

Marjorie S. Greenberg, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, Room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone (301) 458-4245. Information is also available on the NCVHS home page of the HHS website: <http://www.ncvhs.hhs.gov/> where an agenda for the meeting will be posted when available.

Dated: June 28, 2000.

**James Scanlon,**

*Director, Division of Data Policy, Office of the Assistant Secretary for Planning and Evaluation.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[60Day-00-42]

**Proposed Data Collections Submitted for Public Comment and Recommendations**

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 639-7090.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques for other forms of information technology. Send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

*Proposed Projects:* National Disease Surveillance Program—I. Case Reports (0920-0009)—Reinstatement—National

Center for Infectious Diseases (NCID)—Formal surveillance of 19 separate reportable diseases has been ongoing to meet the public demand and scientific interest for accurate, consistent, epidemiologic data. These ongoing diseases include: bacterial meningitis, dengue, hantavirus, HIV/AIDS, Idiopathic CD4+T-lymphocytopenia, Kawasaki syndrome, Legionellosis, Lyme disease, malaria, Mycobacterium avium Complex Disease, plague, Reye Syndrome, tick-borne Rickettsial Disease, toxic shock syndrome, toxocariasis, trichinosis, typhoid fever, and viral hepatitis. Case report forms enable CDC to collect demographic, clinical, and laboratory characteristics of cases of these diseases. This information is used to direct epidemiologic investigations, to identify and monitor trends in reemerging infectious diseases or emerging modes of transmission, to search for possible causes or sources of the diseases, and to develop guidelines for the prevention of treatment. It is also used to recommend target areas in most need of vaccinations for certain diseases and to determine development of drug resistance.

Because of the distinct nature of each of the diseases, the number of cases reported annually is different for each. The total annualized burden is 27,110 hours. The total cost to respondents is estimated at \$406,650.

Respondents	Re-spond-ents	Re-sponses/ respondent	Aver-age <sup>1</sup>
Health care workers ...	55	1	.3

<sup>1</sup> Average burden/respondent (in hours)

Dated: July 5, 2000.

**Nancy Cheal,**

*Acting Associate Director for Policy, Planning, and Evaluation, Centers for Disease Control and Prevention (CDC).*

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**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[Program Announcement 00143]

**Intervention Epidemiologic Research Studies of HIV/AIDS; Notice of Availability of Funds**

**A. Purpose**

The Centers for Disease Control and Prevention (CDC) announces the

availability of fiscal year (FY) 2000 funds for a cooperative agreement program to (1) continue the longitudinal epidemiologic study of perinatal HIV transmission and pediatric disease progression during an era of highly active antiretroviral (ARV) therapy and (2) develop and implement innovative interventions to assist HIV infected children and adolescents (both perinatally and non-perinatally infected) in accessing and maintaining comprehensive HIV related care. The interventions will be directed at sustaining HIV specialist care, improving adherence to complex medical regimens, promoting overall and reproductive health, and decreasing the risk of secondary transmission of HIV infection. This program addresses the "Healthy People 2010" priority area of HIV Infection and Maternal and Infant Health. For a conference copy of "Healthy People 2010" visit the internet site: <<http://www.health.gov/healthypeople/>>.

The purpose of the program is to support three research studies of programmatic interest to the health care community that fosters prevention of HIV-related disease in infants, children, and adolescents. These studies include: (1) Ongoing longitudinal record review of Pediatric HIV disease, (2) development and evaluation of innovative intervention(s) to enhance sustained HIV specialist care and improved adherence to antiretroviral (ARV) medication drug regimens in children, from 5-12 years of age, and (3) development and evaluation of innovative interventions to provide linkages to and help sustain continuity of HIV specialist care, to foster adherence to HIV therapy, improve overall and reproductive health, and reduce transmission from HIV-infected adolescents ages 13-21 years, to others.

The following three Research Studies will be supported:

*I. Ongoing Longitudinal Record Review Study of Pediatric HIV Disease*

Competing continuation applications are invited for the continued prospective follow-up of HIV-infected children enrolled in the Pediatric Spectrum of Disease (PSD) Study between 1988 and 2000. Continued research areas of interest include:

- A. Perinatal HIV Prevention
  1. Characterization of perinatally infected infants with respect to their risk factors for HIV infection and clinical and laboratory outcomes.
  2. Investigation of potential severe adverse events related to exposure to antiretrovirals and/or other HIV-related therapies.

3. Description of circumstances of delivery and associated infant and maternal morbidities.

4. Frequency and description of birth outcomes to perinatally-infected adolescents.

B. Pediatric and Adolescent Management:

1. Factors associated with health and disease progression:

a. Viral load and ARV resistance  
b. Immune function and reconstitution

c. Growth and development, including puberty

d. Timing, type, and duration of therapy

e. Factors affecting adherence (including HIV infection status disclosure)

f. Potential side effects of ARV therapy

2. Identification of barriers to:

a. Timely receipt of care  
b. Durability of relationship with providers

3. Description of family structure and social risk factors

4. Characterization of developmental needs and linkage to special services for HIV-infected adolescents (e.g. health, family planning, STD clinic services, case management around HIV disease, etc.)

## *II. Innovative Intervention(s) To Enhance Sustained HIV Specialist Care and Improved Adherence to Antiretroviral Medication Drug Regimens in Children, From 5–12 Years of Age*

The complex nature of combination antiretroviral regimens emphasizes the need to develop innovative interventions to help children adhere to prescribed drug therapy. Age-appropriate interventions need to be designed and evaluated for both perinatally and non-perinatally infected children. Applications are invited to propose and develop intervention trials for children with evidence of current disease progression or treatment failure. The intent is to examine the impact of intervention strategies which address the following issues:

A. Fostering sustained comprehensive HIV specialist care:

1. Assessing barriers to sustaining continuity of specialist HIV care.

2. Developing and implementing strategies (e.g. reminders, support groups, etc.) to overcome individual and family barriers including HIV disclosure issues.

3. Linking to services which enable continuity of specialist HIV care. (e.g. transportation, day care, family-based care, education, etc.)

4. Developing and implementing methods for locating and re-engaging children lost to follow-up.

B. Promoting adherence to medications:

1. Assessing individual and family barriers to adherence to medication.

2. Linking to services which facilitate adherence (medication education, case management, social, pharmacist, etc.)

3. Developing and implementing strategies (e.g. dosing and medication schedules, child's preferences, in-home assistance, out-of-home adherence, reminders, use of MEMS®Caps, support groups, etc.) to overcome individual and family barriers including HIV disclosure issues.

## *III. Innovative Interventions to Provide Linkages to and Help Sustain Continuity of HIV Specialist Care, To Foster Adherence to HIV Therapy, To Improve Overall and Reproductive Health, and To Reduce Secondary Transmission Among Perinatally or Non-Perinatally HIV-Infected Adolescents, From 13–21 Years of Age*

Applications are invited that propose interventions that are developmentally focused, targeting issues of importance to adolescents and young adults, and address two or more of the following issues:

A. Linking to HIV specialist care:

1. Identifying HIV counseling and testing sites where HIV-infected adolescents are diagnosed.

2. Developing and documenting the procedures for referring identified HIV infected adolescents from counseling/testing sites to HIV specialist care providers appropriate for adolescents.

3. Facilitating the follow through of referrals made to HIV specialist care providers.

B. Maintaining continuity of HIV specialist care.

1. Assessing barriers to sustaining continuity of specialist HIV care.

2. Linking to services which enable continuity of specialist HIV care. (e.g. education, social, etc.)

3. Developing and implementing strategies to overcome individual, family or social barriers including HIV disclosure issues (reminders, support groups, etc.)

4. Developing and implementing age appropriate and culturally relevant strategies for locating and re-engaging adolescents lost to follow-up.

C. Promoting adherence to medication regimens:

1. Assessing individual, family and social barriers to adherence to medication.

2. Linking to services which facilitate adherence (medication education, case management, social, pharmacist, etc.)

3. Developing and implementing strategies to overcome individual, family and social barriers, including addressing HIV disclosure issues (dosing and medication schedules, adolescent's preferences, in-home assistance, reminders, etc.).

D. Develop interventions to support overall and reproductive health of adolescents and that decrease secondary HIV transmission.

1. Developing and implementing counseling strategies for HIV infected adolescents designed to improve their overall and reproductive health and decrease risk of secondary transmission of HIV (e.g. by prevention of sexually transmitted diseases, decreasing risky sexual behaviors, avoidance of illicit drug use, etc.)

2. Evaluating the effectiveness of the counseling intervention.

## **B. Eligible Applicants**

Applications may be submitted by public and private nonprofit organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, other public and private nonprofit organizations, State and local governments or their bona fide agents, and federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations.

For research study area I, (longitudinal medical record review), eligible applicants include only those grantees currently funded for the Pediatric Spectrum of HIV Disease (PSD) Project under CDC Program Announcement 735. These sites include Children's National Medical Center, (Washington, DC), the Puerto Rico Department of Health, the University of Massachusetts Medical Center, the Texas Department of Health, the Public Health Foundation Enterprises, Inc. (Los Angeles), and the New York City Department of Health.

**Note:** Public Law 104–65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

## **C. Availability of Funds**

I. Research area I: Approximately \$1.6 million is available in FY 2000 to fund approximately 6 competitive continuation projects. It is expected that the average award will be \$260,000, ranging from \$180,000 to \$500,000.

II. Research area II: Approximately \$200,000 is available in FY 2000 to fund approximately 2 awards for innovative intervention(s) for children 5–12 years

of age. It is expected that the average award will be \$100,000.

III. Research area III: Approximately \$200,000 is available in FY 2000 to fund approximately 2 awards for innovative interventions for adolescents 13–21 years of age. It is expected that the average award will be \$100,000.

It is expected that all awards will begin on or about September 30, 2000, and will be made for a 12-month budget period, within a project period of up to 4 years. Funding estimates may change.

Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

#### D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities listed under

1. (Recipient Activities), and CDC will be responsible for conducting activities listed under 2. (CDC Activities).

##### 1. Recipient Activities

Applicants addressing the same research issue should be willing to participate in collaborative studies with other CDC-sponsored researchers, including developing and using common data collection instruments, specimen collection protocols, and data management procedures, as determined in post-award grantee planning conferences. Recipients will be required to pool data for analysis and publication. Recipients are also required to work collaboratively as a study group to:

- a. Develop the research study protocols and standardized data collection forms across sites.
- b. Identify, recruit, obtain informed consent from, and enroll an adequate number of study participants as determined by the study protocols and the program requirements.
- c. Follow study participants as determined by the study protocols.
- d. Establish procedures to maintain the rights and confidentiality of all study participants.
- e. Perform laboratory tests (when appropriate) and data analysis as determined in the study protocols.
- f. Collaborate and share data and specimens (when appropriate) with other collaborators to answer specific research questions.
- g. Contribute blood specimens for drug resistance and therapeutic drug level studies for the intervention studies depending on the protocol requirements, for shipment and storage at a centralized repository system at CDC.

h. Conduct data analysis with all collaborators as well as present and publish research findings.

i. Attend biannual meetings with other funded grantees.

##### 2. CDC Activities

a. Provide technical assistance as needed in the design and conduct of the research.

b. Facilitate and assist in the development of a research protocol for Institutional Review Board (IRB) review by all cooperating institutions participating in the research project. The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.

c. Assist as needed in designing a data management system.

d. Assist as needed in performance of selected laboratory tests.

e. Work collaboratively with investigators to help facilitate research activities across sites involved in the same research project.

f. Assist in the analysis of research information and the presentation and publication of research findings.

#### E. Application Content

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop your application. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. Follow the directions for completing the application that are found in the Public Health Service (PHS) 398 kit. If you are applying for more than one activity, you must submit a separate application for each research area.

#### F. Submission and Deadline

Submit the original and five copies of PHS-398 (OMB Number 0925-0001) (adhere to the instructions on the Errata Instruction Sheet for PHS 398). Forms are available at the following Internet address: [www.cdc.gov/...Forms](http://www.cdc.gov/...Forms), or in the application kit. On or before August 21, 2000, submit the application to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

**Deadline:** Applications shall be considered as meeting the deadline if they are either:

- (a) Received on or before the deadline date; or
- (b) Sent on or before the deadline date and received in time for submission to the independent review group. Applicants must request a legibly dated U.S. Postal Service postmark or obtain

a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.

**Late Applications:** Applications that do not meet these criteria are considered late applications, will not be considered, and will be returned to the applicant.

#### G. Evaluation Criteria

Each application will be evaluated individually against the following criteria by an independent review group appointed by CDC. Applicants will be ranked on a scale of 100 maximum points according to the research area identified. All applicants must state which research category they are addressing. Applications must demonstrate the applicant's ability to address the research in a collaborative manner with other recipients. Applications will be reviewed and evaluated based on the information submitted, as they specifically describe the applicant's abilities to meet the following criteria:

##### 1. Familiarity With and Access To Study Population (25 Points)

a. Description of population to be studied, including number, age distribution, and other relevant demographic characteristics is described. The number of HIV-exposed (for Part I) and HIV-infected enrollees (for Parts I–III) to be prospectively monitored, and expected attrition from deaths and losses to follow-up over the study period based on prior experience is specified.

b. Description of the most important trends in disease progression, HIV and other health care needs, including gaps in services, of the population to be studied (e.g. HIV-exposed children, HIV-infected children, HIV-infected adolescents, HIV-infected mothers).

c. Ability to access and review neonatal, pediatric, adolescent and maternal prenatal and labor and delivery records. (Part I)

d. Ability to recruit at least 100 children for the pediatric intervention (Part II) or 50 adolescents for the adolescent intervention. (Part III)

e. Ability to identify and follow HIV-exposed but HIV-uninfected children and HIV-infected children for Part I, HIV-infected children between 5–12 years of age for Part II, and HIV-infected adolescents between 13–21 years of age for Part III. In addition:

- (1) For part I, describes the plan to match HIV-exposed children over time (as long as they are followed in the study and after they are lost to follow-

up) with death, congenital birth defect, cancer and other registries to investigate potential severe side effects of antiretroviral exposure.

(2) For Part III, describes the sites where the majority of HIV-infected adolescents are being diagnosed (if "linkages to care" is included as a research area).

f. Prior research with or service provision to the study population and linkages and collaboration with other organizations providing medical and psychosocial services to the study population. As appropriate, include memoranda of agreement to document collaboration with organizations providing services to the study population.

g. Feasibility of plans for involving the service providers in the design and implementation of research activities.

h. Extent to which intervention plans take developmental stages into account and are appropriate for the population described. (Parts II and III)

i. Existence of linkages to facilitate monitoring the study population (all parts) including memoranda of agreement from the clinical facilities to permit record review. (Part I)

j. Demonstrated collaboration with local health departments and pediatric HIV/AIDS surveillance staff. (Part I)

## 2. Description and Justification of Research Plans (25 Points)

a. Quality of the review of the scientific literature pertinent to the proposed activities, including justification for and relevance of research questions and the proposed intervention. The research issues and a description of which ones must be addressed are described under the Purpose/Areas of Research section.

b. The applicant's understanding of the research objectives as evidenced by high quality of the proposed research plan.

c. The scientific soundness of the methods described by the applicant to:

(1) Abstract data and assure adequate follow-up of the pediatric, adolescent and maternal populations and timely completion of data forms and transfer of data to CDC (Part I)

(2) Develop and evaluate interventions in children 5–12 years of age (Part II), including:

(i) Review laboratory and disease indicators of (highly antiretroviral therapy) HAART failure in children 5–12 years of age (e.g. CD4 counts, HIV viral loads, history of AIDS defining conditions);

(ii) Interview children and their parents about factors potentially

relevant to the children's treatment failure or success;

(iii) Design and operationalize standard and enhanced innovative interventions;

(iv) Randomize participants to one of the interventions and deliver the interventions;

(v) Monitor participants through the end of the study (e.g. monitor adherence to medications, measure drug levels, review laboratory and disease indicators of HAART failure, collect blood spots to measure ARV drug resistance); and

(vi) Evaluate the effectiveness of the interventions, including its cost-effectiveness.

(vii) Develop and deliver an intervention to HIV-infected adolescents from 13–21 years of age, monitor participants through the end of the study and evaluate the effectiveness of the intervention (Part III).

d. Ability and feasibility of collecting additional information from the medical records around the following areas (for Part I):

(1) Issues specific to adolescents;

(2) Issues specific to adherence to medical regimens; and

(3) Laboratory results related to ARV drug resistance.

e. Adequacy of methods for quality assurance including: Supervision of data abstraction, entry and cleaning, validation of accuracy and completeness of data abstraction and data entry, maintenance of consistency in methodology used by abstractors and data entry clerks in their procedures, and monitoring of study progress (Part I).

(1) Training and supervision of staff conducting interventions to ensure consistency in the methodology used for the intervention across all participants. (Parts II and III)

(2) Tracking follow-up of HIV-exposed children (Part I), HIV-infected children (Parts I and II), HIV-infected adolescents (Parts I and III) and HIV-infected mothers (Part I). This should include a description of the experience of the investigator in enrolling and monitoring the population to be studied (all parts) and the procedures used to ensure that participants will complete the interventions. (Parts II and III)

f. Scientific soundness, creativity and thoroughness of plans to analyze local data using quantitative methods and statistical techniques. (Parts I, II, and III).

g. Extent to which the intervention (Parts II and III):

(1) Represents an innovative approach.

(2) Meets unmet needs.

(3) Complements existing interventions.

(4) Avoids duplication of efforts.

(5) Incorporates cutting edge technology (e.g., MEMS®Caps, computer based interviews).

h. Adequacy of plans to disseminate research findings locally (including local collaborating service providers and participants of the study).

i. Extent to which study proposal demonstrates assurance of compliance with multisite research requirements (e.g., common protocol, data collection, and computer and data management systems).

j. The degree to which the applicant has met the CDC Policy requirements regarding the inclusion of ethnic and racial groups in the proposed research. This includes: (1) The proposed plan for the inclusion of racial and ethnic minority populations for appropriate representation; (2) The proposed justification when representation is limited or absent; (3) A statement as to whether the design of the study is adequate to measure differences when warranted; (4) A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with communities and recognition of mutual benefits.

k. Extent to which application identifies and discusses any potential ethical issues associated with the proposed research and describes how these issues will be resolved.

(1) Describes procedures for obtaining IRB approval and maintaining participant confidentiality.

(2) Describes whether there are any additional IRB issues involved in: Reviewing mothers' medical records (Part I.) and matching ARV-exposed children to other registries after they are lost to follow-up to identify potential long term severe side effects which might be associated with ARV prophylaxis (e.g., how long can names be maintained at the local level for matching purposes?).

(3) Describes the state laws about obtaining informed consent in children and their parents (e.g., assent of children > 7 years of age, parental consent) and adolescents for the purposes of conducting an intervention. (Parts II and III).

(4) Describes the state laws for considering an adolescent as an "emancipated minor". (Part III)

(5) Notes whether the site currently has an IRB which has the authority to provide an assurance for the project being proposed or if not, whether they will need assistance from CDC in applying for such an assurance.

The degree to which the applicant has met the CDC Policy requirements

regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes:

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

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

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

4. 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.

**3. Provision of HIV/AIDS Report Data to and Collaboration With Local Pediatric or Adults HIV/AIDS Surveillance Activities (10 Points)**

a. Adequacy of procedures for collaborating with local health department pediatric or adult HIV/AIDS surveillance staff to report children or adolescents with HIV exposure, infection, and/or AIDS (depending on state law). Includes a signed memorandum of agreement detailing the outlined division of responsibilities, joint activities to evaluate completeness, timeliness, validity of the HIV/AIDS report data, methods to ensure security and confidentiality of HIV/AIDS report data, and use of data (Part I.)

b. Feasibility of plans for completion and computer entry of HIV/AIDS report forms and complete and timely transfer of HIV/AIDS case reports to the local HIV/AIDS surveillance unit. (For Part I)

c. Adequacy of measures to assure completeness of HIV/AIDS report forms, data quality and timeliness, and protection of confidentiality. (For Part I)

d. Adequacy of measures to assure timely reporting of HIV/AIDS cases among children and adolescents participating in the intervention studies to the local HIV/AIDS surveillance if mandated by state law, and to assure protection of confidentiality. (For Parts II and III)

**4. Demonstration of Staff's Capability To Conduct Research (20 Points)**

a. Capacity to conduct the proposed activities as evidenced by previous experience and scientific expertise. Demonstration that staff has:

(1) Experience working with the targeted population of study participants;

(2) Principal investigators or staff have previous experience and scientific expertise in the area of research to be conducted (either in epidemiologic research in Part I or behavioral

assessment, intervention, and evaluation research, including evaluation of cost-effectiveness, for Parts II and III. ). Include table of current and previous relevant research projects, their status, sources and levels of funding and principal investigators and list of references of any publications on related research by study staff.

(3) The experience needed to conduct the intervention (e.g., nurse counselor, or study coordinator, etc.)

b. Inclusion of the curriculum vitae for key staff members as well as memoranda of agreement that clearly and specifically document activities to be performed by any external experts, consultants, or collaborating agencies under the cooperative agreement.

**5. Staffing, Facilities, and Time Line (20 Points)**

a. Availability of qualified personnel with realistic and sufficient percentage-time commitments;

b. Clarity of the described duties and responsibilities of existing and proposed project personnel with epidemiologic, administrative, clinical, data management (including HIV/AIDS case reporting to local surveillance unit), and statistical responsibilities.

Organizational chart depicts lines of authority.

c. Adequacy of clinical oversight of the project, especially supervision of data abstraction and entry.

d. Adequacy of base staff to keep pace with anticipated workload such as the biannual medical record review for the number of children to be monitored prospectively (Part I) and the interventions involved with children (Part II) and adolescents (Part III).

e. Adequacy of equipment, facilities and systems to be used for data abstraction and follow-up tracking, data entry and analysis, project management, data security and participant confidentiality.

f. Feasibility of plans to communicate, ensure quality control and consistency, identify and resolve problems, and analyze data in collaboration with other sites.

g. Inclusion of time line showing plan for completion of research activities and goals

**6. Other (Not Scored)**

a. Budget: The extent to which it is reasonable, clearly justified, consistent with the intended use of funds, and allowable. All budget categories should be itemized.

b. Human Subjects: Does the application adequately address the requirements of Title 45 CFR part 46 for

the protection of human subjects?

—Yes No Comments:

**H. Other Requirements**

*Technical Reporting Requirements Provide CDC With Original Plus Two Copies of—*

1. annual progress reports;

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

3. final financial status and performance reports, no more than 90 days after the end of the project period. Send all reports to the Grants Management Specialist identified in paragraph J. Where to Obtain Additional Information.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment 1 in the application kit.

AR-1—Human Subjects Requirements

AR-2—Requirements for Inclusion of

Women and Racial and Ethnic

Minorities in Research

AR-4—HIV/AIDS Confidentiality Provisions

AR-5—HIV Program Review Panel Requirements

AR-6—Patient Care

AR-7—Executive Order 12372 Review

AR-8—Public Health System Reporting Requirements

AR-9—Paperwork Reduction Act Requirements

AR-10—Smoke-Free Workplace Requirements

AR-11—Healthy People 2010

AR-12—Lobbying Restrictions

**I. Authority and Catalog of Federal Domestic Assistance Number**

This program is authorized under sections 301(a) and 317(k)(2) of the Public Health Service Act (42 U.S.C. 241(a) and 247b(k)(2)), as amended. The Catalog of Federal Domestic Assistance number is 93.943.

**J. Where To Obtain Additional Information**

This and other CDC announcements can be found on the CDC home page Internet address—<http://www.cdc.gov> Click on “Funding” then “Grants and Cooperative Agreements.”

To receive additional written information and to request an application kit, call 1-888-GRANTS4 (1-888-472-6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from:

Brenda Hayes, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), Room 3000, 2920 Brandywine Road, Atlanta, GA 30341-4146, telephone number (770) 488-2741, Email address: BHayes@cdc.gov

For program technical assistance, contact: Jeff Efird, MPA, Deputy Chief, Epidemiology Branch, Division of HIV/AIDS Prevention Surveillance & Epidemiology, National Center for HIV, STD, TB Prevention, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop E-45, Atlanta, Georgia 30333, Telephone (404) 639-6130, E-mail: jle1@cdc.gov

Dated: July 5, 2000.

**Ron Van Duyn,**

*Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 00-17445 Filed 7-10-00; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[Program Announcement 00134]

**Leadership and Investment in Fighting an Epidemic (LIFE) Global AIDS Activity; Notice of Availability of Funds**

**A. Purpose**

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2000 funds for a cooperative agreement program to increase United States support for sub-Saharan African countries and India to limit the further spread of HIV and to care for those affected by this devastating disease.

This additional funding is an action by the United States (U.S.) Government recognizing the impact that AIDS continues to have on individuals, families, communities and nations, and the need to do more. Over the next 5 years, it is expected that these activities will contribute to global targets established by the Joint United Nation Programme on AIDS (UNAIDS), in cooperation with the United States Agency of International Development (USAID) and other bilateral and multi-lateral partners. These goals represent the result of the total worldwide contribution of resources and effort. The U.S. Government seeks to further these goals through the LIFE Initiative:

- The incidence of HIV infection will be reduced by 25% among 15-24 year olds by 2005. (Currently 2 million young adults are infected each year in sub-Saharan Africa.)

- At least 75% of HIV infected persons will have access to basic care and support services at the home and community levels, including drugs for common opportunistic infections (TB, pneumonia, and diarrhea). (Currently, less than 1% of HIV infected persons have such access.)

- Orphans will have access to education and food on an equal basis with their non-orphaned peers.

- By 2002, domestic and external resources available for HIV/AIDS efforts in Africa will have doubled to \$300 million per year. (Currently, approximately \$150 million per year is spent on HIV/AIDS prevention in sub-Saharan Africa.)

- By 2005, 50% of HIV infected pregnant women will have access to interventions to reduce mother-to-child HIV transmission. (Currently, less than 1% of HIV infected pregnant women have access to such services in sub-Saharan Africa.) As a key partner in the U.S. Government's Leadership and Investment in Fighting an Epidemic (LIFE) Initiative, CDC, through its Global AIDS Activity (GAA) is working in a collaborative manner with national governments, USAID and other international partners to develop programs of assistance to address the HIV/AIDS epidemic in countries designated as LIFE countries by the U.S. Congress. At present, those countries are Botswana, Cote D'Ivoire, Kenya, South Africa, Uganda, Rwanda, Zimbabwe, Ethiopia, Mozambique, Malawi, Tanzania, Nigeria, Senegal, Zambia and India.

The overall objectives of the CDC's GAA are to:

- Reduce HIV transmission through primary prevention of sexual, mother-to-child, and blood transmission.

- Strengthen the capacity of countries to collect and use surveillance data and to manage national HIV/AIDS programs.

- Improve community and home based care and treatment of HIV and sexually transmitted diseases (STDs) and opportunistic infections.

**B. Eligible Applicants**

*Applicants must:* (1) Be a U.S. Private Volunteer Organization (PVO), and have been granted tax-exempt status under Section 501(c)(3), evidenced by an Internal Revenue Service (IRS) determination letter; and (2) have at least 2 years experience in delivering HIV, STD, or TB prevention and care programs and/or prenatal/obstetric/

reproductive programs in accordance with GAA objectives in at least 5 of the 15 countries (Botswana, Cote d'Ivoire, Ethiopia, Kenya, Malawi, Mozambique, Nigeria, Rwanda, Senegal, South Africa, Tanzania, Uganda, Zambia, Zimbabwe, India).

**Note:** Public Law 104-65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan or any other form.

**C. Availability of Funds**

Approximately \$5,000,000 is available to fund up to 4 awards in FY 2000. It is expected that awards will begin September 30, 2000, and will be made for a 12-month budget period within a project period of up to 5 years. Funding estimates are subject to change.

CDC expects to allocate \$5,000,000 into 2 categories of program activities and services: (A) primary prevention (approximately 70% of available funds), and (B) care, support, and treatment (approximately 30% of available funds). These estimates may vary. In making these awards, CDC will use the "CDC Global AIDS Activities Technical Strategies" as a guide for selecting collaborative activities to be funded (See Attachment I).

Continuation awards within an approved project period will be made on the basis of the availability of funds and the applicant's satisfactory progress toward achieving defined objectives.

Satisfactory progress toward achieving objectives will be determined by progress reports and site visits conducted by CDC representatives.

*Use of Funds*

Funds received from this announcement will not be used for the purchase of antiretroviral drugs for treatment of established HIV infection, 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.

Applicants may contract with other organizations under these cooperative agreements, however, applicants must perform a substantial portion of the activities (including program management and operations and delivery of prevention services for which funds are requested).

*Funding Preference*

Funding will be given to ensuring a geographic distribution of awards covering the 15 GAA countries in African and India.