative (F&A) Costs must be calculated on the basis of the off-site rate of the U.S. sponsoring institution.

For applications that have foreign subcontracts, F&A costs of up to eight percent can be requested by the foreign institutions. F&A costs for a foreign subcontract are considered direct costs on the applicant's application and should be included as part of the \$32,000 that can be requested. Please see

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-028.html>

for more information on the F&A costs allowed for foreign institutions and international organizations.

SENDING AN APPLICATION TO THE NIH: The application, along with all required supplemental information, must be submitted as a single package by the U.S. grantee's institution. 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)
Telephone: 301-435-0715

APPLICATION PROCESSING: Applications must be received by the receipt dates described on the first page of this PA. If the receipt date falls on a weekend or holiday, the deadline is automatically extended to the following Monday or business day. The Center for Scientific Review (CSR) will not accept applications that are submitted after the pertinent deadline. 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. This does not preclude the submission of a substantial revision of an application already reviewed, but such applications must include an Introduction addressing the previous critique.

PEER REVIEW PROCESS

Applications submitted for this PA will be assigned on the basis of established PHS referral guidelines. The research proposals will be reviewed for scientific and technical merit and quality of the collaboration. Applications will be reviewed for scientific and technical merit by study sections under the AIDS and Related Research Initial Review Group in the Center for Scientific Review (CSR), NIH, convened in accordance with the standard NIH peer review procedures (<http://www.csr.nih.gov/refrev.htm>).

As part of the initial merit review, all applications:

- o Will receive a written critique
- o May undergo a selection process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed and assigned a priority score
- o Will receive a second level review by the FIC Advisory Board or by another appropriate national advisory council or board from another IC that may be interested in funding an application.

REVIEW CRITERIA

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. The AIDS FIRCA program also addresses important factors associated with international collaborative research and research capacity building at the foreign research site if the site is a developing country. 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 research will have a substantial impact on the pursuit of these goals:

- o Significance
- o Approach
- o Innovation
- o Investigator
- o Environment
- o Research Capacity Building

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 impact on the scientific field and/or research capacity building of the foreign collaborator, their country or institution, and may thus deserve a meritorious priority score. For example, you may propose to carry out important work that, by its nature, is not innovative but is essential to move a field forward. In one example, an investigator may propose research on an important topic in a developing country with underdeveloped research infrastructure but with unique resources, environment or knowledge not readily available in the U.S. or other developed nations. Such projects may be slower to achieve their scientific goals but may receive special consideration for their potential to build research capacity along with significant scientific impact in the long-term. The criteria are as follows:

(1) SIGNIFICANCE: Does your study address an important problem related to the global HIV/AIDS epidemic or specifically to the HIV/AIDS epidemic in the foreign site, if it is a developing country? If the aims of your application are achieved, how do they advance scientific knowledge? What will be the effect of these studies on the concepts or methods that drive this field?

(2) APPROACH: Are the conceptual framework, design, methods, and analyses adequately developed, well integrated and appropriate to the aims of the project? Do you acknowledge potential problem areas and consider alternative tactics?

(3) INNOVATION: Does your project employ novel concepts, approaches or methods? Are the aims original and innovative? Does your project challenge existing paradigms or develop new methodologies or technologies?

(4) INVESTIGATOR: Are you and the foreign collaborator appropriately trained and well suited to carry out this work? Is the foreign collaborator able to undertake and direct the foreign research efforts? Is the work proposed appropriate to your experience level as the Principal Investigator and to that of the foreign collaborator and other researchers?

(5) ENVIRONMENT: Does the scientific environment in which your work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

In addition, when a developing country is involved as the foreign site, the following additional criterion will be considered:

(6) RESEARCH CAPACITY BUILDING: Does the collaboration have the potential to enhance the research capability of the foreign collaborator and the foreign site? Does the research constitute a substantial scientific endeavor for the foreign collaborator, including creative and scientific input to the research proposal? The foreign site and investigator should not be used merely to gather biological samples (clinical, plants, etc), or behavioral data (interviews, surveys, etc). In all cases, the foreign investigator should be actively involved in analyzing and interpreting the data. Is the research on a problem of particular relevance for the foreign country involved? Are the

resources necessary to perform the research available or obtainable?

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 protection 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 this 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 FIC program priorities; priority will be given to meritorious applications with collaborations in developing countries
- o Relevance to any other NIH Institute's or Center's international AIDS program
- o Participation/interest of other NIH Institute, Center or Office

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 a 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 a 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, the Fogarty International Research Collaboration Award for HIV-AIDS, 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 Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and administered under NIH 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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