a cooperative agreement program for Evaluation of Antiretroviral (ARV) Delivery Systems at The AIDS Support Organization in the Republic of Uganda. The Catalog of Federal Domestic Assistance number for this program is 93.941.

B. Eligible Applicant

Assistance will only be provided to the Medical Research Council (MRC) of the United Kingdom. No other applications are solicited.

The need for research on ARV treatment delivery is extremely urgent and the value of PEPFAR's already substantial investment in ARVs in Uganda will be greatly enhanced by rapid results.

The MRC is the only current CDC partner working with TASO on HIV/AIDS care and treatment projects. They have demonstrated their capacity for rigorous operational research and evaluation with TASO in respect to previous studies of Izoniazid prophylaxis, cotrimoxazole prophylaxis and ART at TASO Entebbe. TASO has been funded under PEPFAR Track 1.5 to implement the provision of ARVs and a basic care package at five centers. One of the centers is in the Jinja District. Because implementation of this program will begin in September 2004, it is necessary to work with an organization already conducting research with TASO at one of its centers. The MRC has a well-staffed and equipped station of experienced researchers who have conducted more than five major research projects at multiple TASO centers since 1994. The MRC has virological and other laboratories in Entebbe. The Entebbe facilities are essential to conducting the research since biomedical evaluation of adherence must be conducted by measuring HIV viral load.

No other partner could develop the capacity which MRC and TASO have in combination within a few months.

C. Funding

Approximately $550,000 is available in FY 2004 to fund this award. It is expected that the award will begin on or before September 1, 2004, and will be made for a 12-month budget period within a project period of up to three 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 program technical assistance, contact: Jonathan Mermin, MD, MPH, Global Aids Program [GAP], Uganda Country Team, National Center for HIV, STD and TB Prevention, Centers for Disease Control and Prevention [CDC], PO Box 49, Entebbe, Uganda. Telephone: +256–41320776, E-mail: *jhm@cdc.gov.*

For financial, grants management, or budget assistance, contact: Shirley Wynn, Contract Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: (770) 488–1515, E-mail: *zbx6@cdc.gov.*

Dated: June 18, 2004.

William P. Nichols,

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

[FR Doc. 04–14306 Filed 6–23–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Early Screening and Diagnosis of Duchenne Muscular Dystrophy

Announcement Type: New.

Funding Opportunity Number: PA 04216.

Catalog of Federal Domestic Assistance Number: 93.283.

Dates: Letter of Intent Deadline: July 14, 2004.

Application Deadline: August 9, 2004.

I. Funding Opportunity Description

Authority: This program is authorized under Sections 317 (k)(2)(42 U.S.C. section 247b(k)(2)) and sections 311 and 317(C) of the Public Health Service Act [42 U.S.C. 241, 243, and 247b–4 as amended].

Purpose and Research Objectives: The purpose of the program is to develop, implement and evaluate creatine kinase-based screening programs for the early detection of Duchenne Muscular Dystrophy (DMD) during the newborn period (part A) and during infancy (part B). This program addresses the ''Healthy People 2010'' focus area of Disability and Secondary Conditions. Measurable outcomes of the program will be in alignment with the following performance goal for the National Center on Birth Defects and Developmental Disabilities: To improve the health and quality of life of Americans with disabilities.

DMD is the most common form of muscular dystrophy in children. It causes progressive muscle deterioration, leading to the inability to walk around the age of 12 years, and death in the teens or early 20s, most commonly due to severe respiratory or heart problems, or both. The gene for DMD is on the X chromosome so DMD affects males almost exclusively. In the absence of newborn screening, DMD is usually diagnosed when a child is three to six years of age. DMD does not meet the traditional criteria for inclusion in routine newborn screening panels in the United States, because there is insufficient evidence that early detection and intervention leads to an improved medical outcome for children with DMD. However, an earlier age of diagnosis has potential non-medical benefits to the family, including knowledge of recurrence risk, avoidance of a long diagnostic process, and more time for financial and other planning related to raising a child with a disabling condition. In addition, earlier age at diagnosis will offer more opportunity to study the potential medical benefits of earlier treatments. In several countries, families are offered newborn screening for DMD based on creatine kinase activity in dried bloodspots.

Two approaches to screening have been employed; screening after birth and screening at 6–12 months of age. Sensitivity, specificity, and other characteristics of the screen are dependent on the age of screening, the particular assay utilized, and cut-off levels used. DMD screening offered to parents of male neonates, with informed consent and in conjunction with existing routine newborn screening systems, is one potential approach to decreasing the age of diagnosis in the United States. However, complications of this approach include the difficulty in obtaining uniform and informed consent (contingent on promoting complete understanding by parents of genetic and outcome factors) during the prenatal or immediate neonatal period, and the potential impact of test results on parent-infant bonding.

A second potential approach is to offer screening to families of male infants (6 to 12 months) through pediatric health care services. This approach offers more time for informed consent, but a major complication is disparities in access to pediatric health care.

Both approaches require well-planned protocols for follow-up of positive screening results. The purpose of this cooperative agreement is to develop, implement and evaluate early screening

programs in both neonates (part A) and infants (part B) in order to: (a) Assess the feasibility of early screening for DMD; (b) identify challenges related to each approach; and (c) evaluate the risks and benefits of each approach.

Activities: Applicants may apply for funding under part A and/or part B. Please note that if applicants choose to apply for both part A and part B, separate applications are required. There is no provision which allows the submission of consolidated applications addressing the requirements of both part A and part B under one application.

Awardee activities for part A of this program are as follows:

• Develop, implement and evaluate laboratory protocols for DMD newborn screening based on creatine kinase activity levels in dried blood spots of male newborns. The evaluation component should include determination of sensitivity, specificity, negative predictive value and positive predictive value of the screening methodology in the newborn period.

• Develop, implement, and evaluate protocols for informed consent, follow-up of positive screening results, diagnostic testing, and referral to clinical care. The evaluation component should include assessments of (1) parental understanding of informed consent, (2) factors that influence the entire process for screening, (3) factors that influence loss to follow-up, (4) acceptability of screening to parents and health care providers, (5) impact of transient positive screening results on families, (6) attitudes of diagnosed families toward the screening and diagnostic process, (7) attitudes of transient positive and true negative families (both screen-negative and DMD not present) toward the screening process, (8) assessments of other potential risks and benefits of newborn screening for DMD, and (9) the overall economic costs of screening.

Awardee activities for part B of this program are as follows:

• Develop, implement and evaluate laboratory protocols for DMD infant screening based on creatine kinase activity levels in dried blood spots or other suitable biologic specimens from male infants. The evaluation component should include determination of sensitivity, specificity, and positive predictive value of screening methodology in infancy (6–12 months).

• Develop, implement, and evaluate protocols for informed consent, follow-up of positive screening results, diagnostic testing, and referral to clinical care. The evaluation component should include assessments of (1) factors that influence access to and uptake of infant screening, (2) parental understanding of informed consent, (3) factors that influence loss to follow-up, (4) acceptability of screening to parents and health care professionals, (5) impact of transient positive screening results on families, (6) attitudes of diagnosed families toward the screening and diagnostic process, (7) attitudes of transient positive and true negative families toward the screening process, (8) assessments of other potential risks and benefits of infant screening for DMD, and (9) the overall economic costs of screening.

CDC Responsibilities: In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring. In this cooperative agreement, a CDC Scientist (Scientific Liaison) within the National Center on Birth Defects and Developmental Disabilities (NCBDDD) is an equal partner with scientific and programmatic involvement during the conduct of the project through technical assistance, advice, and coordination. The Scientific Liaison will:

1. Participate in the development of the protocol.

2. Participate in the analysis, interpretation, and reporting of findings in the scientific literature and other media to the community at large and the public policy community within the Federal government.

3. Participate in data management, analysis of data, and interpretation and dissemination of findings.

4. Provide scientific consultation and technical assistance in the design and conduct of the project, including protocol adherence, outcome measures, and analytical approaches in participation with the recipient organization.

CDC Scientific Program Administrator (SPA)

The CDC NCBDDD will appoint an SPA, apart from the NCBDDD Scientific Liaison who will:

1. Serve as the Program Official for the funded research institutions.

2. Carry out continuous review of all scientific and administrative activities to ensure objectives are being met.

3. Attend Coordination Committee meetings for purposes of assessing overall progress and for program evaluation purposes.

4. Provide scientific consultation and technical assistance in the conduct of the project as requested.

5. Conduct site visits to recipient institutions to determine the adequacy of the research and to monitor performance against approved project objectives.

Collaborative Responsibilities

The planning and implementation of the cooperative aspects of the study will be effected by a Coordination Committee consisting of the Principal Investigator from the participating institution(s) and the CDC Scientific Liaison. This Coordinating Committee will formulate a plan for cooperative research.

At periodic coordination committee meetings, the group will: (1) Make recommendations on the study protocol and data collection approaches; (2) discuss the target populations that have been or will be recruited; (3) identify and recommend solutions to unexpected study problems; and (4) discuss ways to efficiently coordinate study activities and best practices.

II. Award Information

Part A. DMD During the Newborn Period

Type of Award: Cooperative Agreement.

CDC involvement in this program is listed in the Activities section above.

Fiscal Year Funds: 2004.

Approximate Total Funding: $250,000.

Approximate Number of Awards: One.

Approximate Average Award: $250,000 (this amount is for the first 12-month budget period, and includes both direct and indirect costs).

Floor of Award Range: None.

Ceiling of Award: None.

Anticipated Award Date: September 1, 2004.

Budget Period Length: 12 months.

Project Period Length: Three years. Throughout the project period, CDC'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.

Part B. DMD During the Infancy Period

Type of Award: Cooperative Agreement.

CDC involvement in this program is listed in the Activities section above.

Fiscal Year Funds: 2004.

Approximate Total Funding: $250,000.

Approximate Number of Awards: One.

Approximate Average Award: $250,000 (this amount is for the first 12-month budget period, and includes both direct and indirect costs).

Floor of Award Range: None.

Ceiling of Award: None.

Anticipated Award Date: September 1, 2004.

Budget Period Length: 12 months.

Project Period Length: Three years.

Throughout the project period, CDC'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.

III. Eligibility Information

III.1. Eligible Applicants

Applications may be submitted by public and private non-profit organizations and by governments and their agencies, such as:

- Public non-profit organizations
- Private non-profit organizations
- Universities
- Colleges
- Non-profit Research Institutions and Hospitals
- State and local governments or their *bona fide* agents (this includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau)
- Political subdivisions of States (in consultation with States)

A *bona fide* agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If you are applying as a *bona fide* agent of a state or local government, you must provide a letter from the state as documentation of your status. Place this documentation behind the first page of the application form.

III.2. Cost Sharing or Matching

Matching funds are not required for this program.

III.3. Other

If your application is incomplete or non-responsive to the requirements listed below, it will not be entered into the review process. You will be notified that your application did not meet submission requirements.

Applicants must document their present infrastructure, capacity, expertise, and experience (within organization or within organizations of collaborators) in conducting population-based newborn or infant screening and follow-up for genetic diseases.

Applicants must provide specific evidence to substantiate this capacity, experience, and expertise. Through documentation of two pages in length, applicants must provide specific evidence that they can fully meet these eligibility criteria in order to be considered for formal review. This information must be included as part of the application and inserted immediately after the Face Page of the application.

Individuals Eligible to Become Principal Investigators: Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institution to develop an application for support. Individuals from under-represented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for CDC programs.

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 398 (OMB number 0925–0001 rev. 5/2001). Forms and instructions are available in an interactive format on the CDC Web site, at the following Internet address: *http://www.cdc.gov/od/pgo/forminfo.htm.*

Forms and instructions are also available in an interactive format on the National Institutes of Health (NIH) web site at the following Internet address: *http://grants.nih.gov/grants/funding/phs398/phs398.html.*

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

IV.2. Content and Form of Application Submission

Letter of Intent (LOI): The LOI must be written in the following format:

- Maximum number of pages: Two
- Font size: 12-point unreduced
- Paper size: 8.5 by 11 inches
- Page margin size: One-inch margins
- Printed only on one side of page
- Single-spaced
- Written in plain language; avoiding jargon

The LOI must contain the following information: Name, address, and telephone number of the proposed Principal Investigator, number and title of this program announcement, intent to apply under part A or part B or both, names of other key personnel, designations of collaborating institutions and entities, and an outline of the proposed work, recruitment approach, and expected outcomes.

Application: Follow the PHS 398 application instructions for content and formatting of your application. For further assistance with the PHS 398 application form, contact PGO–TIM staff at (770) 488–2700, or contact GrantsInfo, Telephone (301) 435–0714, e-mail: *GrantsInfo@nih.gov*.

You must submit a signed original and five copies of your application form. The PHS 398 grant application form requires the applicant to enter the project title on page 1 (Form AA, ''Face Page'') and the project description (abstract on page 2).

The main body of the application should not exceed 25 single-spaced pages. This narrative research plan should address activities to be conducted over the entire project period.

Additional information may be included in the application appendices. The appendices will not be counted toward the narrative page limit. This additional information may include curriculum vitae and resumes for key project staff, organizational charts, graphic workplan/time charts, letters of commitment, etc.; and should be limited to those items relevant to the requirements of this announcement.

Applicants must include a graphic work plan (which may be placed in the appendices) that outlines major project goals and objectives with timelines established for each calendar quarter covering the entire project period.

All material must be typewritten, with 10 characters per inch type (12 point) on 8½ by 11 inch white paper with one-inch margins, no headers or footers (except for applicant-produced forms such as organizational charts, c. vitae, graphs and tables, etc.). Applications must be held together only by rubber bands or metal clips, and not bound together in any way (including attachments/appendices).

You are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the Federal government. Your DUNS number must be entered on line 11 of the face page of the PHS 398 application form. 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 CDC Web site at: *http://www.cdc.gov/od/pgo/funding/pubcommt.htm*.

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

IV.3. Submission Dates and Time

Letter of Intent (LOI) Deadline Date: July 14, 2004.

CDC requests that you send an LOI if you intend to apply for this program. Although the LOI is not required, not binding, and does not enter into the review of your subsequent application, the LOI will be used to gauge the level of interest in this program, and will allow CDC to plan the application review. LOI should include intent to apply under part A or part B or both.

Application Deadline Date: August 9, 2004.

Explanation of Deadlines: Applications must be received in the CDC Procurement and Grants Office by 4 p.m. eastern time on the deadline date. If you send your application by the United States Postal Service or commercial delivery service, you must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If CDC receives your application after closing due to: (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 be given the opportunity to submit documentation of the carrier's guarantee. If the documentation verifies a carrier problem, CDC will consider the application as having been received by the deadline.

This announcement is the definitive guide on application submission address and deadline. It supersedes information provided in the application instructions. If your application does not meet the deadline above, it will not be eligible for review, and will be discarded. You will be notified that your application did not meet the submission requirements.

CDC will not notify you upon receipt of your application. 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 three days after the application deadline. This will allow time for applications to be processed and logged.

IV.4. Intergovernmental Review of Applications

Executive Order 12372 does not apply to this program.

IV.5. Funding Restrictions

Restrictions, which must be taken into account while writing your budget, are that project funds cannot be used to supplant other available applicant or collaborating agency funds for construction or for lease or purchase of facilities or space.

If you are requesting indirect costs in your budget, you must include a copy of your indirect cost rate agreement. If your indirect cost rate is a provisional rate, the agreement must be less than 12 months from the application due date.

IV.6. Other Submission Requirements

LOI Submission Address: Lisa T. Garbarino, Public Health Analyst, National Center on Birth Defects and Developmental Disabilities, CDC, 1600 Clifton Road, Mailstop E–87, Atlanta, Georgia 30333. E-mail address: *lgt1@cdc.gov*.

Application Submission Address: Submit the original and five copies of your application by mail or express delivery service to: Technical Information Management—PA 04216, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, Georgia 30341. Applications may not be submitted by fax or e-mail at this time.

V. Application Review Information

V.1. Criteria

You are required to provide measures of outcome and 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. These measures of effectiveness must be submitted with the application and will be an element of evaluation.

The goals of CDC-supported research are to advance the understanding of biological, environmental, and human behavior systems; public health delivery/intervention systems; improvement of the control and prevention of disease and injury; and to enhance health. In the written comments, reviewers will be asked to evaluate the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. The scientific review group will address the applications' overall score, weighting them as appropriate for each application. The application does not have to be strong in all categories to be judged to have major scientific impact and thus deserve a high priority score.

Under the evaluation criteria noted below, applicants must describe how they will address the program components as they relate to the Purpose and Research Objectives, and the Recipient/Awardee Activities as cited in this Announcement.

Your application will be evaluated against the following criteria:

1. *Resources and Organizational Capacity:*

- This includes applicant infrastructure, experience, and capacity within its organization and/or with partners in early screening and diagnosis programs for genetic conditions, including genetic counseling and other appropriate follow-up activities; and to access target populations for screening.
- This indicates that based on the organizational capacity and resources the proposed project goals and objectives will be relevant, specific, achievable, and measurable; and can be addressed through the proposed methods and within the established timelines.

2. *Methods and Activities:*

- This includes that the proposed methods and activities convincingly and comprehensively meet the intent and purpose of the announcement.
- This considers that the overall process for planning, implementation, and evaluation is comprehensive and appropriate to accomplish the stated goals and objectives.
- This includes that: (a) The methods and activities are feasible within programmatic and fiscal restrictions; (b) the methods will produce accurate, valid and reliable data; (c) the potential capacity of the research design is adequate to generate meaningful results during the study period, the design can be replicated for future use; and (d) adequate and appropriate plans are in place for dissemination of findings and recommendations.

3. *Project Management and Staffing:*

- This criteria includes whether the proposed personnel, staff qualifications and experience and project organization are sufficient to address the planning, operations, and management/analysis activities of the program.
- This includes the process by which the applicant will assemble an effective

team and how the applicant presents specified tasks and responsibilities to be assigned for key personnel and positions.

• This includes how well the proposed approaches to meeting proposed goals and specific objectives are convincing and likely to achieve all objectives within the prescribed time frames.

4. *Evaluation Plan:* This assesses that: (a) Evaluation components described in the announcement have been addressed in the proposal; (b) measurable time-phased goals and objectives are included in the proposal; and (c) the evaluation plan includes a process for evaluation of sub-components and the entire project, including the assignment of responsibility for ongoing review of specified components.

5. *Budget Description and Justification:* This includes the comprehensiveness and adequacy of the proposed budget in relation to program operations, collaborations, and services; and the extent to which the budget is reasonable, clearly justified, accurate, and consistent with the purposes of this research.

6. *Protections:* Does the application adequately address the requirements of title 45 CFR part 46 for the protection of human subjects? This criteria will not be scored; however an application can be disapproved if the research risks are sufficiently serious and protection against risks is so inadequate as to make the entire application unacceptable.

7. *Inclusion:* Does the application adequately address the CDC policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research? This includes:

a. The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

b. The proposed justification when representation is limited or absent.

c. A statement as to whether the design of the study is adequate to measure differences when warranted.

d. A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO), and for responsiveness by NCBDDD. Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will be notified that their application did not meet submission requirements and will not receive further consideration.

Applications, which are complete and responsive, will be subjected to a preliminary evaluation (triage) by a scientific review group (Special Emphasis Panel—SEP) composed of external (non-CDC) peer reviewers to determine if each application is of sufficient technical and scientific merit to warrant further review by the SEP. Applications that are determined to be non-competitive will not be considered. Subsequent to the review meeting CDC will notify the investigator/program director and the official signing for the applicant organization of that determination.

Applications determined to be competitive will then be reviewed and scored under the formal SEP peer review process. The review of these fully competitive applications will result in the determination of the score and ranking for those applications.

Subsequent to the formal peer review of all competitive applications by the SEP a second level of review will be conducted by senior CDC program staff. This review will not revisit the scientific merit of the applications, but will evaluate the overall budget implications of the applications against funding ceilings and may not make recommendations as to the final ordering of the top ranked applications for part A and part B, they may not actually change the ranking order (or scores). It is possible that the second level of review may recommend funding the highest ranked proposal under part A (or part B) and also funding that same organization under its application for the other part of the announcement. That could occur in the event that an organization with the highest ranking in one part ranks among the highest three applicants in the other part. This would be done to take into account economies of scale and establish the capacity to conduct non-redundant programs to best meet the purposes of this announcement. In such a case, the total approved budget may be less than the sum of the two applications due to staff time commitment duplications and other considerations.

V.3. Anticipated Award Date

September 1, 2004.

VI. Award Administration Information

VI.1. Award Notices

If your application is to be funded, you will receive a Notice of Grant Award (NGA) from the CDC Procurement and Grants Office. The NGA shall be the only binding, authorizing document between the recipient and CDC. The NGA will be signed by an authorized Grants Management Officer, and mailed 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 Parts 74 and 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–1 Human Subjects Requirements
• AR–2 Requirement for Inclusion of Women and Racial and Ethnic Minorities in Research
• AR–10 Smoke-Free Workplace Requirements
• AR–11 Healthy People 2010
• AR–12 Lobbying Restrictions
• AR–14 Accounting Systems Requirements
• AR–15 Proof of Non-Profit Status
• AR–22 Research Integrity
• AR–25 Release and Sharing of Data

Additional information on these requirements can be found on the CDC Web site at the following Internet address: *http://www.cdc.gov/od/pgo/funding/ARs.htm*.

VI.3. Reporting Requirements

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

Interim progress report, (PHS 2590, OMB Number 0925–0001, rev. 5/2001), on a date to be determined for your project for each subsequent budget year. 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.

e. Additional Requested Information.

f. Measures of Effectiveness.

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

3. Final financial and performance reports, no more than 90 days after the

end of the project period. These reports must be sent to the Grants Management Specialist listed in the ''Agency Contacts'' section of this announcement.

VII. Agency Contacts

For general questions about this announcement, contact: Technical Information Management Section (PGO–TIM), CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, Georgia 30341, Telephone: (770) 488–2700.

For program technical assistance, contact: Lisa T. Garbarino, Public Health Analyst, National Center on Birth Defects and Developmental Disabilities, CDC, 1600 Clifton Road, Mailstop E–87, Atlanta, Georgia 30333. E-mail address: *lgt1@cdc.gov*. Telephone: (404) 498–3979.

For budget assistance, contact: Sylvia Dawson, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, Georgia 30341. Telephone: (770) 488–2771. E-mail: *snd8@cdc.gov*.

Dated: June 18, 2004.

William P. Nichols,

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

[FR Doc. 04–14311 Filed 6–23–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

HIV Treatment for Research Subjects or by Researchers in Kenya

Announcement Type: New.

Funding Opportunity Number: PA 04264.

Catalog of Federal Domestic Assistance Number: 93.941.

Key Dates:

Letter of Intent Deadline: Not required.

Application Deadline: July 26, 2004.

I. Funding Opportunity Description

Authority: This program is authorized under sections 307 and 317(k)(2)of the Public Health Service Act, [42 U.S.C. 242l and 247b(k)(2)] 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].

Purpose: The Centers for Disease Control and Prevention (CDC) announces the availability of Fiscal Year (FY) 2004 funds for a cooperative agreement program to provide support for organizations conducting bio-medical research related to HIV in Kenya in order to provide treatment to HIV-infected research subjects.

The Global AIDS Program (GAP) has established field operations to support national HIV/AIDS control programs in 25 countries. The CDC's GAP exists to help prevent HIV infection, improve care and support, and build capacity to address the global AIDS pandemic. GAP provides financial and technical assistance through partnerships with governments, community- and faith-based organizations, the private sector, and national and international entities working in the 25 resource-constrained countries. CDC/GAP works with the Health Resources and Services Administration (HRSA), the National Institutes of Health (NIH), the U.S. Agency for International Development (USAID), the Peace Corps, the Departments of State, Labor and Defense, and other agencies and organizations. These efforts complement multilateral efforts, including UNAIDS, the Global Fund to Combat HIV, TB and Malaria, World Bank funding, and other private sector donation programs.

The U.S. Government seeks to reduce the impact of HIV/AIDS in specific countries within sub-Saharan Africa, Asia, and the Americas through the Presidential Emergency Plan for AIDS Relief (PEPFAR). Through this new initiative, CDC's GAP will continue to work with host countries to strengthen capacity and expand activities in the areas of: (1) Primary HIV prevention; (2) HIV care, support, and treatment; and (3) capacity and infrastructure development, especially for surveillance and training. Targeted countries represent those with the most severe epidemics where the potential for impact is greatest and where U.S. government agencies are already active. Kenya is one of these targeted countries. A specific mandate of this initiative is to provide treatment to HIV-infected participants identified through U.S. government funded research agencies. In addition, the ambitious targets for treatment under this initiative make it imperative to capitalize on any existing technical expertise related to the administration of medical treatment for HIV.

To carry out its activities in these countries, CDC is working in a collaborative manner with national governments and other agencies to develop programs of assistance to address the HIV/AIDS epidemic. CDC's program of assistance to Kenya focuses on several areas of national priority including scaling up activities and funding for HIV prevention, care, and treatment, improvement of the national blood safety program, and support for the National AIDS and STD Control Program.

A number of research scientists, working independently or in collaboration with Kenyan institutions such as the University of Nairobi or the Kenya Medical Research Institute have, or will, identify research participants with HIV as part of their research work. Many of these scientists have technical capacity related to the treatment of HIV. Under PEPFAR, CDC Kenya plans to support treatment of HIV-infected individuals by providing funds and additional technical assistance as needed to allow the research groups to implement or expand HIV treatment programs.

The measurable outcomes of the program will be in alignment with goals of the GAP to reduce HIV transmission and improve care of persons living with HIV. They also will contribute to the goals of the PEPFAR which are: within five years treat more than 2 million HIV-infected persons with effective combination anti-retroviral therapy (ART); care for 10 million HIV-infected and affected persons including those orphaned by HIV/AIDS; and prevent 7 million infections in 14 countries throughout the world.

The key specific measurable outcomes from this program will be: (1) The numbers of individuals receiving basic care packages; (2) The number of pregnant women receiving a comprehensive package of PMCT and PMCT+ services; (3) the number of new patients served with ART; and (4) those current ART patients receiving continuous service for more than 12 months.

Activities

Awardee activities for this program are as follows:

• Develop programs to provide care and treatment for people with HIV infection, including, but not limited to, participants in research programs. The individuals to whom services are provided may include both participants in research programs and individuals who are not participating in research (family members, other individuals seen at the same site, individuals seen at other sites). The care should include testing and ongoing counseling, prevention services (for example efforts to reduce risk that an HIV infected individual will transmit HIV to an uninfected partner), diagnosis and management of opportunistic infections, and treatment with antiretroviral (ARV) drugs in accordance with U.S.