7. Human Subjects (Not Scored)

The extent to which procedures for the protection of human subjects are described and adequately address the requirements of the Department of Health and Human Resources (45 CFR part 46) for the protection of human subjects.

8. Budget (Not Scored)

The extent to which the budget request is clearly explained, adequately justified, reasonable, sufficient for proposed year 1 activities and consistent with the intended use of these cooperative agreement funds.

I. Other Requirements

Technical Reporting Requirements

Provide CDC with the original and two copies of:

1. A semiannual progress report no later than 30 days after the end of each six month period. Semiannual progress reports should include:

a. A brief description of the project;

b. A comparison of the actual accomplishments to the goals and objectives established for the period;

c. Documentation of both the reason for the deviation and the anticipated corrective action or deletion of the activity from the project if established goals and objectives were not accomplished or were delayed; and

d. Other pertinent information, including the analysis of information collected.

2. Financial status reports are required no later than 90 days after the end of each budget period.

3. Final financial status and performance reports are required 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 Addendum 1.

AR–1 Human Subjects Requirements
AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR–9 Paperwork Reduction Act Requirements
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2000
AR–12 Lobbying Restrictions
AR–13 Prohibition on Use of CDC Funds for Certain Gun Control Activities

J. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 301(a), 391, and 393 (42 U.S.C. 241(a), 280b, and 280b–1a) of the Public Health Service Act, as amended. The Catalog of Federal Domestic Assistance number is 93.262.

K. Where To Obtain Additional Information

This and all other CDC Announcements may be found and downloaded from the CDC homepage. Internet address: http://www.cdc.gov (click on funding).

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: Ricky Willis, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99067, Centers for Disease Control and Prevention 2920 Brandywine Road, Suite 3000, Mailstop E–13, Atlanta, GA 30341–4146; Telephone (770) 488–2719; E-mail: rqw0@cdc.gov

For program technical assistance contact: Wendy Watkins, Project Officer, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, 4770 Buford Highway, NE, Mailstop K–60, Atlanta, GA 30341;Telephone (770)–488–1567; E-mail address: dmw7@cdc.gov

Dated: May 19, 1999.

John L. Williams,

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

[FR Doc. 99–13141 Filed 5–24–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 99100]

Human Immunodeficiency Virus (HIV) Related Applied Research and Professional Education Projects; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of funds beginning in fiscal year (FY) 1999 for cooperative agreements to conduct human immunodeficiency virus (HIV) related applied research and professional education in the control and prevention of HIV. The purpose of this program is to encourage new and innovative methods to further the prevention of HIV infection. Projects that will be considered for funding are applied research or professional education for the control and prevention of HIV. This program addresses the ''Healthy People 2000'' priority areas of HIV Infection, Sexually Transmitted Diseases, and Immunization and Infectious Diseases.

National Program Goals

CDC's national strategic goals for the programs supported by the National Center for HIV, STDs and TB Prevention are:

1. Increase public understanding of, involvement in, and support for HIV, STDs, and TB prevention.

2. Ensure completion of therapy for persons identified with active TB or TB infection.

3. Prevent or reduce behaviors or practices that place persons at risk for HIV and STDs infection or, if already infected, place others at risk.

4. Increase individual knowledge of HIV sero status and improve referral systems to appropriate prevention and treatment services.

5. Assist in building and maintaining the necessary State, local, and community infrastructure and technical capacity to carry out necessary prevention programs.

6. Strengthen the current systems and develop new systems to accurately monitor HIV, STDs, and TB, as a basis for assessing and directing prevention programs.

B. Eligible Applicants

Eligible applicants will include universities, colleges, research institutions, hospitals, public and private non-profit organizations, community-based, national, and regional organizations, State and local governments or their bona fide agents or instrumentalities, federally recognized Indian Tribal governments, Indian tribes or organizations.

Note: Pub. L. 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 $500,000 is available in FY 1999 to fund approximately four awards. It is expected that the average award will be $125,000, ranging from $100,000–$300,000. Funding estimates

are subject to change. It is expected that awards will begin in September, 1999, and will be made for a 12 month budget period within a project period of up to three years. Funding estimates are subject to change. Continued support in future years will be based on the availability of funds and success in demonstrating progress toward achievement of objectives.

Program Priority Areas

Funding Priorities

Interested persons are invited to comment on the proposed funding priorities. All comments received within 30 days after publication in the **Federal Register** will be considered before the final funding priority is established. If the funding priority changes because of comments received, a revised announcement will be published in the **Federal Register**, and revised applications will be accepted before the final selections are made. Address comments to the Grants Management Specialist listed in the ''Where to Obtain Additional Information'' section of this announcement.

1. Among HIV-infected persons receiving medical care, prevent development of opportunistic infections and prevent or delay progression to AIDS and death.

2. Develop, pilot, evaluate, and transfer technology of HIV rapid testing and counseling strategies.

3. Among national organizations representing health professionals who provide prenatal or neonatal care, assist in the national dissemination of perinatal HIV transmission information, resources, and interventions to pediatricians, obstetricians, family practitioners, nurse practitioners, and other health care providers.

4. The identification and characterization of recently HIV-infected persons in specific populations or geographic areas; or the assessment of HIV incidence in selected high-risk populations or social networks in geographically-defined communities where HIV incidence is known or expected to be high; or use of HIV incidence data to evaluate prevention interventions.

5. Develop and implement methods to improve access to care of HIV-infected person and to reduce HIV associated morbidity and mortality among persons in medical care.

6. Pilot test, implement, and evaluate perinatal HIV transmission prevention programs to domestic and global prevention partners, e.g., ministries of health, UNAIDS, UNICEF.

D. Program Requirements

Recipient activities to achieve the purposes of this program will vary by project. CDC will be responsible for the activities under CDC Activities.

1. Recipient Activities (applied research).

a. Complete the development of the research protocol.

b. Carry out the activities according to the approved protocol.

c. Ensure that appropriate approvals are secured for the protection of human subjects, Office of Management and Budget and Paperwork Reduction Act, privacy, confidentiality, and data security.

d. Compile and disseminate findings.

2. Recipient Activities (professional education).

a. Develop and disseminate HIV prevention education and training programs and materials.

b. Evaluate the materials and their dissemination.

c. Report and disseminate results and recommendations and relevant HIV prevention and education and training information to appropriate health-care providers, HIV/AIDS prevention and service organizations, and the general public.

3. CDC Activities.

a. Monitor and evaluate scientific and operational accomplishments of the project through periodic site visits, frequent telephone calls, and review of technical reports and interim data analysis.

b. For recipients whose project involves collaboration with a State or local health department, CDC will assist in facilitating the planning and implementation of the necessary linkages with local or State health departments and assist with the developmental strategies for applied clinical or prevention oriented research programs.

c. Facilitate the technological and methodological dissemination of successful prevention and intervention models among appropriate target groups, such as, State and local health departments, community based organizations, and other health professionals.

d. As requested, provide technical assistance in planning and evaluating strategies and protocols.

E. Application Content

Letter of Intent (LOI)

Potential applicants must submit an original and two copies of a two-page typewritten Letter of Intent (LOI) that briefly describes the title of the project, purpose and need for the project, and funding priority which it addresses. Current recipients of CDC funding must provide the award number and title of the funded programs. No attachments, booklets, or other documents accompanying the LOI will be considered.

LOI's will be reviewed by CDC program staff and an invitation to submit a full application will be made based on the documented need for the proposed project, relationship to funding priorities, and the availability of funds. LOI's may focus on more than one programmatic priority area.

An invitation to submit a full application does not constitute a commitment by CDC to fund the applicant.

Application

Applications may be submitted only after a Letter of Intent has been approved by CDC and a written invitation from CDC has been extended to the prospective applicant. Applicants who are invited to submit a full application must 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. The application narrative should consist of:

1. Abstract (Not to exceed 1 page): An executive summary of your program covered under this announcement, specifying whether your program is applied research or professional education.

2. Program Plan (Not to exceed 10 pages): In developing the application under this announcement, please review the recipient activities and, in particular, evaluation criteria and respond concisely and completely.

3. Budget: Submit an itemized budget and supporting justification that is consistent with your proposed program plan.

F. Submission and Deadlines

Letter of Intent (LOI)

One Original and Two Copies of the LOI must be postmarked on or before June 21, 1999. (Facsimiles Are Not Acceptable.)

Application

Submit the original and five copies of the application on Form PHS 398 (OMB Number 0925–0001). Forms are available at the following Internet address: HTTP://WWW.CDC.GOV/OD/PGO/FROMINFO.HTM or in the application kit. On or before July 23, 1999, submit your application to the Grants Management Specialist listed in

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

Deadline: Letters of Intent and Applications shall be considered as meeting the deadline if they are either:

1. Received on or before the deadline date, or

2. Postmarked on or before the deadline date and received in time for submission to the objective review committee. (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.)

Applications that do not meet these criteria are considered late applications and will be returned to the applicant without review.

G. Evaluation Criteria

Letters of Intent responding to this announcement will be evaluated on the documented need for the proposed activities and the relationship to the listed funding priorities.

Each application will be evaluated individually against the following criteria by an independent review group appointed by CDC.

1. Applied Research

a. The inclusion of a brief review of the scientific literature pertinent to the study being proposed and specific research questions or hypotheses that will guide the research. The originality and need for the proposed research, the extent to which it does not replicate past or present research efforts, and how findings will be used to guide prevention and control efforts. (25 points)

b. The quality of the plans to develop and implement the study, including 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 communities and recognition of mutual benefits. (25 points)

c. Extent to which proposed activities, if well executed, support attaining project objectives. (25 points).

d. Extent to which personnel involved in this project are qualified, including evidence of past achievements appropriate to the project, and realistic and sufficient time commitments. Evidence of adequacy of facilities and other resources supported to carry out the project. (25 points).

e. Other (not scored).

(1) Budget: Will be reviewed to determine the extent to which it is reasonable, clearly justified, consistent with the intended use of the funds, and allowable. All budget categories should be itemized.

(2) Human Subjects: Does the application adequately address the requirements of Title 45 CFR part 46 for the protection of human subjects?

2. Professional Education

a. Extent to which the applicant demonstrates the scientific soundness of the technology to be transferred. (25 points)

b. The extent to which the applicant's description of the proposed material relates to HIV prevention and education, responds to a specific public health need, and can be expected to influence public health practices. (25 points)

c. The adequacy and commitment of institutional resources to administer the program. (25 points)

d. The degree to which the application demonstrates that all key personnel have education and expertise relative to its objectives. (25 points)

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

Funding decisions on approved applications will depend on the area of interest of the proposals, their relationship to NCHSTP National Program Goals, and the quality of the application.

H. Other Requirements

Technical Reporting Requirements Provide CDC with original plus two copies of:

1. An annual progress report,

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

3. Final financial status report and performance report, 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 (applied research only)
AR–2—Inclusion of Women and Racial and Ethnic Minorities in Research Requirements (applied research only)
AR–4—HIV/AIDS Confidentiality Provisions
AR–5—HIV Program Review Panel Requirements
AR–6—Patient Care Prohibitions
AR–9—Paperwork Reduction Act Requirements
AR–10—Smoke-Free Workplace Requirements
AR–11—Healthy People 2000
AR–12—Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under the Public Health Service Act, section 317(k)(2)(42 U.S.C. 247b(k)(2)), as amended. The Catalog of Federal Domestic Assistance numbers are 93.941, HIV Demonstration, Research, Public and Professional Education; 93.943, Epidemiologic Research Studies of Acquired Immunodeficiency Syndrome (AIDS) and Human Immunodeficiency Virus (HIV) Infection in Selected Population Groups.

J. Where to Obtain Additional Information

To receive additional written information and to request an application kit, call 1–888–472–6874. You will be asked to leave your name and address and will be instructed to identify the announcement of interest.

This and other CDC announcements are also available through the CDC home page on the Internet. The address for the CDC home page is HTTP://www.cdc.gov.

If you have questions after reviewing the contents of all documents, business management technical assistance may be obtained from: Sheryl Disler, Grants Management Specialist, Grants Management Branch, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Mailstop E–15, Room 3000, Atlanta, GA 30341–4146, telephone (770) 488–2756 or facsimile at (770) 488–2777, or INTERNET address: HTTP://WWW.SJD9@CDC.GOV

You may obtain programmatic technical assistance from: Peggy Bloom, National Center for HIV, STD and TB Prevention, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE, Atlanta, GA 30333, Telephone (404) 639–0927, INTERNET

address: HTTP://WWW.PMB1@CDC.GOV

Dated: May 19, 1999.

John L. Williams,

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

[FR Doc. 99–13140 Filed 5–24–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement Number 99139]

Grants for Minority Health Statistics Dissertation Research; Notice of Availability of Funds; Amendment

A notice announcing the availability of Fiscal Year 1999 funds to fund Grants for Minority Health Statistics Dissertation Research which was published in the **Federal Register** on May 18, 1999, (Vol. 64, No. 95, Pages 26975–26977). The notice is amended as follows:

On page 26975, Second Column, under Section C. Availability of Funds, delete the last two sentences. Add the following sentence:

The awards will be made for a 12-month budget/project period.

Dated: May 19, 1999.

John L. Williams,

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

[FR Doc. 99–13142 Filed 5–24–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–1387]

Agency Information Collection Activities; Agency Emergency Processing Request Under OMB Review; Survey of Licensed Biologics Manufacturers and Registered Blood Establishments for Year 2000 Compliance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information concerns a survey of manufacturers of biological products, including both licensed biologics manufacturers and registered blood establishments, to obtain information about the Year 2000 compliance status of the facilities used to manufacture regulated products. The information will be made available to the public via FDA's web site.

DATES: Submit written comments on the collection of information by June 1, 1999.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j)) and 5 CFR 1320.13. FDA is requesting certain information on the Year 2000 compliance status of biologics manufacturing processes. This information is needed immediately in order to allow the agency to: (1) Assess the impact of the Year 2000 problem on the continued availability of an adequate supply of safe and effective biological products, (2) properly advise the healthcare industry and U.S. public regarding the preparedness of the biologics industry, and (3) assess the need for additional government actions to address potential supply disruptions. This information is essential to the mission of the agency. The potential existence of the Year 2000 problems in the biologics industry could pose potentially serious health and safety consequences. The use of normal clearance procedures would prolong the time needed to assess the Year 2000 compliance by regulated industry.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Survey of Licensed Biologics Manufacturers and Registered Blood Establishments for Year 2000 Compliance

Facilities will be asked to provide information about their Year 2000 readiness. They will also be asked if they have established contingency plans to address potential Year 2000 related problems and if those contingency plans address issues with foreign suppliers. The request will ask licensed manufacturers if they expect to file supplements to their applications for Year 2000 related manufacturing changes or as part of contingency planning. The survey will also request manufacturers to provide information about their plans and capability to increase production should there be an increased demand for their products. The survey will request that respondents identify contact information, including, where available, the address of a web site where more information about their Year 2000 activities can be found. The respondents will be able to provide information via facsimile or paper copy.

FDA intends to use the survey information to provide information to health care providers and the general public on the status of Year 2000 readiness of biologics facilities. FDA needs this information in a timely manner so as to have sufficient time in which to analyze the data received and make the information available.

Respondents: Licensed biologics manufacturers and registered blood establishments.

FDA estimated the number of respondents through its licensing and registration data bases. FDA estimates that it will take firms an average of 18 hours to collect, prepare, and submit the requested information.

FDA estimates the burden for this collection of information as follows: