an application can be disapproved if the research risks is so inadequate and protection against risks is so inadequate as to make the entire application unacceptable.)

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of

1. Semiannual progress reports;
2. Financial status 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 and;
4. Obtain annual program specific audit by a U.S.-based audit firm with international branches and current licensure/authority in-country, and in accordance with the International Accounting Standards or equivalent standard(s) approved in writing by CDC.

A fiscal Recipient Capability Assessment, pre or post award, may be required with the potential grantee, in order to review their business management and fiscal capabilities in handling of U.S. Federal funds.

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 I of the announcement.

AR–1 Human Subjects Requirements
AR–4 HIV/AIDS Confidentiality Provisions
AR–6 Patient Care
AR–10 Smoke-Free Workplace Requirements
AR–12 Lobbying Restrictions
AR–14 Accounting System Requirements

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 307 of the Public Health Service Act, (42 U.S.C. 2421), as amended. The Catalog of Federal Domestic Assistance number is 93.941.

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 Program Announcement number of interest.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Dorimar Rosado, Grants Management Specialist Grants Management Branch, Procurement and Grants Office Centers for Disease Control and Prevention 2920 Brandywine Road, Room 3000 MS–15 Atlanta, GA 30341–4146 Telephone number: (770) 488–2782 email address: dpr7@cdc.gov.

For program technical assistance, contact: Lawrence H. Marum, M.D., FAAP, MPH CDC LIFE Initiative, PO Box 30137, Nairobi Office: National AIDS/STD Control Programme (NASCOP) Phone: +254–72–721–781 or +254–2–729–549 Fax: +254–2–714–745 Email: Lmarum@nairobi.mimcom.net P.O. Box 30137 Nairobi, Kenya US Mail: Unit 64112 APO, AE 09831–4112

Dated: July 12, 2001.

John L. Williams,

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

[FR Doc. 01–17911 Filed 7–17–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 01138]

Epidemiologic HIV/AIDS Research in African-American and Hispanic Men Who Have Sex With Men; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2001 funds for a cooperative agreement program to support research on the sociocultural, structural, psychological, and behavioral factors that promote HIV infection in African-American and Hispanic men who have sex with men (MSM).

The purpose of the research is to increase understanding of the manner in which these factors relate to the prevalence of HIV infection and incidence of recent infection in these populations. Additionally, under this program, it is expected that the investigators will use the data collected to begin to develop culturally-tailored intervention strategies, although the actual conduct of those interventions will not be part of this cooperative agreement. This announcement addresses goals of CDC's HIV prevention strategic plan through 2005.

Research Study

The program will support four sites to work collaboratively with each other and with CDC investigators in conducting a cross-sectional study that includes HIV testing and counseling. Two sites will be devoted to the recruitment and assessment of African-American MSM, and two sites will be devoted to the recruitment and assessment of Hispanic MSM. Applicants should indicate clearly whether their application pertains to Hispanics or African-Americans. At each site, it is expected that grantees will enroll a minimum of 500 MSM, including gay identified MSM, non-gay-identified MSM, and MSM who inject drugs.

Applicants should develop (1) sampling and recruitment strategies that ensure that the study includes a demographically diverse group of MSM, (2) culturally-sensitive measures of antecedent and outcome variables, including both quantitative and qualitative assessments, (3) a core set of measures that will facilitate ethnic and cultural comparisons, and (4) stringent safeguards for protecting confidentiality of participants.

In conducting the research, it is also expected that grantees will establish a partnership with at least one community-based organization (CBO) to consult on all aspects of conducting the study and to help link participants to prevention and medical services.

We invite applicants to develop protocols and assessment instruments that will increase understanding of a broad array of sociocultural, structural, psychological, and behavioral factors as they relate to HIV infection risk in African-American and Hispanic MSM. These factors may include, but are not limited to:

Cultural attitudes and values
Social and economic discrimination
Social and sexual networks
Acculturation and immigration
Family relations
Community involvement
Experience with and influence of correctional systems
Homophobia
Self-esteem
Resiliency
Religious Beliefs
Beliefs about HIV disease and its treatment
HIV testing history and perceived and actual barriers to testing
Bisexual practices

Drug use
Fluidity of risk behavior

Assessment of the prevalence of HIV infection and incidence of early infection is also a central component of the research. Understanding the risk factors associated with recent HIV seroconversion will inform the design of behavioral interventions. Grantees should be prepared to perform HIV testing of participants using both standard serologic assays and the detuned assay and provide culturally-tailored pre- and post-test counseling and referral to medical care, prevention services, and to other services (social, mental health, drug treatment) as needed. After sites are funded, but before research activities begin, grantees and CDC investigators will work collaboratively to refine the protocols so that they fit together as a whole and address the research issues in a scientifically rigorous manner.

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, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of Samoa, Guam, the Federated States of Mircronesia, the Republic of the Marshall Islands, and the Republic of Palau, 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 $800,000 is expected to be available in FY 2001 to fund up to four awards. It is expected that the average award will be approximately $200,000 in the first year and will begin on September 30, 2001. The award 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, satisfactory participant accrual, and the availability of funds. Increased funding may be available in years two and three after protocols are established and research has started.

Funding Preference

Funding decisions will attempt to achieve regional diversity of the two African-American MSM sites and the two Hispanic MSM sites (e.g., Northeast, South, Central, West). Funding decisions will also take into consideration geographical locations that afford ample numbers of MSM from which to sample and locations that provide the investigators with the opportunity to consult with CBOs in conducting the study.

D. Program Requirements

In conducting activities to achieve the purpose of these programs, the recipient will be responsible for the activities listed under Recipient Activities, and CDC will be responsible for conducting activities listed under CDC Activities:

1. Recipient Activities

Collaborate 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. Attend meeting(s) at CDC to develop collaborative research protocol.

b. Develop the research study protocols and standardized data collection forms across sites.

c. Identify, recruit, obtain informed consent from, and enroll an adequate number of study participants as determined by the study protocols and the program requirements.

d. Follow study participants as determined by the study protocols.

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

f. Perform laboratory tests (when appropriate) and data analysis as determined in the study protocols.

g. Collaborate and share data and specimens (when appropriate) with other collaborators to answer specific research questions.

h. Conduct data analysis with all collaborators.

i. Present and publish research findings.

j. Participate in biweekly conference calls with all collaborators.

k. 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.

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 and at the following Internet address: *www.cdc.gov/od/pgo/forminfo.htm*

On or before August 30, 2001, 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 of timely mailing.)

Late Applications: Applications which do not meet the criteria in 1. or 2. Above 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. Applications will be ranked on a scale of 100 maximum points. Applications will be reviewed and evaluated based on the evidence submitted and the applicant's abilities to meet the following criteria:

1. Familiarity with and Access to Study Population (25 points)

a. Extent of the applicant's knowledge of issues faced by study population and experience in working with the population.

b. Existence of linkages to facilitate recruitment from and referral to programs providing services for the study population and letters of support.

c. Feasibility of plans to involve the study population, their advocates, or service providers in the development of research activities and to inform them of research results.

d. Evidence that plans for recruitment and outreach for study participants will include establishing partnerships with communities.

2. Description and Justification of a Research Plan (40 points)

a. Quality of the review of the scientific literature pertinent to the proposed study, including the theoretical basis for the investigation and relevance of research questions.

b. The originality of the research, including the extent to which it addresses important gaps in knowledge and has strong relevance for guiding behavioral interventions.

c. Applicant's understanding of the research objectives as evidenced by the quality of the proposed research plan and specific study design.

d. Feasibility of plan to sample, recruit, and enroll study participants in a culturally and linguistically appropriate manner. This includes plans for achieving a demographically diverse sample within the African-American or Hispanic MSM populations (including gay identified MSM, non-gay-identified MSM, and MSM who inject drugs), conducting multi-venue sampling, and demonstration of statistical power to address research questions.

e. Feasibility of plan for collecting both quantitative and qualitative research data.

f. Comprehensiveness of the plan to protect the rights and confidentiality of all participants.

g. Feasibility of plan for conducting HIV counseling and testing in a culturally-sensitive manner.

h. Feasibility of plan for collecting, testing, storing, and shipping blood specimens.

i. Thoroughness of statistical analysis plans, including data cleaning, management, and substantive analyses.

j. 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).

k. 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.

3. Demonstration of Staff's Capability to Conduct Research (20 points)

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

b. Evidence of plan for establishing a partnership with at least one CBO to consult on all aspects of conducting the study and to link participants with prevention and medical services as needed.

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

d. Demonstration that principal investigator and staff have experience working with the targeted population of study participants.

e. Demonstration that investigative team includes a staff member with expertise in qualitative data analysis.

4. Staffing, Facilities, and Time-Line (15 points)

a. Availability of qualified personnel with realistic and sufficient percentage-time commitments; clarity of the described duties and responsibilities of project personnel including clear lines of authority and supervisory capacity over the behavioral, epidemiologic, administrative, clinical, laboratory, data management, and statistical aspects of the research.

b. Adequacy of the facilities, equipment, data processing and analysis capacity, and systems for management of data security and participant confidentiality.

c. Adequacy of base staff to keep pace with anticipated workload.

d. Adequacy of time-line for conducting the research.

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? __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.

4. Projects that involve the collection of information from 10 or more individuals and funded by cooperative agreement will be subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Send all reports to the Grants Management Specialist identified in section J (''Where to Obtain Additional Information'') of this document.

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–9 Paperwork Reduction Act Requirements
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2010

AR–12 Lobbying Restrictions

AR–22 Research Integrity

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 ''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: Ann Cole, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement #01138, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Rd., Room 3000, Mailstop E–15, Atlanta, GA 30341, Telephone: (770) 488–2731, Email address: *zlr5@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, Email address: *jle1@cdc.gov*.

Dated: July 12, 2001.

John L. Williams,

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

[FR Doc. 01–17912 Filed 7–17–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–R–215]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Note: For this submission, CMS is requesting public comments on the information requirements in the Final Rule published October 11, 2000 for ''Additional DMEPOS Supplier Standards'' only. CMS made an error in the last PRA submission whereas the ''Surety Bond'' requirements were referenced. Please be advised that all Surety Bond requirements have been removed and are not to be commented on at this time.

Type of Information Collection Request: Revision of a currently approved collection; *Title of Information Collection:* Information Collection Requirements Referenced in 42 CFR 424.57: Additional DMEPOS Supplier Standards; *Form No.:* CMS–R–215 (OMB# 0938–0717); *Use:* The respondents for these information collection requirements are suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). CMS requires, upon request, documentation that the DMEPOS supplier has both advised beneficiaries that they may either rent or purchase inexpensive or routinely purchased equipment and discussed the purchase option for capped rental equipment. This criteria is necessary to determine if the supplier has met the supplier standards; *Frequency:* Annually, On occasion; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 65,400; *Total Annual Responses:* 35,000; *Total Annual Hours:* 280,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards, Attention: Dawn Willinghan, CMS–R–215, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: July 10, 2001.

Julie Brown,

Acting, CMS Reports Clearance Officer, CMS Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards.

[FR Doc. 01–17877 Filed 7–17–01; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1674]

Agency Information Collection Activities; Announcement of OMB Approval; Specific Requirements on Content and Format of Labeling; Geriatric Use Subsection

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Specific Requirements on Content and Format of Labeling; Geriatric Use Subsection'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600