

Public Health Service Act, (42 U.S.C. section 241, 247b, and 280b–280b–3), as amended. The Catalog of Federal Domestic Assistance number is 93.136.

J. Where To Obtain Additional Information

This and other CDC announcements, the necessary applications, and associated forms can be found on the CDC home page Internet address—<http://www.cdc.gov>. Click on “Funding” then “Grants and Cooperative Agreements.”

For business management technical assistance, contact: Angie N. Nation, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146. Telephone number: (770) 488–2719. E-mail address: aen4@cdc.gov.

For program technical assistance, contact: Linda Anne Valle, Behavioral Scientist, Division of Violence Prevention, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, 4770 Buford Highway, NE., (K–60), Atlanta, GA 30341–3724. Telephone number: (770) 488–4297. E-mail address: adv2@cdc.gov.

Dated: May 3, 2002.

Sandra R. Manning,

*Director, Procurement and Grants Office,
Center for Disease Control and Prevention.*
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 02088]

Prevention of Complications of Thalassemia; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2002 funds for a cooperative agreement program for Prevention of Complications of Thalassemia. This program addresses the “Healthy People 2010” focus area(s) Access to Quality Health Services and Disability and Secondary Conditions.

The purpose of the program is to assist in: (1) Providing comprehensive healthcare services through a network of thalassemia treatment and prevention centers to prevent complications

through assessment, surveillance, outreach, education, consultation, and management; (2) participating in blood safety monitoring and surveillance efforts; (3) maintaining a prevention evaluation network to assess the efficacy of prevention services; and (4) collaborating with lay organizations to deliver consistent prevention messages aimed at preventing complications.

Measurable outcomes of this program will be in alignment with one or more of the following performance goals for the National Center for Infectious Diseases (NCID):

1. Protect Americans from priority infectious diseases.
2. Apply scientific findings to prevent and control infectious diseases.

B. Eligible Applicants

Assistance will be provided only to specialized thalassemia treatment and prevention centers that provide comprehensive treatment and prevention services to patients with thalassemia.

A thalassemia treatment and prevention center is a specialty, prevention, diagnostic and treatment program. Their goal is to provide family-centered, state-of-the-art medical and psycho-social evaluation and care, dental, educational, nutritional, genetic, research, and support services for individuals and families affected by thalassemia including beta thalassemia major, beta thalassemia intermedia, Hemoglobin H (Hb H) disease, Hb H Constant Spring or another variant.

Applicants must serve a minimum of 25 regularly transfused thalassemia patients (thalassemia major) and be able to demonstrate experience in providing multi-disciplinary treatment and prevention services to patients with thalassemia.

Note: Title II of the United States Code section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant or loan.

C. Availability of Funds

Approximately \$1,000,000 is available in FY 2002 to fund approximately six awards. It is expected that the average award will be \$150,000, ranging from \$100,000 to \$200,000. It is expected that the awards will begin on or about September 1, 2002, and will be made for a 12-month budget period within a project period of up to five 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.

Funding Preference

Preference will be given to applicants with a minimum of 25 patients with severe forms of thalassemia who require chronic blood product transfusion therapy (thalassemia major).

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. The thalassemia treatment and prevention center applicant should develop and coordinate a plan in which a treatment center network within their catchment area would:

(1) Provide comprehensive prevention services to persons with thalassemia directed at attaining and measuring specific outcomes to prevent or reduce complications by using a multi-disciplinary team approach. The treatment center should work closely with other specialists and local health care providers to meet specific needs of persons with thalassemia to increase quality of life from birth throughout life. It should also assist individuals with the prevention and management of complications.

(2) Assess unmet needs and underserved populations. Participate in outreach efforts to identify patients who can benefit from treatment and prevention services and encourage patient participation in treatment center programs.

(3) Participate in development and implementation of CDC surveillance efforts (including the Thalassemia Universal Data Collection Program, investigations of sero-conversions, suspected blood-borne agents, and suspected bacterial contamination), other data collection and surveillance efforts by complying with federal and other required regulations, and offering programs to all active eligible patients to obtain informed consent or refusal.

(4) Identify any patients who have become infected with HIV or hepatitis A, B, C viruses (HAV, HBV, or HCV), new variant Creutzfeld-Jakob Disease (nvCJD), or bacterial contamination possibly as a result of contaminated blood products.

(5) Obtain appropriate assurances as required by the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS). Develop and maintain

strict policies on protecting the confidentiality of patients, and ensure the security of databases and other records through controlled access to areas with confidential information, database password protection, locking file cabinets, and other security features.

(6) Establish a mechanism for consumer input and involvement in planning, implementing, and assessing center prevention activities that include education and outreach by collaborating with local and national consumer organizations, or ad hoc consumer consultation committee.

b. If subcontracting with satellite centers, the applicant should develop appropriate management and evaluation systems to ensure that subcontractors implement the recipient activities of this program appropriately (as outlined in section "D. Program Requirements"), and comply with federal and other required regulations. The applicant should conduct program assessments, site visits, assist treatment centers with problem solving, assess local needs, and provide technical assistance when needed.

c. For all activities, develop and implement an evaluation plan which measures the effectiveness of the activities involved, and document lessons learned.

2. CDC Activities

a. Assist in determining priority areas and long term goals for prevention of complications of thalassemia as a collaborative effort. Encourage treatment and prevention centers to seek input from providers, Community Based Organizations (CBOs), and consumer representatives.

b. Provide consultation, scientific and technical assistance in planning, implementing, and evaluating activities to prevent the complications of thalassemia by using surveillance data to develop interventions and assess their effectiveness. Coordinate the development, implementation, and evaluation of prevention intervention protocols.

c. Assist in the analysis and reporting of aggregate clinical outcomes data, coordinate and consolidate the transfer of tabulated data, analyses, and conclusions among participating treatment and prevention centers, as needed.

d. Provide necessary follow-up and technical assistance, as needed, to treatment and prevention centers implementing changes or recommendations resulting from program evaluations, assessments, or activities required to meet federal and other regulations.

e. Provide technical assistance and coordinate routine annual testing of patient samples for HAV, HBV, HCV, HIV, and other clinically significant tests and reporting of results back to treatment centers. Provide technical assistance to designated laboratory for permanent storage of blood samples.

f. Collaborate with treatment centers and appropriate State or local health departments to investigate any suspected HIV, HAV, HBV, HCV seroconversions, nvCJD, bacterial contaminant or other reported potential blood borne agents.

g. Ensure that surveillance data systems developed through this program will adhere to the National Electronic Disease Surveillance System (NEDSS) Standards as they become available to increase the interoperability of systems and the exchange of data among the users of these systems.

h. 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.

E. Content

Letter of Intent (LOI)

A LOI is optional for this program. The narrative should be no more than three single-spaced pages, printed on one side, with one inch margins, and un-reduced font. Your letter of intent will be used to enable CDC to plan for the review, and should include the following information: (1) The program announcement number 02088, (2) name and address of institution, (3) name, address, and telephone number of a contact person. Notification can be provided by facsimile, postal mail, or electronic mail (e-mail).

Applications

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 25 double-spaced pages, printed on one side, with one inch margins, and un-reduced font.

The application should include:

1. Background, Unmet Need, and Capacity

Describe the need for blood safety monitoring, data collection, education, outreach, and treatment and prevention

services and programs. Explain the basis for providing such programs, expected outcomes and the relevance to preventing complications among people with thalassemia. Describe applicant's experience in providing treatment and prevention services to this population and other activities related to, but not supported by, the cooperative agreement.

2. Objectives

Establish long-term (five year) and short-term (one year) objectives for programmatic plans. Objectives should be specific, measurable, time-phased and realistic.

3. Operational Plan

Describe the methods by which the objectives will be achieved, including their sequence. Address CDC policy requirements as described in the evaluation criteria.

4. Evaluation Plan

Describe the plans to monitor the progress of the program, as well as to evaluate the outcomes of the proposed activities.

5. Program Management

Describe the roles and responsibilities of all project staff in the proposed project, regardless of their funding source. The description should include their titles, qualifications, and experience, as well as the percentage of time each will devote to the project, and the portions of their salaries to be paid by the cooperative agreement.

6. Budget

A detailed first year's budget and budget justification for the cooperative agreement with projections for the next four additional years. Separate detailed budgets with line-item descriptive justifications should be submitted for each sub-grantee if requested. For each performance site (applicant and sub-grantees), include the name and address of the person and organization to receive the contract.

F. Submission and Deadline

Letter of Intent (LOI)

On or before June 15, 2002, submit the LOI to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

Application

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

On or before July 15, 2002, submit the application to: Technical Information Management-PA02088, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Rd., Room 3000, Atlanta, GA 30341-4146.

Deadline: Applications shall be considered as meeting the deadline if they are received on or before the deadline date.

Late: Applications which do not meet the criteria above will be returned to the applicant.

G. Evaluation Criteria

Applicants are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. Measures of effectiveness must relate to the performance goal (or goals) as stated in section "A. Purpose" of this announcement.

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

1. Background and need (20 points)

The extent to which the applicant understands the needs, problems, objectives and complexities of the project. Rationale for selection of the targeted community and documentation of health needs and risk factors.

2. Objectives (15 points)

The degree to which the proposed objectives are clearly stated, realistic, time-phased, and related to the purpose of the project.

3. Operational Plan (Total 35 points)

a. The adequacy of the operational plans for carrying out the various initiatives involved in the project. (30 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 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 community(ies) and recognition of mutual benefits. (5 points)

4. Collaboration (10 points)

The extent of community sanction/liaison. Evidence of access to, interaction with, and participation of collaborative interactions among all project participants. Demonstration of effective communication channels among researchers.

5. Staff Qualifications (5 points)

The extent to which professional personnel proposed to be involved in this project are qualified, including evidence of past achievements appropriate to this project and capacity to fulfill program goals and objectives.

6. Evaluation Plan (10 points)

The quality and feasibility of the evaluation plan for the various initiatives involved in the project.

7. Measures of Effectiveness (5 points)

The extent to which the applicant provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. The extent to which the measures are objective/quantitative and adequately measure the intended outcome.

8. Human Subjects (Not Scored)

The extent to which the application adequately address the requirements of Title 45 CFR part 46 for the protection of human subjects.

9. Budget (Not scored)

The extent to which the applicant provides justification for budget expenditures as well as appropriateness of activities proposed in their application.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with the original plus two copies of:

1. Semiannual progress reports (the progress report will include a data requirement that demonstrates measures of effectiveness).

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.

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 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 Review

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

AR-22 Research Integrity

I. Authority and Catalog of Federal Domestic Assistance Number

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

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 obtain business management technical assistance, contact: Merlin Williams, Grants Management Specialist, Acquisition and Assistance, Branch B, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, MS K75, Atlanta, GA 30341-4146.

Telephone Number: 770-488-2765.

E-mail Address: mqw6@cdc.gov.

For program technical assistance, contact: Sally O. Crudder, Acting Deputy Chief, Hematologic Diseases Branch, National Center for Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road, MS E64, Atlanta, GA 30333.

Telephone Number: 404-371-5270.

E-mail Address: SCrudder@cdc.gov.

Dated: May 4, 2002.

Sandra R. Manning,

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

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