

Government Country Program Office. The panel may include both Federal and non-Federal participants.

Applications will be funded in order by score and rank determined by the review panel. HHS/CDC will provide justification for any decision to fund out of rank order.

### *V.3. Anticipated Announcement and Award Dates*

September 23, 2005.

## **VI. Award Administration Information**

### *VI.1. Award Notices*

Successful applicants will receive a Notice of Award (NoA) from the HHS/CDC Procurement and Grants Office. The NoA shall be the only binding, authorizing document between the recipient and HHS/CDC. An authorized Grants Management Officer will sign the NoA, and mail it to the recipient fiscal officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review by mail.

### *VI.2. Administrative and National Policy Requirements*

45 CFR Part 74 and Part 92.

For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: <http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>.

The following additional requirements apply to this project:

- AR-4 HIV/AIDS Confidentiality Provisions
- AR-6 Patient Care
- AR-8 Public Health System Reporting Requirements
- AR-10 Smoke-Free Workplace Requirements
- AR-12 Lobbying Restrictions
- AR-14 Accounting System Requirements

Applicants can find additional information on the requirements on the HHS/CDC Web site at the following Internet address: <http://www.cdc.gov/od/pgo/funding/ARs.htm>.

You need to include an additional Certifications form from the PHS5161-1 application needs in your Grants.gov electronic submission only. Please refer to <http://www.cdc.gov/od/pgo/funding/PHS5161-1-Certificates.pdf>. Once you have filled out the form, please attach it to the Grants.gov submission as Other Attachments Form.

### *VI.3. Reporting Requirements*

You must provide HHS/CDC with an original, plus two hard copies, of the following reports:

1. Interim progress reports (annual): a brief, comprehensive narrative progress report should be submitted no less than 90 days after the end of the budget period. The progress report will serve as your non-competing continuation application, and must contain the following elements:

- a. Current Budget Period Activities Objectives.
- b. Current Budget Period Financial Progress.
- c. New Budget Period Program Proposed Activity Objectives.
- d. Detailed Line-Item Budget.
- e. Measures of Effectiveness,

including progress against the numerical goals of the President's Emergency Plan for AIDS Relief for Namibia.

f. Additional Requested Information.

2. Financial status report due no more than 90 days after the end of the budget period.

3. Final financial and performance reports, due no more than 90 days after the end of the project period.

4. Annual progress report, due no more than 60 days after the end of the budget period. Reports should include progress against the numerical goals of the President's Emergency Plan for AIDS Relief for Namibia.

Recipients must mail these reports to the Grants Management Specialist listed in the "Agency Contacts" section of this announcement.

## **VII. Agency Contacts**

We encourage inquiries concerning this announcement.

For general questions, contact: Technical Information Management Section, CDC Procurement and Grants Office, U.S. Department of Health and Human Services, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-2700.

For program technical assistance, contact: Leonard Floyd, Project Officer, U.S. Department of State, 2540 Windhoek Place, Washington, DC 20521-8320, Telephone: 011 264 61224 149, E-mail: [FloydL@nacop.net](mailto:FloydL@nacop.net).

For financial, grants management, or budget assistance, contact: Shirley Wynn, Grants Management Specialist, CDC Procurement and Grants Office, U.S. Department of Health and Human Services, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: (770) 488-1515, E-mail: [SWynn@cdc.gov](mailto:SWynn@cdc.gov).

## **VIII. Other Information**

Applicants can find this and other CDC funding opportunity announcements on the HHS/CDC Web site, Internet address: <http://www.cdc.gov> (Click on "Funding" then

"Grants and Cooperative Agreements"), and on the Web site of the HHS Office of Global Health Affairs, Internet address: <http://www.globalhealth.gov>.

Dated: August 5, 2005.

**William P. Nichols,**

*Director, Procurement and Grants Office, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Disease Control and Prevention**

### **Strengthen HIV/AIDS Prevention, Care, and Treatment Services for Infants of HIV Positive Mothers in the Republic of Haiti Through Provision of Improved Pediatric HIV/AIDS Laboratory Diagnosis**

*Announcement Type:* New.  
*Funding Opportunity Number:* RFA AA178.

*Catalog of Federal Domestic Assistance Number:* 93.067.

*Key Dates:*

*Application Deadline:* September 6, 2005.

### **I. Funding Opportunity Description**

**Authority:** This program is authorized under Sections 301(a) and 307 of the Public Health Service Act [42 U.S.C. Sections 241 and 242], as amended, and under Public Law 108-25 (United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003) [22 U.S.C. 7601].

**Background:** President Bush's Emergency Plan for AIDS Relief (The Emergency Plan) has called for immediate, comprehensive and evidence-based action to turn the tide of global HIV/AIDS. The initiative aims to prevent at least seven million new HIV infections by 2010; to treat more than two million people with effective combination anti-retroviral therapy by 2008; and to provide care for ten million HIV-infected and affected persons, including those orphaned by HIV/AIDS, by 2008, with a focus on 15 priority countries. The five-year strategy for the Emergency Plan is available at the following Internet address: <http://www.state.gov/s/gac/rl/or/c11652.htm>.

Under the leadership of the U.S. Global AIDS Coordinator, as part of the President's Emergency Plan, the U.S. Department of Health and Human Services (HHS) works with host countries and other key partners to assess the needs of each country and

design a customized program of assistance that fits within the host nation's strategic plan.

An essential element of preventing new cases of HIV is to ensure that high-risk groups have adequate access to screening, treatment, and care facilities. Haiti's HIV prevalence rate in adults is reported to be 5.6 percent, according to the Joint United Nations Programme on HIV/AIDS (UNAIDS) 2004 Annual Report. Access to prevention and treatment is limited to the Haitian population because of the underdeveloped public health infrastructure and lack of clinical capacity.

Haiti's Central Plateau region is a rural area northeast of the capital, Port-au-Prince. Years of neglect and ill-conceived engineering projects have left the region's population largely destitute and reliant on largely subsistence farming for survival. Access to this region is difficult due to the poor transportation infrastructure. These social, economic and physical barriers have prevented significant numbers of Haitian non-governmental organizations from emerging and offering services in the Central Plateau.

*Purpose:* The purpose of this funding announcement is to progressively build an indigenous, sustainable response to the national HIV epidemic through the rapid expansion of innovative, culturally appropriate, high-quality HIV/AIDS prevention and care interventions. In Haiti, Emergency Plan goals include treatment of at least 25,000 HIV-infected individuals and care for 125,000 HIV-infected and affected individuals, including orphans.

Measurable outcomes of the program will be in alignment with the numerical performance goals of the President's Emergency Plan and one (or more) of the following performance goal(s) for the National Center for HIV, sexually transmitted diseases and Tuberculosis Prevention of the Centers for Disease Control and Prevention (CDC) within the U.S. Department of Health and Human Services (HHS): Increase the proportion of HIV-infected people who are linked to appropriate prevention, care and treatment services; strengthen the capacity nationwide to monitor the epidemic; develop and implement effective HIV prevention interventions; and evaluate prevention programs.

This announcement is only for non-research activities supported by HHS. If an applicant proposes research, we will not review the application. For the definition of research, please see the HHS/CDC web site at the following Internet address: <http://www.cdc.gov/od/ads/opsoll1.htm>

*Activities:* The awardee will either implement activities directly or will implement them through its subgrantees and/or subcontractors; the awardee will retain overall financial and programmatic management under the oversight of HHS/CDC and the strategic direction of the Office of the Global AIDS Coordinator. The awardee must show a measurable progressive reinforcement of the capacity of indigenous organizations and local communities to respond to the national HIV epidemic, as well as progress towards the sustainability of activities.

Applicants should describe activities in detail as part of a four-year action plan (U.S. Government Fiscal Years 2005–2008 inclusive) that reflects the policies and goals outlined in the five-year strategy for the President's Emergency Plan.

HHS/CDC, under the guidance of the U.S. Global AIDS Coordinator, will approve funds on an annual basis, based on documented performance toward achieving Emergency Plan goals, as part of the annual Emergency Plan for AIDS Relief Country Operational Plan review and approval process.

This program announcement seeks proposals from Haitian organizations to strengthen and expand pediatric testing and diagnosis for infants of HIV-positive mothers. The funding through this cooperative agreement will establish and provide ongoing and effective pediatric HIV/AIDS testing and diagnosis and strengthen laboratory support services and personnel integral in reducing the incidence of pediatric HIV/AIDS in Haiti. Program proposals should include program strategies that address the following activities:

1. Provide pediatric testing and diagnosis to infants.
2. Strengthen laboratory services to support pediatric diagnosis and treatment, and build capacity in lab personnel internally and within the HIV/AIDS service-delivery network.
3. Record and report sample collection results regularly.
4. Reduce the incidence of pediatric HIV/AIDS through partnering with prevention of mother-to-child transmission (PMTCT) linkages to ensure access to pediatric HIV/AIDS information and care.
5. Expand services and transfer pediatric diagnostic testing technology to other sites.
6. Administer anti-retroviral (ARV) treatment in adherence with Department of Health and Human Services (HHS) guidelines.
7. Provide basic laboratory services in support of pediatric HIV/AIDS diagnosis and treatment.

1. Perform CD4 counts.
2. Perform complete blood counts.
3. Perform HIV rapid testing.
4. Perform confirmatory HIV/AIDS testing.
8. Provide post-test counseling, care, and other social services, as needed by the newborn.
9. Provide appropriate referrals to ensure that HIV-infected pregnant women receive care for their own health, and to prevent HIV transmission to their babies.
10. Provide referrals to appropriate prevention,<sup>1</sup> treatment, care and support services.
11. Implement monitoring and evaluation strategies, assessing:
  1. Number of infants tested.
  2. Number of infants receiving treatment and follow-up.
  3. Number of technical assists provided to other lab sites.
12. Work to link activities described here with related HIV care and other social services in the area, and promote coordination at all levels, including through bodies such as village, district, regional and national HIV coordination committees and networks of faith-based organizations.
13. Participate in relevant national technical coordination committees and in national process(es) to define, implement and monitor simplified small grants program(s) for faith- and community-based organizations, to ensure local stakeholders receive adequate information and assistance to engage and access effectively funding opportunities supported by the President's Emergency Plan and other donors.
14. Progressively reinforce the capacity of faith- and community-based organizations and village and district AIDS committees to promote quality, local ownership, accountability and sustainability of activities.

<sup>1</sup> Prevention interventions directed toward behavior change should promote the ABC model. Methods and strategies should emphasize abstinence for youth and other unmarried persons, mutual faithfulness and partner reduction for sexually active adults, and correct and consistent use of condoms by those populations who are engaged in high-risk behaviors. Behaviors that increase risk for HIV transmission include: engaging in casual sexual encounters, engaging in sex in exchange for money or favors, having sex with an HIV-positive partner or one whose status is unknown, using drugs or abusing alcohol in the context of sexual interactions, and using intravenous drugs. Women, even if faithful themselves, can still be at risk of becoming infected by their spouse, regular male partner, or someone using force against them. Other high-risk persons or groups include men who have sex with men and workers who are employed away from home. Awardees may not implement condom social marketing without also implementing the abstinence and faithfulness behavior-change interventions outlined above.

15. Develop and implement a project-specific participatory monitoring and evaluation plan by drawing on national and U.S. Government requirements and tools, including the strategic information guidance provided by the Office of the U.S. Global AIDS Coordinator.

*Administration:* Comply with all HHS management requirements for meeting participation and progress and financial reporting for this cooperative agreement. (See HHS Activities and Reporting sections below for details.) Comply with all policy directives established by the Office of the U.S. Global AIDS Coordinator.

In a cooperative agreement, HHS staff is substantially involved in the program activities, above and beyond routine grant monitoring.

HHS Activities for this program are as follows:

1. Organize an orientation meeting with the awardee to brief them on applicable U.S. Government, HHS, and Emergency Plan expectations, regulations and key management requirements, as well as report formats and contents. The orientation could include meetings with staff from HHS agencies and the Office of the U.S. Global AIDS Coordinator.

2. Review and approve the process used by the awardee to select key personnel and/or post-award subcontractors and/or subgrantees to be involved in the activities performed under this agreement, as part of the Emergency Plan for AIDS Relief Country Operational Plan review and approval process, managed by the Office of the U.S. Global AIDS Coordinator.

3. Review and approve awardee's annual work plan and detailed budget, as part of the Emergency Plan for AIDS Relief Country Operational Plan review and approval process, managed by the Office of the U.S. Global AIDS Coordinator.

4. Review and approve awardee's monitoring and evaluation plan, including for compliance with the strategic information guidance established by the Office of the U.S. Global AIDS Coordinator.

5. Meet on a monthly basis with awardee to assess monthly expenditures in relation to approved work plan and modify plans as necessary.

6. Meet on a quarterly basis with awardee to assess quarterly technical and financial progress reports and modify plans as necessary.

7. Meet on an annual basis with awardee to review annual progress report for each U.S. Government Fiscal Year, and to review annual work plans and budgets for subsequent year, as part

of the Emergency Plan for AIDS Relief review and approval process for Country Operational Plans, managed by the Office of the U.S. Global AIDS Coordinator.

8. Support an electronic medical record (EMR) database system; provide and support a surveillance database system.

9. Provide and install of hardware necessary for the use of database systems.

10. Assist in organizing regional meetings.

11. Provide technical laboratory consultations to support all activities related to pediatric diagnosis.

12. Provision of laboratory consultations to pediatric diagnosis and coordination of this project.

## II. Award Information

*Type of Award:* Cooperative Agreement.

HHS involvement in this program is listed in the Activities Section above.

*Fiscal Year Funds:* 2005.

*Approximate Total Funding:* \$1,000,000 (This amount is an estimate, and is subject to availability of funds.).

*Approximate Number of Awards:* One.

*Approximate Average Award:* \$200,000 (This amount is for the first 12-month budget period, and includes direct costs.).

*Floor of Award Range:* \$200,000.

*Ceiling of Award Range:* \$200,000.

*Anticipated Award Date:* September 15, 2005.

*Budget Period Length:* 12 months.

*Project Period Length:* Five years.

Throughout the project period, HHS's commitment to continuation of awards will be conditioned on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the Federal Government, through the Emergency Plan for AIDS Relief review and approval process for Country Operational Plans, managed by the Office of the U.S. Global AIDS Coordinator.

## III. Eligibility Information

### III.1. Eligible Applicants

Eligible applicants must:

- Be private, non-profit organizations, indigenous to Haiti, and may be faith-based organizations.
- Have between three to five years of experience in HIV/AIDS pediatric diagnosis and testing.
- Currently work in HIV/AIDS care in the Central Plateau Region of Haiti.

- Already be integrated into the Haitian national HIV/AIDS program.

### III.2. Cost-Sharing or Matching

Matching funds are not required for this program.

### III.3. Other

If applicants request a funding amount greater than the ceiling of the award range, HHS/CDC will consider the application non-responsive, and it will not enter into the review process. We will notify you that your application did not meet the submission requirements.

*Special Requirements:* If your application is incomplete or non-responsive to the special requirements listed in this section, it will not enter into the review process. We will notify you that your application did not meet submission requirements.

- HHS/CDC will consider late applications non-responsive. See section "IV.3. Submission Dates and Times" for more information on deadlines.

- **Note:** Title 2 of the United States Code Section 1611 states that an organization described in Section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, or loan.

## IV. Application and Submission Information

### IV.1. Address to Request Application Package

To apply for this funding opportunity use application form PHS 5161-1.

*Electronic Submission:* HHS strongly encourages the applicant to submit the application electronically by using the forms and instructions posted for this announcement on <http://www.grants.gov>, the official Federal agency wide E-grant Web site. Only applicants who apply on-line are permitted to forego paper copy submission of all application forms.

*Paper Submission:* Application forms and instructions are available on the HHS/CDC web site, at the following Internet address: <http://www.cdc.gov/od/pgo/forminfo.htm>.

If you do not have access to the Internet, or if you have difficulty accessing the forms on-line, you may contact the HHS/CDC Procurement and Grants Office Technical Information Management Section (PGO-TIM) staff at: 770-488-2700. We can mail application forms to you.

### IV.2. Content and Form of Submission

*Application:* You must submit a project narrative with your application

forms. You must submit the narrative in the following format:

- Maximum number of pages: 30. If your narrative exceeds the page limit, only the first pages which are within the page limit will be reviewed.

- Font size: 12 point un-reduced
- Paper size: 8.5 by 11 inches
- Page margin size: One inch
- Printed only on one side of page.
- Held together only by rubber bands or metal clips; not bound in any other way.

- Submitted in English.

Your narrative should address activities to be conducted over the entire project period, and must include the following items in the order listed:

- Executive Summary: Provide a clear and concise summary of the proposed goals, major objectives and activities required for achievement of program goals, and amount of funding requested for budget year one of this cooperative agreement.

- Project Context and Background (Understanding and Need)

- Project Strategy—Description and Methodologies

- Project Goals
- Project Outputs
- Project Contribution to the Goals and Objectives of the Emergency Plan for AIDS Relief

- Work Plan and Description of Project Components and Activities

- Performance Measures
- Timeline (e.g., GANNT Chart)
- Management of Project Funds and Reporting.

You may include additional information in the application appendices. The appendices will not count toward the narrative page limit. This additional information includes the following:

- Budget Justification (only for Year 01)

- Curricula Vitae
- Organizational Charts
- Letters of Support

You must have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the Federal government. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access <http://www.dunandbradstreet.com> or call 1-866-705-5711. For more information, see the HHS/CDC web site at: <http://www.cdc.gov/od/pgo/funding/grantmain.htm>. If your application form does not have a DUNS number field,

please write your DUNS number at the top of the first page of your application,

and/or include your DUNS number in your application cover letter.

Additional requirements that could require you to submit additional documentation with your application are listed in section "VI.2. Administrative and National Policy Requirements."

Administrative and National Policy Requirements."

#### IV.3. Submission Dates and Times

##### Application Deadline Date:

September 6, 2005.

##### Explanation of Deadlines:

Applications must be received in the HHS/CDC Procurement and Grants Office by 4 p.m. Eastern Time on the deadline date.

Applications may be submitted electronically at <http://www.grants.gov>. We consider applications completed on-line through Grants.gov as formally submitted when the applicant organization's Authorizing Official electronically submits the application to <http://www.grants.gov>. We will consider electronic applications as having met the deadline if the applicant organization's Authorizing Official has submitted the application electronically to Grants.gov on or before the deadline date and time.

If submittal of the application is done electronically through Grants.gov (<http://www.grants.gov>), the application will be electronically time/date stamped, which will serve as receipt of submission. Applicants will receive an e-mail notice of receipt when HHS/CDC receives the application.

If you submit your application by the United States Postal Service or commercial delivery service, you must ensure the carrier will be able to guarantee delivery by the closing date and time. If HHS/CDC receives your submission after closing because of: (1) Carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time; or (2) significant weather delays or natural disasters, you will have the opportunity to submit documentation of the carrier's guarantee. If the documentation verifies a carrier problem, HHS/CDC will consider the submission as received by the deadline.

If a hard copy application is submitted, HHS/CDC will not notify you upon receipt of your submission. If you have a question about the receipt of your application, first contact your courier. If you still have a question, contact the PGO-TIM staff at: 770-488-2700. Before calling, please wait two to three days after the submission deadline. This will allow time for us to process and log submissions.

This announcement is the definitive guide on application content,

submission address, and deadline. It supersedes information provided in the application instructions. If your submission does not meet the deadline above, it will not be eligible for review, and we will discard it. We will notify you that you did not meet the submission requirements.

#### IV.4. Intergovernmental Review of Applications

Executive Order 12372 does not apply to this program.

#### IV.5. Funding Restrictions

Restrictions, which you must take into account while writing your budget, are as follows:

- Funds may not be used for research.
- Reimbursement of pre-award costs is not allowed.

- Funds may be spent for reasonable program purposes, including personnel, travel, supplies, and services. Equipment may be purchased if deemed necessary to accomplish program objectives; however, prior approval by HHS/CDC officials must be requested in writing.

- All requests for funds contained in the budget shall be stated in U.S. dollars. Once an award is made, HHS/CDC will not compensate foreign grantees for currency exchange fluctuations through the issuance of supplemental awards.

- The costs that are generally allowable in grants to domestic organizations are allowable to foreign institutions and international organizations, with the following exception: With the exception of the American University, Beirut and the World Health Organization, Indirect Costs will not be paid (either directly or through sub-award) to organizations located outside the territorial limits of the United States or to international organizations regardless of their location.

- The applicant may contract with other organizations under this program; however, the applicant must perform a substantial portion of the activities (including program management and operations, and delivery of prevention services for which funds are required).

- You must obtain annual audit of these HHS/CDC funds (program-specific audit) by a U.S.-based audit firm with international branches and current licensure/authority in-country, and in accordance with International Accounting Standards or equivalent standard(s) approved in writing by HHS/CDC.

- A fiscal Recipient Capability Assessment may be required, prior to or post award, in order to review the

applicant's business management and fiscal capabilities regarding the handling of U.S. Federal funds.

- Funds received from this announcement will not be used for the purchase of anti-retroviral drugs for treatment of established HIV infection, with the exception of nevirapine in PMTCT cases and with prior written approval, occupational exposures, and non-occupational exposures and will not be used for the purchase of machines and reagents to conduct the necessary laboratory monitoring for patient care.
- No funds appropriated under this act shall be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

#### Prostitution and Related Activities

The U.S. Government is opposed to prostitution and related activities, which are inherently harmful and dehumanizing, and contribute to the phenomenon of trafficking in persons.

Any entity that receives, directly or indirectly, U.S. Government funds in connection with this document ("recipient") cannot use such U.S. Government funds to promote or advocate the legalization or practice of prostitution or sex trafficking. Nothing in the preceding sentence shall be construed to preclude the provision to individuals of palliative care, treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides.

A recipient that is otherwise eligible to receive funds in connection with this document to prevent, treat, or monitor HIV/AIDS shall not be required to endorse or utilize a multisectoral approach to combating HIV/AIDS, or to endorse, utilize, or participate in a prevention method or treatment program to which the recipient has a religious or moral objection. Any information provided by recipients about the use of condoms as part of projects or activities that are funded in connection with this document shall be medically accurate and shall include the public health benefits and failure rates of such use.

In addition, any recipient must have a policy explicitly opposing prostitution and sex trafficking. The preceding sentence shall not apply to any "exempt organizations" (defined as the Global Fund to Fight AIDS, Tuberculosis and Malaria, the World Health Organization and its six Regional Offices, the International AIDS Vaccine Initiative or to any United Nations agency).

The following definition applies for purposes of this clause:

- Sex trafficking means the recruitment, harboring, transportation, provision, or obtaining of a person for the purpose of a commercial sex act. 22 U.S.C. 7102(9).

All recipients must insert provisions implementing the applicable parts of this section, "Prostitution and Related Activities," in all subagreements under this award. These provisions must be express terms and conditions of the subagreement, must acknowledge that compliance with this section, "Prostitution and Related Activities," is a prerequisite to receipt and expenditure of U.S. government funds in connection with this document, and must acknowledge that any violation of the provisions shall be grounds for unilateral termination of the agreement prior to the end of its term. Recipients must agree that HHS may, at any reasonable time, inspect the documents and materials maintained or prepared by the recipient in the usual course of its operations that relate to the organization's compliance with this section, "Prostitution and Related Activities."

All prime recipients that receive U.S. Government funds ("prime recipients") in connection with this document must certify compliance prior to actual receipt of such funds in a written statement that makes reference to this document (e.g., "[Prime recipient's name] certifies compliance with the section, 'Prostitution and Related Activities.'" ) addressed to the agency's grants officer. Such certifications by prime recipients are prerequisites to the payment of any U.S. Government funds in connection with this document.

Recipients' compliance with this section, "Prostitution and Related Activities," is an express term and condition of receiving U.S. Government funds in connection with this document, and any violation of it shall be grounds for unilateral termination by HHS of the agreement with HHS in connection with this document prior to the end of its term. The recipient shall refund to HHS the entire amount furnished in connection with this document in the event HHS determines the recipient has not complied with this section, "Prostitution and Related Activities."

You can find guidance for completing your budget on the HHS/CDC web site, at the following Internet address: <http://www.cdc.gov/od/pgo/funding/budgetguide.htm>.

#### IV.6. Other Submission Requirements

*Application Submission Address:*  
Electronic Submission: HHS/CDC strongly encourages applicants to submit applications electronically at <http://www.Grants.gov>. The application package can be downloaded from <http://www.Grants.gov>. Applicants are able to complete it off-line, and then upload and submit the application via the Grants.gov Web site. We will not accept e-mail submissions. If the applicant has technical difficulties in Grants.gov, the applicant can reach customer service at <http://www.grants.gov/CustomerSupport> or by phone at 1-800-518-4726 (1-800-518-GRANTS). The Customer Support Center is open from 7 a.m. to 9 p.m. Eastern Time, Monday through Friday.

HHS/CDC recommends that submittal of the application to Grants.gov should be early to resolve any unanticipated difficulties prior to the deadline. Applicants may also submit a back-up paper submission of the application. We must receive any such paper submission in accordance with the requirements for timely submission detailed in Section IV.3. of the grant announcement. You must clearly mark the paper submission: "BACK-UP FOR ELECTRONIC SUBMISSION."

The paper submission must conform to all requirements for non-electronic submissions. If we receive both electronic and back-up paper submissions by the deadline, we will consider the electronic version the official submission.

We strongly recommend that the applicant submit the grant application by using Microsoft Word, Microsoft Excel, etc.). If the applicant does not have access to Microsoft Office products, you may submit a PDF file. Directions for creating PDF files can be found on the Grants.gov Web site. Use of file formats other than Microsoft Office or PDF could make the file unreadable for our staff.

*or*  
*Paper Submission:* Submit the original and two hard copies of your application by mail or express delivery service to the following address: Technical Information Management-AA178, CDC Procurement and Grants Office, U.S. Department of Health and Human Services, 2920 Brandywine Road, Atlanta, GA 30341.

#### V. Application Review Information

##### V.1. Criteria

Applicants must provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative

agreement. Measures of effectiveness must relate to the performance goals stated in the "Purpose" section of this announcement. Measures must be objective and quantitative, and must measure the intended outcome. Applicants must submit these measures of effectiveness with the application and they will be an element of evaluation.

We will evaluate your application against the following criteria:

1. Need (20 Points) To what extent does the applicant justify the need for this program within the target community?

2. Plan (20 Points) Does the applicant display knowledge of the five-year strategy and goals of the President's Emergency Plan, such that it can build on these to develop a comprehensive, collaborative project to reach underserved populations? Does the applicant describe strategies that are pertinent and match those identified in the five-year strategy of the President's Emergency Plan and describe activities that are evidence-based, realistic, achievable, measurable and culturally appropriate in Haiti? Is the plan appropriate to the social, political and cultural context in Haiti? Is the plan adequate to carry out the proposed objectives? How complete and comprehensive is the plan for the entire project period? Does the plan include quantitative process and outcome measures?

3. Monitoring Evaluation and Reporting (20 points) Does the applicant have a system for reviewing and adjusting program activities based on monitoring information? Applicants must develop indicators for each program milestone and incorporate them into the periodic financial and programmatic reports. Applicants must draw all indicators from the President's Emergency Plan for AIDS Relief Indicator Guide, and be consistent with the guidance established by the Office of the U.S. Global AIDS Coordinator. Applicants must generate periodic financial and program reports to show disbursement of funds and progress towards achieving program objectives.

4. Methods (15 Points).

Are the proposed methods feasible? To what extent will they accomplish the program goals?

5. Management and Personnel (15 Points).

Do the staff members have appropriate experience? Are the staff roles clearly defined? As described, will the staff be sufficient to accomplish the program goals? Is there a plan to manage the resources of the program, prepare reports, monitor and evaluate activities and audit expenditures?

6. Eligibility (10 points).

Organizations indigenous to Haiti must have between three to five years of experience in HIV/AIDS pediatric diagnosis and testing, must currently work in HIV/AIDS care in the Central Plateau, and must be integrated into the Haitian national HIV/AIDS program.

7. Budget and Justification (Reviewed, but not scored) Is the itemized budget for conducting the project, along with justification, reasonable and consistent with the five-year strategy and goals of the President's Emergency Plan, Emergency Plan activities in Haiti, and the National Haitian HIV/AIDS program?

#### V.2. Review and Selection Process

The HHS/CDC Procurement and Grants Office (PGO) staff will review applications for completeness, and HHS Global AIDS program will review them for responsiveness. Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will receive notification that their application did not meet submission requirements.

An objective review panel will evaluate complete and responsive applications according to the criteria listed in the "V.1. Criteria" section above. All persons who serve on the panel will be external to the U.S. Government Country Program Office. The panel may include both Federal and non-Federal participants.

Applications will be funded in order by score and rank determined by the review panel. HHS/CDC will provide justification for any decision to fund out of rank order.

In addition, the following factors could affect the funding decision:

- Maintaining geographic diversity
- Preference to organizations in certain geographic areas

HHS/CDC will provide justification for any decision to fund out of rank order.

#### V.3. Anticipated Announcement and Award Dates

September 15, 2005

### VI. Award Administration Information

#### VI.1. Award Notices

Successful applicants will receive a Notice of Award (NoA) from the HHS/CDC Procurement and Grants Office. The NoA shall be the only binding, authorizing document between the recipient and HHS/CDC. An authorized Grants Management Officer will sign the NoA, and mail it to the recipient fiscal officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review by mail.

#### VI.2. Administrative and National Policy Requirements

45 CFR Part 74 and Part 92

For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: <http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>

The following additional requirements apply to this project:

- AR-4 HIV/AIDS Confidentiality Provisions
- AR-10 Smoke-Free Workplace Requirements
- AR-12 Lobbying Restrictions
- AR-14 Accounting System Requirements

Applicants can find additional information on these requirements on the HHS/CDC web site at the following Internet address: <http://www.cdc.gov/od/pgo/funding/ARs.htm>.

You need to include an additional Certifications form from the PHS 5161-1 application in your Grants.gov electronic submission only. Please refer to <http://www.cdc.gov/od/pgo/funding/PHS5161-1-Certificates.pdf>. Once you have filled out the form, please attach it to the Grants.gov submission as Other Attachment Forms.

#### VI.3. Reporting Requirements

You must provide HHS/CDC with an original, plus two hard copies of the following reports:

1. Interim progress report, due no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application, and must contain the following elements:
  - a. Current Budget Period Activities and Objectives.
  - b. Current Budget Period Financial Progress.
  - c. New Budget Period Program Proposed Activities and Objectives.
  - d. Budget and budget narrative with justification.
  - e. Measures of Effectiveness, including progress against the numerical goals of the President's Emergency Plan for AIDS Relief for Haiti.
  - f. Additional Information.

2. Annual reports are due within 30 days of the end of the budget period. The report should detail progress toward achieving program milestones and projected next year activities. Indicators must be developed for each program milestone and incorporated

into the annual financial and programmatic reports. All indicators need to be drawn from the Emergency Plan.

3. Financial status report, no more than 90 days after the end of the budget period. The financial report must show obligations, disbursements and funds remaining by program activity. Indicators must be developed for each program milestone and incorporated into the periodic financial and programmatic reports. All indicators need to be drawn from The Emergency Plan Indicator Guide.

4. Final performance reports, no more than 90 days after the end of the project period.

Recipients must mail these reports to the Grants Management or Contract Specialist listed in the "Agency Contacts" section of this announcement.

### VII. Agency Contacts

We encourage inquiries concerning this announcement. For general questions, contact: Technical Information Management Section, CDC Procurement and Grants Office, U.S. Department of Health and Human Services, 2920 Brandywine Road, Atlanta, GA 30341. Telephone: 770-488-2700.

For program technical assistance, contact: Kathy Grooms, Project Officer, Global AIDS Program, HHS/CDC National Center for HIV, STD, and TB Prevention, 1600 Clifton Road, Mailstop E-04, Atlanta, GA 30333. Telephone: 404-639-8394.

For financial, grants management, or budget assistance, contact: Vivian Walker, Grants Management Specialist, CDC Procurement and Grants Office, U.S. Department of Health and Human Services, 2920 Brandywine Road, Atlanta, GA 30341. Telephone: 770-488-2724. E-mail: [vwalker@cdc.gov](mailto:vwalker@cdc.gov).

### VIII. Other Information

Applicants can find this and other HHS/CDC funding opportunity announcements on the HHS/CDC web site, Internet address: <http://www.cdc.gov> (Click on "Funding," then "Grants and Cooperative Agreements"), and on the web site of the HHS Office of Global Health Affairs, Internet address: <http://www.globalhealth.gov>.

Dated: August 5, 2005.

#### William P. Nichols,

*Director, Procurement and Grants Office, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.*

[FR Doc. 05-15893 Filed 8-10-05; 8:45 am]

BILLING CODE 4163-18-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[Program Announcement AA134]

#### Strengthening HIV/AIDS, TB and STI Prevention, Control and Treatment Activities Within the Police Force of Ethiopia; Notice of Intent To Fund Single Eligibility Award

##### A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the intent to fund fiscal year (FY) 2005 funds for a cooperative agreement program to strengthen the activities in the prevention, control, and treatment of HIV/AIDS, Sexually Transmitted Infections (STI) and Tuberculosis (TB) within the Police Force of Ethiopia. The project particularly aims to: (1) Improve HIV/AIDS, STI and TB prevention following the Abstinence, Be Faithful, and Correct and Consistent Condom Use (ABC) strategies, care and treatment services within the Police Force of Ethiopia; (2) strengthen human resource capacity of the police force for HIV/AIDS/STI/TB services; and (3) implement and support targeted monitoring and evaluation. The Catalog of Federal Domestic Assistance number for this program is 93.067.

##### B. Eligible Applicant

Assistance will be provided only to the FPC of the Federal Democratic Republic of Ethiopia for this project.

The FPC of Ethiopia is the most appropriate and qualified agency to conduct the activities because:

1. FPC's HIV Prevention and Control Office is the only office uniquely positioned in terms of legal authority, ability, and credibility to coordinate and support prevention, care, and treatment activities among members of the police force and their dependents.

2. The FPC administers all the police force health facilities which constitute the only facilities where members of the police force and their dependents receive care.

3. FPC is the umbrella entity that can access the police force and their dependents at the national and regional levels.

4. FPC is mandated by the Federal Government of Ethiopia to work on HIV/AIDS in behalf of the police force and their dependents with international organizations and civil societies in the prevention and control of HIV/AIDS.

5. The Police Hospital is the only referral hospital for the police and their

dependants in the country playing a leading role in providing an integrated and comprehensive HIV/AIDS treatment and care and serving also as a major training center for all cadres of health care professionals deployed at the police force health facilities in the country that also integrate training, service and research.

##### C. Funding

Approximately \$140,000 is available in FY 2005 to fund this award on September 15, 2005, and will be made for a 12-month budget period within a project period of up to five years. Funding estimates may change.

##### D. Where To Obtain Additional Information

For general comments or questions about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341-4146. Telephone: 770-488-2700.

For technical questions about this program, contact: Tadesse Wuhib, MD, MPH, Country Director, CDC-Ethiopia, P.O. Box 1014, Entoto Road, Addis Ababa. Telephone: (Office) 251-1-66-95-33; (Cell) 251-9-228543. E-mail address: [wuhibt@etcdc.com](mailto:wuhibt@etcdc.com).

Dated: August 4, 2005.

#### William P. Nichols,

*Director, Procurement and Grants Office, Centers for Disease Control and Prevention.*

[FR Doc. 05-15894 Filed 8-10-05; 8:45 am]

BILLING CODE 4163-18-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Medical Device User Fee Rates for Fiscal Year 2006

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the fee rates and payment procedures for medical device user fees for fiscal year (FY) 2006. The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) and the Medical Device User Fee Stabilization Act of 2005 (MDUFSA), authorizes FDA to collect user fees for certain medical device applications. The FY 2006 fee rates are provided in this notice. For all applications submitted on or after October 1, 2005, and through September 30, 2006, fees must be paid