Contact, ATSDR, M/S E–56, 1600 Clifton Road, NE, Atlanta, GA 30333, telephone 404/639–6002.

The Director, Management Analysis and Services office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: July 3, 2000.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 00–17292 Filed 7–7–00; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY–47–00]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–7090. Send written comments to CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Projects

AIDS Prevention and Surveillance Project Reports (0920–0208)—extension—National Center for HIV, STD, and TB Prevention (NCHSTP), Centers for Disease Control and Prevention (CDC)—proposes to continue data collection for the AIDS Prevention and Surveillance Project Reports, previously approved under OMB No. 9020–0208. This request is for a 3-year extension of clearance. CDC funds cooperative agreements for 65 HIV Prevention Projects (50 states, 6 cities, 7 territories, Washington, D.C., and Puerto Rico). The cooperative agreements support counseling, testing, referral, and partner notification programs conducted by official public health agencies of states, territories, and localities (project areas). HIV counseling and testing in STD clinics, Women's Health Centers, Drug Treatment Centers, and other health agencies has been described as a primary prevention strategy of the national HIV Prevention Program. These project areas have increased HIV counseling and testing activities to specifically reach more minorities and women of child bearing age.

CDC is responsible for monitoring and evaluating HIV prevention activities conducted under the cooperative agreement. Counseling and testing programs are a major component of the HIV Prevention Program. Without data to measure the impact of counseling and testing programs, priorities cannot be assessed and redirected to prevent further spread of the virus in the general population. CDC needs information from all project areas on the number of at-risk persons tested and the number positive for HIV. The HIV Counseling and Testing Report Form provides a simple yet complete means to collect this information.

Respondents will be able to use either a manual or an electronic scan form. Seventeen respondents (project areas) will use the manual data collection tool. It takes approximately 2 hours to complete the form. The respondents will complete the form 4 times each year for a total burden of 8 hours per year per project area. Forty-eight (48) respondents (project areas) will use the scan form or client record format. It will take approximately 15 minutes for each project area to transfer data electronically on a quarterly basis for a total burden per project area of 1 hour per year. Therefore, the total annualized burden hours are 184. This request is for a 3 year extension.

Respondents	Number of respondents	Number of responses per respondent	Average burden response (in hrs.)
Manual Form Project Areas	17	4	2
Scan Form Project Areas	48	4	.25

Dated: June 30, 2000.

Kathy Cahill,

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

[FR Doc. 00–17177 Filed 7–7–00; 8:45 am]

BILLING CODE 4163–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 00006]

Intervention Epidemiologic Research Study 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 support a prospective study to develop and evaluate the role of different levels of assistance with and observation of the administration of antiretroviral (ARV) therapy for the treatment of HIV–1 infection. This program addresses the ''Healthy People 2010'' focus area of HIV.

The purpose of the program is to investigate whether different levels of support have an impact on: improving virologic, immunologic, and clinical outcomes of HIV disease; on the development of HIV–1 ARV drug resistance; and on therapeutic plasma drug concentrations. Innovative applications are invited that assess the impact of three different levels of administration and oversight of antiretroviral treatment: (1) Directly observed antiretroviral therapy (DART), the relative ''gold standard'' of what is achievable with maximum adherence support—any setting or system in which antiretroviral medications are routinely dispensed by dose and per-dose medication record is kept. Possible examples of such settings include but

are not limited to residential treatment facilities, prisons, and methadone clinics; (2) Standard of care: provision of the level of support typically available through comprehensive HIV care clinics, and may include measures such as individual counseling, group counseling, and use of ancillary aids; (3) Intensive adherence support: any setting or system for support in which the HIV-infected person has at least weekly, and ideally more frequent, contact with the adherence support model. Possible settings include but are not limited to day health centers, methadone clinics, or visiting/home services. This arm could allow for the development or refinement of creative adherence support systems that may be integrated into ongoing care and services.

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.

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 $400,000 is available in FY 2000 to fund approximately 2 awards. It is expected that the average award will be approximately $200,000. It is expected that the 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 four 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 these programs, 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

Successful applicants addressing the same research issue should be willing to jointly develop the study protocol in collaboration with other CDC-sponsored researchers. This will include 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 encouraged to work collaboratively as a study group to:

a. Develop the research study protocols and standardized data collection forms, specimen collection, and laboratory testing across sites. This includes transfer of certain specimens to a central repository and transfer of other specimens to designated laboratories for specific laboratory studies.

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. Continue to follow study participants as determined by the study protocols.

d. Establish procedures to maintain the rights and confidentiality of all study participants.

e. Contribute blood specimens of study participants as determined by the protocol requirements for shipment and storage at a centralized repository system.

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

2. CDC Activities

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

b. 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 in designing a data management system.

d. Assist 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 form.

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 in the application kit.

On or before August 17, 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:

(1) Received on or before the deadline date; or

(2) 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 or timely mailing.

Late Applications: Applications that do not meet the criteria in (1) and (2) above 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. 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 evidence submitted, as they specifically describe the applicant's abilities to meet the following criteria:

1. Recruitment, Retention, and Adherence to Study Protocol (35 Points)

a. Extent of applicant's experience in HIV infection epidemiologic research.

b. Evidence of ability to successfully recruit and follow HIV-infected persons in longitudinal research studies.

c. Evidence of ability to provide at least two or preferably three types of adherence support: DART (each dose dispensed and per-dose medication record kept); intensive adherence support (at least weekly and ideally more frequent contact with care model);

and standard of care (such as support provided at comprehensive HIV treatment clinics).

d. Ability to recruit and retain at least 50 and ideally 100 HIV-infected persons in each adherence model annually (150–300 persons total) fulfilling the objectives of the study. Multiple sites may be used to accomplish these goals.

e. Evidence of availability of comparable populations among the three adherence models, especially with regards to stage of disease, quality of clinical care, and antiretroviral experience.

f. Evidence of ability to collect complete data and to obtain regular blood samples and sufficiently large blood samples from HIV-infected persons for testing as will be determined in the study protocol.

g. Ability to oversee specimen collection for the timely processing, storage, and retrieval of laboratory specimens as needed for the study.

h. Ability to measure costs associated with adherence interventions as well as those associated with HIV care provision.

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

a. Extent of familiarity and quality of experience pertinent to proposed research activities.

b. Understanding of research objectives as evidence by the high quality and scientific rigor of the proposed plan for research and a study design that is appropriate to answer research questions.

c. The inclusion of innovative approaches to provide intensive adherence support. These approaches may be existing or may be designed and implemented specifically for this study.

d. As more than one applicant may be funded, extent to which the applicant demonstrates willingness to work with all successful applicants to develop a common core research protocol across funded sites.

e. Feasibility of plans to follow study participants particularly treatment experienced patients. This includes demonstration of the experience of the investigator in following HIV-infected persons, and the comprehensiveness of the plan to protect the rights and confidentiality of all participants.

f. Thoroughness of plans for data management, data analysis, and laboratory analysis; reasonableness of data collected; and statistical rigor.

g. Extent to which the application demonstrates feasible plans for coordinating research activities of multiple local study sites, where appropriate, and with CDC. Letters of support from cooperating organizations that demonstrate the nature and extent of such cooperation should be included.

h. 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 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.

3. Research and Intervention Capability (20 Points)

a. Applicant's ability to carry out the proposed research as demonstrated by the training and experience of the proposed research team and organizational setting, including demonstration of ability to collect, manage, and analyze accurate data in a timely manner.

b. Demonstration of working relationships with the proposed investigators and extent to which services to be provided by external experts or consultants are documented by memoranda of agreement.

c. Demonstration of epidemiologic, behavioral, clinical, administrative, laboratory, data management and statistical analysis expertise needed to conduct proposed research.

d. Ability to sustain adherence support mechanisms at the cessation of study.

4. Staffing, Facilities, and Time line (20 Points)

a. Availability of qualified and experienced personnel with sufficient time dedicated to the proposed project.

b. Clarity of the described duties and responsibilities of project personnel.

c. Adequacy of plans for project oversight to assure quality of data.

d. Adequacy of facilities, equipment, data management resources, and systems for ensuring data security and patient confidentiality.

e. Adequacy of time line for completion of project activities.

5. 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?

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 the ''Where to Obtain Additional Information'' section of this announcement.

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–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. section 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, Announcement 00006, Centers for Disease Control and Prevention (CDC), Grants Management Office Room 3000, Attn: Colgate Building, 2920 Brandywine Rd., Mailstop E–15, Atlanta, GA 30341, telephone (770) 488–2741, Email address bkh4@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, and 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 3, 2000.

Ron Van Duyne,

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

[FR Doc. 00–17294 Filed 7–7–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Grant for Research on the Impact of Laws and Policies on Public Health, Program Announcement #00051

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Grant for Research on the Impact of Laws and Policies on Public Health, Program Announcement #00051.

Times and Dates: 7 p.m.–7:30 p.m., August 1, 2000 (Open); 7:30 p.m.–9:30 p.m., August 1, 2000 (Closed); 8 a.m.–4:30 p.m., August 2, 2000 (Closed).

Place: Airport Crowne Plaza Hotel, Virginia Avenue, Atlanta, Georgia 30344. Telephone 404/768–6660.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement #00051.

Contact Person for More Information: Richard A. Goodman, M.D., M.P.H., Senior Advisor for Science and Policy, Centers for Disease Control and Prevention, 1600 Clifton Road m/s D03, Atlanta, Georgia 30333. Telephone 404/639–7400, email rag4@cdc.gov.

The Director, Management Analysis and Services office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: July 3, 2000.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention CDC.

[FR Doc. 00–17293 Filed 7–7–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food Safety Research: Availability of Cooperative Agreements; Request for Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of research funds for fiscal year (FY) 2000 to support research in the following areas of produce safety, egg safety, development of extraction procedures of foodborne viruses from foods to enhance detection, and food service, transportation, and consumer practices. Approximately $600,000 will be available in FY 2000. FDA anticipates making three to four awards at $100,000 to $200,000 (direct and indirect costs) per award per year. Support of these agreements may be up to 3 years. The number of agreements funded will depend on the quality of the applications received and the availability of Federal funds to support the project. After the first year, additional years of noncompetitive support are predicated upon performance and the availability of Federal fiscal year funds.

DATES: Submit applications by August 24, 2000.

ADDRESSES: Application forms are available from, and completed applications should be submitted to: Maura C. Stephanos, Grants Management Specialist, Grants Management Office (HFA–520), Division of Contracts and Procurement Management, Office of the Director, Food and Drug Administration, 5600 Fishers Lane, rm. 2129, Rockville, MD 20857, 301–827–7183, FAX 301–827–7106, e-mail: mstepha1@oc.fda.gov. (Applications hand-carried or commercially delivered should be addressed to rm. 2129, 5630 Fishers Lane, Rockville, MD 20852).

FOR FURTHER INFORMATION CONTACT: Regarding the administrative and financial management aspects of this notice: Maura C. Stephanos (address above).

Regarding the programmatic aspects of this notice: Marianna D. Miliotis, Food Safety Initiative Extramural Research Coordinator, Office of Plants, Dairy Foods, and Beverages (HFS–327), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4824, e-mail: mmilioti@bangate.fda.gov.

SUPPLEMENTARY INFORMATION: FDA will support the research studies covered by this notice under section 301 of the Public Health Service Act (42 U.S.C. 241). FDA's research program is described in the Catalog of Federal Domestic Assistance, No. 93.103.

The Public Health Service (PHS) strongly encourages all award recipients to provide a smoke-free workplace and to discourage the use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

FDA is committed to achieving the health promotion and disease prevention objectives of ''Healthy People 2010,'' a national activity to reduce morbidity and mortality and to improve the quality of life. Applicants may obtain a hard copy of the ''Healthy People 2010'' objectives, vols. I and II, conference edition (B0074) for $22 per set, by writing to the Office of Disease Prevention and Health Promotion (ODPHP) Communication Support Center (Center), P.O. Box 37366, Washington, DC 20013–7366. Each of the 28 chapters of ''Healthy People 2010'' is priced at $2 per copy. Telephone orders can be placed at the Center on 301–468–5690. The Center also sells the complete conference edition in CD–ROM format (B0071) for $5. This publication is available as well on the Internet at www.health.gov/healthypeople. Internet viewers should proceed to ''Publications.''