DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 99024]

Prevention of Complications in Hemophilia; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1999 funds for a cooperative agreement program for Prevention of Complications in Hemophilia. This program addresses the ''Healthy People 2000'' priority area of Diabetes and Chronic Disabling Conditions. The purpose of this program is to assist eligible Hemophilia Treatment Centers (HTC) in determining the prospective incidence and risk factors of central venous access device (CVAD) infections in patients with Hemophilia and to assist in the design of interventions to prevent this complication in the future.

B. Eligible Applicants

Assistance will be provided only to comprehensive hemophilia treatment centers (HTCs), defined as public or private, nonprofit entities that provide directly or through contract: (1) regional services to support hemophilia comprehensive treatment centers or (2) diagnostic and treatment services to persons with Hemophilia and other congenital blood disorders. This definition of HTCs is currently used by the Health Resources Services Administration (HRSA) to fund a grant program.

Because of the low prevalence and degree of specialization required in the treatment of hemophilia, competition is limited to hemophilia treatment centers (HTCs) that routinely provide comprehensive health care to two thirds of persons with hemophilia in the United States. HTCs are the only health care facilities administering to the number of persons with hemophilia required for this study.

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 two awards. It is expected that the average award will be $250,000, ranging from $250,000 to $500,000. It is expected that the awards will begin on or about July 15, 1999, and will be made for a 12-month budget period within a project period of up to two 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. below, and CDC will be responsible for conducting activities under 2. below:

1. Recipient Activities

a. Develop standardized study protocols, data collection instruments, and questionnaires to be used across collaborating sites.

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, and in other methods of data collection as appropriate and provided for in the study protocols. It will be the responsibility of the recipient to ensure uniform training of study personnel at all data collection sites and to ensure that the data is collected in a uniform manner at all locations.

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.

e. Develop clinical specimen laboratory testing for successful completion of the research.

f. Publish the results of the study.

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 quesstionnaires, consent forms, support in statistical and epidemiologic methods to conduct data analysis, development of the clinical laboratory specimen testing, and in publication of the results.

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 with recipients to exchange operational experiences.

E. Application Content

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. The narrative should be no more than 20 double-spaced pages, printed on one side, with one inch margins, and unreduced font.

Noncompeting Continuation Applications

For noncompeting continuation applications submitted within the project period need only include:

1. A brief progress report that describes the accomplishments of the previous budget period.

2. Any new or significantly revised items or information (objectives, scope of activities, operational methods, evaluation), that is, not included in year 01 or subsequent continuation applications.

3. An annual budget and justification. Existing budget items that are unchanged from the previous budget period do not need rejustification. Simply list the items in the budget and indicate that they are continuation items.

F. Submission and Deadline

Application

Submit the original and two copies of PHS–5161 (OMB Number 0937–0189). Forms are in the application kit. On or before May 3, 1999, submit the application to: Locke Thompson, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99024, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Mailstop E–18, Atlanta, Georgia 30341.

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

1. Received on or before the deadline date.

2. Sent on or before the deadline date and received in time for submission to the objective review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered

postmarks shall not be acceptable as proof of timely mailing).

Late applications: Applications that do not meet the criteria in (a) or (b) above are considered late applications. Late applications will not be considered in the current competition 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 (Total 100 points).

1. Background and Need

The extent to which the applicant presents data that central venous access devices (CVADs) are utilized in persons with hemophilia and risk factors identified in the literature. The extent to which the applicant compares the experience in persons with hemophilia with other persons with CVADs and the complications they experience, especially infection. The extent to which the applicant discusses the long-term consequences of CVAD and blood stream infections. Does the applicant propose an experimental rationale that would explain why persons with hemophilia would be more susceptible to develop infections with CVADs, especially those with inhibitors? (10 points)

2. Goals and Objectives

The extent to which the applicant's proposed goals and objectives meet the required activities specified under the ''Recipient Activities'' section of this announcement, and that are measurable, specific, time-phased, and realistic. (15 points)

3. Capacity (Total 30 Points)

a. The capacity of the applicant to accrue 380 persons with CVADs currently in place or placed during the first year of the study. Each participating HTC must be able to enroll a minimum of 20–30 patients who meet the above criteria. The capacity to accrue patients to this study will be measured by (1) the number of patients who are seen annually at each HTC, and (2) the average number of CVADs placed in each HTC 3 years prior to the start of the study. (15 points)

b. Qualifications of proposed staff to meet stated objectives and goals, and the availability of facilities to be used during the project period. The applicant should provide evidence that there is experience in collaborating in multi-site studies. (15 points)

4. Methods and Activities (Total 30 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 stated goals and objectives; (2) acceptable to the needs of the patient population (e.g., likely to produce compliance); (3) feasible within programmatic and fiscal restrictions. (20 points)

b. The recipient should demonstrate a basic knowledge and describe how they will implement their protocol at various HTCs; (1) develop progress report forms: (2) and collect and edit the data. (10 points)

5. Program Management and Evaluation

The recipient should demonstrate the ability to design information management systems to ensure that valid and reliable data are collected to achieve the proposed goals and objectives. The applicant should present specific plans to evaluate data periodically, quality assurance measures to be used and operations will be changed based on the above information. The recipient should demonstrate adequate biostatistical support for protocol design, study implementation and data management. The degree to which the applicant has met the CRC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes: (a) the proposed plan for the inclusion of both sexes, racial and ethnic minority populations for appropriate representation, (b) the proposed justification when representation is limited or absent, (c) a statement as to whether the design of the study is adequate to measure differences when warranted, and (d) 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. (15 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)

_____Yes _____No

Comments: _____

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of

1. Progress reports (annual);

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: Locke Thompson, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Mailstop E–18, Atlanta, Georgia 30341.

The following additional requirements are applicable to this program. For the 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–8 PHS Reporting Requirements
AR–9 Paperwork Reduction Act Requirements
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2000
AR–12 Lobbying Restrictions
AR–15 Proof of Non-Profit Status

I. Authority and Catalog of Federal Domestic Assistance Number (CFDA)

This program is authorized under the Public Health Service Act Sections 301(a) [42 U.S.C. 241(a)], 317(k)(1) [42 U.S.C. 247b(k)(1)], 317(k)(2) [42 U.S.C. 247b(k)(2)], as amended. The Catalog of Federal Domestic Assistance number is 93.283.

J. Where To Obtain Additional Information

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 any questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Locke Thompson, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99024, Centers for Disease Control and Prevention (CDC), 2929 Brandywine Road, Mailstop E–18, Atlanta, Georgia 30341, telephone (404) 842–6595, Email address 1xt1.@cdc.gov.

See also the CDC home page on the Internet: *http://www.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., Mailstop E–64. Atlanta, Georgia 30333, telephone (404) 639–4025, e-mail address 1fr8@cdc.gov.

John L. Williams,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Grants to States for Access and Visitation—Program Data.

OMB No.: New.

Description: As required by Paragraphs 303.109(a), (b) and (c) of the PRWROA Act, States are directed to monitor and evaluate their access and visitation programs using a set of criteria aimed at providing detailed descriptions of each funded program. To that end, States will use collection techniques available to the Administration for Children and Families and the Office of Child Support Enforcement.

Specifically, paragraph (a) requires States to monitor all access and visitation programs to ensure that services funded under these programs are: (1) authorized under section 469B(a) of the Act and (2) efficiently and effectively provided while complying with reporting and evaluation requirements, as set forth in paragraphs 303.109(b) and 303.109(c). Paragraph 303.109(b) allows State programs funded by section 469B of the act to be evaluated using data gathered to measure the effectiveness of program operations. States also are required to assist in the evaluation of programs deemed significant or promising by the Department, as directed by program memorandum. Paragraph 303–109(c) requires that States provide a detailed description of each funded program by including such information as: service providers and administrators, service area, population serviced, program goals, application or referral process, referral agencies, nature of the program, activities provided, and length and features of a ''completed'' program. Other required information from the program also includes: number of applicants or referrals for each program, the number of program participants in the aggregate and by eligible activity, and the total number of graduates in the aggregate and by eligible activities (e.g., mediation, education, etc.).

This information is proposed in order to assess: (1) the demand for the program and effectiveness of outreach and ability of the program to meet demand, (2) the service population served and scope and size of the program, and (3) whether such recipients are completing standard program requirements. States would be required to report this information annually, collected at a date and in a form as the Secretary may prescribe in program instructions from time to time.

The Office of Child Support Enforcement will use information gathered from the data collection instrument to report on the programs to the Congress in its annual report. States may use this information to assess demand for any utilization of their programs when considering funding options and make appropriate program changes from year to year. Funded agencies will use the information to assess effectiveness of project administration and design. Public interest groups will use the information to keep apprised of services provided to constituencies.

Respondents: State, Local or Tribal Government.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Access and Visitation	216	1	24	5,184

Estimated Total Annual Burden Hours: 5,184.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW, Washington, DC 20447, Attn: ACF Reports Clearance Officer.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 to 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW, Washington, DC 20503, Attn: Ms. Lori Schack.

Dated: January 29, 1999.

Bob Sargis,

Acting Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Proposed Program Priorities—ACF/ACYF/RHYP 99–1]

Runaway and Homeless Youth Program: Fiscal Year (FY) 1999; Proposed Program Priorities

AGENCY: Family and Youth Services Bureau (FYSB), Administration on Children, Youth, and Families (ACYF), Administration for Children and Families (ACF), HHS.

ACTION: Notice of request for public comments on proposed FY 1999 Runaway and Homeless Youth (RHY) Program Priorities.