comments and recommendations for the proposed information collection should be sent directly to the OMB desk officer designated above at the following address: Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street N.W., Washington, D.C. 20503.

Comments may also be sent to Cynthia Agens Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200 Independence Avenue S.W., Washington, DC 20201. Written comments should be received within 30 days of this notice.

Dated: April 20, 2000.

Dennis P. Williams,

Deputy Assistant Secretary, Budget.

[FR Doc. 00–10558 Filed 4–27–00; 8:45 am]

BILLING CODE 4150–04–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 00048]

Patient Follow-Up Study of Prevention of the Joint Complications of Hemophilia; 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 for the Mountain State Regional Hemophilia Treatment Center (MSRHTC), University of Colorado Health Sciences Center to conduct a follow-up study of patients enrolled in a trial of primary prophylactic therapy for the prevention of joint disease in children with hemophilia. CDC is committed to achieving the health promotion and disease prevention objectives of ''Healthy People 2010,'' a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the focus areas of Diabetes. For the conference copy of ''Healthy People 2010'', visit the internet site http://www.health.gov/healthypeople.

The purpose of the program is to provide continued assistance MSRHC in the follow-up of patients enrolled in the current randomized, controlled trial of primary prophylaxis in previously untreated patients with severe hemophilia A and no demonstrable factor VIII inhibitors. Cost and efficacy of early intervention to prevent joint complications should be determined in the treatment groups and should be compared to similar data from appropriately treated, control subjects. The cumulative risk of factor VIII inhibitor development should be determined for each treatment group and total costs and complication rates ascertained as well. Molecular characterization of factor VIII defects in an effort to predict which subjects will develop inhibitors should be carried out.

Further, follow-up of patients will continue to improve understanding of specific public health issues and enhance preparedness to meet changes.

B. Eligible Applicants

Assistance will be provided only to the MSRHTC. No other applications are solicited. The MSRHTC was the only applicant that applied under the original Program Announcement 95019 and was subsequently awarded. It is the only Hemophilia Treatment Center (HTC) capable of carrying out the follow-up of the hemophilia patients enrolled in this clinical trial because they began and continue the enrollment of patients under the original clinical trial. The enrollment of Hemophilia patients for this program will be completed on September 29, 2000, and it is the intention of CDC to allow for a smooth transition into this follow-up study.

MSRHTC already possesses the necessary data required for the follow-up study for the prevention of the joint complications of hemophilia. MSRHTC's patient data is proprietary, and no other HTC would have ready access.

C. Availability of Funds

Approximately $250,000 is available in FY 2000 to fund this award. It is expected that the award 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. The funding estimate 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 under 1. (Recipient Activities), and CDC will be responsible for the activities listed under 2. (CDC Activities).

1. Recipient Activities

a. Develop standardized study protocols, data collection instruments, interview questionnaires, progress report forms.

b. Train study coordinators and medical personnel in methods of data collection and patient assessment in the use of standard data abstraction instruments, in techniques of reviewing medical records, in interviewing patients, and in other methods of data collection as appropriate and provided for in the study protocols. It is the responsibility of the recipient to ensure uniform training of study personnel at all data collection sites. The recipient must ensure that the data is collected in a uniform manner at all data collection sites.

c. Develop appropriate management and evaluation systems to ensure that study personnel use data collection and interview instruments according to standard study protocols.

d. Collect and edit all data from all sites, including cost effectiveness data.

e. Obtain sufficient clinical specimens for specialized laboratory analysis and genetic testing, including plasma and cell pellets, to meet the requirements of the study.

f. Develop papers and publish the results.

2. CDC Activities

a. Provide consultation, scientific and technical assistance in planning and implementing the study protocol, as requested. This assistance may include the development of study protocols, data abstraction instruments, interview questionnaires, consent forms, support in statistical and epidemiologic methods to conduct data analysis, and development of the clinical laboratory specimen testing.

b. Assist in the development of a research protocol for Institutional Review Board (IRB) review by all 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. Collaborate in the planning, coordination, and facilitation of initial and periodic meetings.

d. Perform sufficient clinical specimens for specialized laboratory analysis and genetic testing, including plasma and cell pellets, as requested.

E. Application Content

Use the information in the Purpose, Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. The application should describe MSRHTC's ability to address the purpose and required activities of this announcement. The application

will be evaluated on the criteria listed, so it is important to follow them specifically in laying out the program plan. The narrative should be no more than 20 double-spaced pages, printed on one side, with one inch margins, and unreduced font.

F. Submission and Deadline

Application

Submit the original and two copies of the PHS–5161–1 (OMB Number 0920–0428). Forms are available at the following Internet address: www.cdc.gov/Forms, or in the application kit.

On or before June 1, 2000, submit the application to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

G. Evaluation Criteria

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

1. Background and Need: (10 Points)

Extent to which applicant summarizes new information (literature) on the prevention of joint disease among persons with hemophilia; describes how this information enhances the need for the clinical trial; describes in as much detail as possible, how the study will enhance future management of children less than six years old with hemophilia.

2. Goals and Objectives: (15 Points)

Extent to which the proposed goals and objectives meet the purpose of the collaborative agreement and the required activities specified in the ''Recipient Activities'' section of this announcement and that are measurable, specific, time-phased, and realistic.

3. Capacity: (35 Points)

a. Extent to which knowledge, ability, and experience with primary prophylaxis studies initiated early in life as a form of ''low-dose'' immune tolerance are described in a plan to ensure a high level of follow-up among patients enrolled on the current study. Extent to which applicant describes, in detail, how a high loss to follow-up will affect the results and conclusions that can be drawn from the final analysis of the study. (30 points)

b. Extent to which applicant details the qualifications of the current staff to meet the stated objectives and goals, and the availability of facilities to be used during the project follow-up period. The person (or persons) who will be directly responsible for the follow-up should be identified and their duties specified in detail. (5 points)

4. Methods and Activities: (25 Points)

a. The quality of the applicant's plan for conducting program activities and the extent to which the study design proposed is (1) appropriate to accomplish the stated goals and objectives; (2) acceptable to the needs of the patient population (*e.g.,* likely to produce compliance); and (3) feasible within the programmatic and fiscal restrictions. (10 points)

b. Extent to which applicant demonstrates knowledge of implementing patient follow-up procedures and describes methods for patient follow-up among all currently collaborating sites.

Note: Description of patient follow-up protocol is critical for ascertaining that long-term follow-up of enrolled patients will occur over the project period. The applicant should indicate in the application how they plan to monitor sites to identify problems with maintaining an acceptable loss to follow-up rate as described in section 3.a. above. (15 points)

5. Program Management and Evaluation: (15 Points)

a. Extent to which applicant should describes the information management systems currently available for this study, detailing any system modifications required to accomplish collecting follow-up data versus enrollment data. Extent to which applicant describes, in detail, specific plans to evaluate data on a quarterly basis, quality assurance measures to be used and how operations will be changed based on the above information. Extent to which applicant describes study close-out procedures once all patients have completed follow-up data collection. Extent to which applicant demonstrates adequate biostatistical support for study completion, data management and data analysis. (10 points)

b. 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, 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, and (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. (5 points)

6. Budget

The extent to which the budget is reasonable and consistent with the intended use of the cooperative agreement funds. (Not scored)

7. Human Subjects Requirements

Does the application adequately address the requirements of Title 45 CFR part 46 for the protection of human subjects? (not scored)

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Progress reports quarterly;

2. Financial Status Report (FSR), no more than 90 days after the end of the budget period; and

3. Final FSR 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 I in the application kit.

AR–1 Human Subjects Requirements
AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR–7 Executive Order 12372
AR–9 Paperwork Reduction Act Requirements
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2010
AR–12 Lobbying Restrictions
AR–15 Proof of Non-profit Status

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 301(a) [42 U.S.C. 241(a)] and 317(k)(2) [42 U.S.C. 247b(k)], as amended. The Catalog of Federal Domestic Assistance number is 93.283.

J. Where To Obtain Additional Information

To obtain additional information, contact: Merlin Williams, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146, Telephone: (770) 488–2765, E-mail address: mqw6@cdc.gov.

For program technical assistance, contact: Lisa Richardson, MD, MPH, Hematologic Diseases, Branch, Division of AIDS, STD, and TB Laboratory

Research, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE, Mail-stop E–64. Atlanta, GA 30333, Telephone: (404) 371–5264, E-mail address: lfr8@cdc.gov.

The CDC Homepage address on the Internet is: http://www.cdc.gov

Dated: April 24, 2000.

John L. Williams,

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

[FR Doc. 00–10680 Filed 4–27–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 00053]

Cooperative Agreement for Collaborating Centers for Public Health Law; 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 for the development and operation of a collaborating center (or centers) for public health law. This program addresses all the Healthy People 2010 focus areas, but especially focus area 23, the public health infrastructure objectives. For the conference copy of ''Healthy People 2010'' visit the Internet site: http://www.health.gov/healthypeople.

Laws serve as a framework for public health and can be used as a public health intervention. A large and diverse array of laws and legally enforceable policies of federal, state, and local jurisdictions affect public health. These laws include statutes, ordinances, and bylaws that authorize public health programs and specific authorities of public health agencies and officials; case law; taxes and fees; rules, regulations, and contracts; and laws enacted for other purposes that indirectly or directly affect public health.

Healthy People 2010 recognizes that laws are an essential part of the public health infrastructure, and calls on local, State, Tribal, and federal jurisdictions to ''review and evaluate the extent to which their statutes, ordinances, and bylaws assure the delivery of essential public health services.'' In support of this goal, CDC proposes to fund one or more organizations that will work toward establishing a strong legal foundation for effective public health practice through training and education, collaboration, communication, and analysis. Specific goals of the collaborating center(s) will be to: (a) improve the effectiveness of laws as a type of public health intervention; (b) improve the quality, accessibility, and scientific basis of information about laws related to public health; (c) improve the knowledge of laws related to public health among public health practitioners, the legal community, and public policy makers; and (d) stimulate contributions by organizations and individuals to improvement of the legal foundation for public health. (See Addendum 1 for the definition of the term ''public health law'' used in this announcement.)

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, other public and private nonprofit organizations, and State and local governments or their bona fide agents, and federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations. CDC specifically encourages applications from consortia composed of accredited schools of public health or medicine, accredited schools of law, and accredited schools of public policy and/or public administration.

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 $300,000 is available in FY 2000 to fund one to three awards. 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 3 years. Funding estimates may change, and awards could be supplemented by additional funding.

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

1. Recipient Activities

a. Identify and evaluate existing training and continuing education in the area of public health law for public health practitioners, professionals in the legal community, and public policy makers; develop training and continuing education to address identified gaps; conduct training using both existing and newly developed training and continuing education materials, with priority on training for public health practitioners. Newly developed training and continuing education materials should support core competencies as outlined in Essential Service 6 of ''The Public Health Workforce: An Agenda for the 21st Century''. Addendum 2, full text available at the following Internet site: http://www.health.gov/phfunctions/pubhlth.pdf

b. Research laws that affect public health, addressing the following general objectives: (1) Identify and analyze existing and proposed laws relevant to public health; (2) assess the distribution, provisions, and trends in laws that affect public health; (3) develop and implement a research agenda for public health law with broad stakeholder involvement; (4) synthesize and translate research on laws affecting public health; and (5) disseminate results and findings from analyses.

c. Stimulate collaboration and communication among organizations active in public health, law, public policy, and related fields by developing, linking, and disseminating information regarding laws and public health through an Internet website and/or other means; convening conferences and other meetings; and producing, sponsoring, and disseminating reports, analyses, and other publications.

2. CDC Activities

a. Provide technical assistance to the grantee(s) on an as-needed basis.

b. Collaborate with the grantee(s) to identify appropriate audiences, content, and media for training and continuing education, for information dissemination, for conferences and other meetings, and for publications.

c. Collaborate with the grantee(s) in developing a research agenda for public health law.

d. Provide appropriate scientific information and data relating to prevention, health promotion, public health practice, and related topics.

E. Application Content

Use the information in the Program Requirements, Other Requirements, and