

Service Act, The Catalog of Federal Domestic Assistance number is 93.136.

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.”

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Nancy Pillar, 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 number 770-488-2721. e-mail address: nfp6@cdc.gov.

For program technical assistance, contact: John Hemphill, Project Officer, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, Division of Injury Disability Outcomes and Programs, 4770 Buford Highway, NE, Mailstop KO2, Atlanta, GA 30341-3724. Telephone (770) 488-1285.

Dated: May 4, 2002.

Sandra R. Manning,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 02123]

Parenting Program Attrition and Compliance Efficacy Trial; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announce the availability of fiscal year (FY) 2002 funds for a cooperative agreement program for a Parenting Program Attrition and Compliance Efficacy Trial. This program addresses the “Healthy People 2010” focus area: Injury and Violence Prevention.

The purpose of the program is to test strategies and techniques for reducing attrition and enhancing compliance with extant parenting programs for the prevention of child maltreatment. At a minimum, competitive applicants must have previously demonstrated program

efficacy or effectiveness in enhancing family functioning and reducing child maltreatment. The project should examine rigorous tests of specific interventions focused on enhancing participation and participant compliance in existing efficacious or effective parenting programs.

Measurable outcomes of the program will be in alignment with the following performance goal for the National Center for Injury Prevention and Control: Reduce the risk of child maltreatment.

B. Eligible Applicants

Applications may be submitted by public and private non-profit organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, other public and private non-profit 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 the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau, federally recognized Indian Tribal governments, Indian Tribes, or Indian Tribal Organizations.

Note: Title 2 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 \$400,000 is available in FY 2002 to fund one to two awards. It is expected that the average award will be \$200,000, ranging from \$200,000 to \$400,000. It is expected that the award will begin on or about September 30, 2002 and will be made for a 12 month budget period within a project period of up 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 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) Design and conduct research to address the described goals of this

cooperative agreement. This may include, formative research or pilot work.

(b) Collaborate with CDC in the development of the human subjects protocol for the CDC Institutional Review Board (IRB), implementation and evaluation of project delivery.

(c) Collaborate with CDC to write and disseminate reports of research activities to regional, state, and local partners.

(d) Obtain approval of the study protocol by the recipient's local IRB.

(e) Collaborate with CDC to analyze data, perform cost analyses, and publish findings in peer-reviewed journals.

2. CDC Activities

(a) Provide scientific and technical assistance for the design and implementation of this research.

(b) Collaborate with the grantee in the development of a research protocol for IRB review by all collaborating institutions. The CDC's IRB will review the protocol initially and on an annual basis until the project is complete.

(c) Collaborate with the grantee to ensure human subjects assurances are in place as needed.

(d) Participate in the analysis and dissemination of study findings.

(e) Monitor and evaluate the scientific and operational accomplishments of the project through conference calls, site visits, and review of technical reports.

(f) Provide cost analyses of the design and implementation of this research.

E. Content

Letter of Intent (LOI)

A LOI is optional for this program. The program announcement title and number must appear in the LOI. The narrative should be no more than two pages, double spaced, printed on one side, with one inch margins, and unreduced font. Your letter of intent will be used to enable CDC to determine level of interests in the announcement.

Applications

The Program Announcement title and number must appear in the application. 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 40 pages, double spaced, printed on one side, with one-inch margins, and unreduced fonts. The narrative should consist of, at a minimum, a Plan,

Objectives, Methods, Evaluation and Budget.

F. Submission and Deadline

Letter of Intent (LOI)

On or before June 1, 2002, submit the LOI to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

Application

Submit the application on or before June 24, 2002. Forms are available at the following Internet address:

www.cdc.gov/od/pgo/forminfo.htm.

Application forms must be submitted in the following order:

- Cover Letter
- Table of Contents
- Application (PHS 398)
- Budget Information Form
- Budget Justification
- Checklist
- Assurances
- Certifications
- Disclosure Form
- HIV Assurance Form (if applicable)
- Human Subjects Certification (if applicable)
- Indirect Cost Rate Agreement (if applicable)
- Narrative

On or before 5:00PM Eastern Time June 24, 2002, submit the application to the Technical Information Section, 2920 Brandywine Road, Suite 3000, Atlanta, Georgia 30341.

Deadline: Letters of intent and applications shall be considered as meeting the deadline if they are received before 5 p.m. Eastern Time on the deadline date. Applicants sending applications by the United States Postal Service or commercial delivery services must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If an application is received after closing due to (1) carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or (2) significant weather delays or natural disasters, CDC will upon receipt of proper documentation, consider the application as having been received by the deadline.

Applications which do not meet the above criteria will not be eligible for competition and will be discarded. Applicants will be notified of their failure to meet the submission requirements.

G. Evaluation Criteria

Applicants are required to provide Measures of Effectiveness (*i.e.*, rigorous designs and direct measures of

outcomes with extended follow-up). Rigorous designs could include experimental designs in which families, communities, or other units are randomly assigned to the intervention group (with level to be determined by assessment) and control or comparison groups, or strong quasi-experimental designs in which families, communities, or other units are matched appropriately. Measures of Effectiveness must relate to the National Center for Injury Prevention and Control performance goal of reducing the risk of child maltreatment.

Upon receipt, applications will be reviewed by CDC staff for completeness and responsiveness as outlined under the Eligible Applicants Section (Items 1–5). Incomplete applications and applications that are not responsive will be returned to the applicant without further consideration. It is especially important that the applicant's abstract reflects the project's focus, because the abstract will be used to help determine the responsiveness of the application.

Applications which are complete and responsive may be subjected to a preliminary evaluation (triage) by a peer review committee, the Injury Research Grant Review Committee (IRGRC), to determine if the application is of sufficient technical and scientific merit to warrant further review by the IRGRC; CDC will withdraw from further consideration applications judged to be non-competitive and promptly notify the principal investigator/program director and the official signing for the applicant organization. Those applications judged to be competitive will be further evaluated by a dual review process.

Competitive supplemental grant awards may be made if end of fiscal year funds are available, to support research work or activities not previously approved by the IRGRC. Competitive supplemental applications should be clearly labeled to denote their status as requesting supplemental funding support. These applications will be reviewed by the IRGRC and the secondary review group.

All awards will be determined by the Director of the NCIPC based on priority scores assigned to applications by the primary review committee IRGRC, recommendations by the secondary review committee Advisory Committee for Injury Prevention and Control (ACIPC), consultation with NCIPC senior staff, and the availability of funds.

1. The primary review will be a peer review conducted by the IRGRC. All applications will be reviewed for scientific merit using current National

Institutes of Health (NIH) criteria to evaluate the methods and scientific quality of the application. Factors to be considered will include:

a. **Significance:** Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

b. **Approach:** Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? Does the project include plans to measure progress toward achieving the stated objectives? Is there an appropriate work plan included?

c. **Innovation:** Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge or advance existing paradigms, or develop new methodologies or technologies?

d. **Investigator:** Is the principal investigator appropriately trained and well suited to carry out this work? Is the proposed work appropriate to the experience level of the principal investigator and other significant investigator participants? Is there a prior history of conducting injury-related research?

e. **Environment:** Does the scientific environment in which the work will be done contribute to the probability of success? Does the proposed research take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support? Is there an appropriate degree of commitment and cooperation of other interested parties as evidenced by letters detailing the nature and extent of the involvement?

f. **Ethical Issues:** What provisions have been made for the protection of human subjects and the safety of the research environments? How does the applicant plan to handle issues of confidentiality and compliance with mandated reporting requirements, *e.g.*, suspected child abuse? Does the application adequately address the requirements of 45 CFR part 46 for the protection of human subjects? (An application can be disapproved if the research risks are sufficiently serious and protection against risks is so inadequate as to make the entire application unacceptable.) 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 or communities and recognition of mutual benefits.

g. *Study Samples*: Are the samples sufficiently rigorously defined to permit complete independent replication at another site? Have the referral sources been described, including the definitions and criteria? What plans have been made to include women and minorities and their subgroups as appropriate for the scientific goals of the research? How will the applicant deal with recruitment and retention of subjects?

h. *Dissemination*: What plans have been articulated for disseminating findings?

i. *Measures of Effectiveness*: The peer Review panel shall assure that measures set forth in the application are in accordance with CDC's performance plans (see attachment 4). How adequately has the applicant addressed these measures?

The IRGRC will also examine the appropriateness of the proposed project budget and duration in relation to the proposed research and the availability of data required for the project.

2. The secondary review will be conducted by the Science and Program Review Committee (SPRS) from the ACIPC. The ACIPC Federal *ex officio* members will be invited to attend the secondary review and will receive modified briefing books (*i.e.*, abstracts, strengths and weaknesses from summary statements, and project officer's briefing materials). Federal *ex officio* members will be encouraged to participate in deliberations when applications address overlapping areas of research interest so that unwarranted duplication in federally funded research can be avoided and special subject area expertise can be shared. The NCIPC Division Associate Directors for Science (ADS) or their designees will attend the secondary review in a similar capacity as the Federal *ex officio* members to assure that research priorities of the announcement are understood and to provide background regarding current

research activities. Only SPRS members will vote on funding recommendations, and their recommendations will be carried to the entire ACIPC for voting by the ACIPC members in closed session. If any further review is needed by the ACIPC, regarding the recommendations of the SPRS, the factors considered will be the same as the factors that the SPRS considered.

The committee's responsibility is to develop funding recommendations for the NCIPC Director based on the results of the primary review, the relevance and balance of proposed research relative to the NCIPC programs and priorities, and to assure that unwarranted duplication of federally-funded research does not occur. The Secondary Review Committee has the latitude to recommend to the NCIPC Director, to reach over better ranked proposals in order to assure maximal impact and balance of proposed research. The factors to be considered will include:

a. The results of the primary review, including the application's priority score as the primary factor in the selection process.

b. The relevance and balance of proposed research relative to the NCIPC programs and priorities.

c. The significance of the proposed activities in relation to the priorities delineated in the National Research Agenda.

d. Budgetary considerations.

3. Continued Funding

Continuation awards made after FY 2002, but within the project period, will be made on the basis of the availability of funds and the following criteria:

a. The accomplishments reflected in the progress report of the continuation application indicate that the applicant is meeting previously stated objectives or milestones contained in the project's annual work plan and satisfactory progress demonstrated through presentations at work-in-progress monitoring workshops.

b. The objectives for the new budget period are realistic, specific and measurable.

c. The methods described will clearly lead to achievement of these objectives.

d. The evaluation plan will allow management to monitor whether the methods are effective.

e. The budget request is clearly explained, adequately justified, reasonable and consistent with the intended use of grant funds.

H. Other Requirements

Measures of Effectiveness Requirements

Applicants are required to provide Measures of Effectiveness that will

demonstrate the accomplishment of the various identified objectives of the cooperative agreement. Measures must be objective/quantitative, and must measure the intended outcome. These Measures of Effectiveness shall be submitted with the application and shall be an element of evaluation.

Technical Reporting Requirements

Provide CDC with original plus one:

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.

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 II of the announcement.

AR-1 Human Subjects Requirements

AR-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research

AR-3 Animal Subjects Requirements

AR-4 HIV/AIDS Confidentiality Provisions

AR-5 HIV Program Review Panel Requirements

AR-6 Patient Care

AR-7 Executive Order 12372 Review

AR-8 Public Health System Reporting Requirements

AR-9 Paperwork Reduction Act Requirements

AR-10 Smoke-Free Workplace Requirements

AR-11 Healthy People 2010

AR-12 Lobbying Restrictions

AR-13 Prohibition on Use of CDC Funds for Certain Gun Control Activities

AR-14 Accounting System Requirements

AR-15 Proof of Non-Profit Status

AR-16 Security Clearance Requirement

AR-17 Peer and Technical Reviews of Final Reports of Health Studies—ATSDR

AR-18 Cost Recovery—ATSDR

AR-19 Third Party Agreements—ATSDR

AR-20 Conference Support

AR-21 Small, Minority, Women-Owned Businesses

AR-22 Research Integrity

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 301,317,and 391–394 of the

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 Creutzfeldt-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