

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 01032]

Cooperative Agreement Program with the National Blood Data Resource Center; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2001 funds for a cooperative agreement program with the National Blood Data Resource Center (NBDRC). This program addresses the "Healthy People 2010" focus area of Immunization and Infectious Diseases. For additional information on "Healthy People 2010" visit the internet site: <http://www.health.gov/healthypeople>.

The purpose of the program is to continue an active, nationwide study begun in 1997 of recipients of blood products from identified classic or variant Creutzfeldt-Jakob Disease (CJD) donors to assess the risk of blood-borne transmission of these diseases.

The emergence of human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) and its transmission to patients through blood products has led to continued heightened concerns in the United States about blood safety. These concerns increasingly focused on classic and variant CJD when the latter illness emerged in Europe in the mid 1990s, representing spread of the outbreak of bovine spongiform encephalopathy (BSE, commonly called mad cow disease) to humans.

In the late 1990s, these concerns and several characteristics of classic and variant CJD, such as their severity, their transmissibility, the resistance of the agents to disinfection, and the absence of a practical screening test for infection, has led to an evolving blood safety policy concerning these illnesses. In 2000, this policy has included, for example, newly instituted screening criteria that excludes as blood or plasma donors, anyone with a history of being in the United Kingdom for 6 months or longer between 1980 and 1996, the period of greatest risk for human exposure to the agent of BSE. The policy has also provided for withdrawals of blood components derived from donors who subsequently develop either classic or variant CJD.

The blood safety policy in the United States and the Emerging Infectious Disease Plan elucidated the need for

surveillance projects to detect and improve the understanding of newly recognized potential threats to public health, and to enable meaningful evaluations of the associated public health prevention efforts.

B. Eligible Applicants

Assistance will be provided only to NBDRC. No other applications are solicited.

NBDRC is the only presently existing national, nonprofit organization whose primary functions include collecting and disseminating national data about blood and blood products and coordinating information from multiple blood collection sites. Further, the NBDRC is the only organization that has the professional affiliations already in place that will allow it to generalize data to the entire nation and to ensure that no duplication of data occurs.

NBDRC, because of its earlier participation in the CJD Investigational Lookback Study, has unique possession of the personal identifiers of over 100 living recipients of blood components from reported donors who subsequently developed CJD. Further, NBDRC has the personal identifiers on many donor cases of CJD for which recipient reports have been collected. It is this existing data that is critical to the strength of the statistical power and success of this project.

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 \$50,000 is available in FY 2001 to fund one award. It is expected that the award will begin on or about September 30, 2001, and will be made for a 12-month budget period within a project period of up to five years. The funding estimate may change.

A continuation award 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. Maintain collaborative relationships with U.S. blood banks to identify classic and variant CJD blood donors and gather available, relevant, medical, and demographic information on such donors.

b. Trace classic and variant CJD donor blood components to final disposition.

c. Maintain collaborative relations with final disposition sites and collect vital statistics information from pre-existing records about recipients of the classic or variant CJD blood components.

d. Maintain study information about the recipients of the blood components from classic CJD donors who were previously identified in this study and continue to monitor these recipients' vital status, including the causes of death should they die.

e. Develop a plan that will:

(1) Search national, state, and local organizational databases to match vital statistics and causes of death for the component recipients, including utilizing non-National Death Index databases to confirm the vital status of the component recipients.

(2) Assess the risk of blood-borne transmission of CJD.

f. Publish and disseminate results of the study.

2. CDC Activities

a. Collaborate on investigation, evaluation, and assessment of the reported classic or variant CJD illness in donors and recipients in this project, as appropriate.

b. Provide assistance in development of methodologies and analysis, as needed.

c. Provide technical assistance in data pooling, management, analysis, and interpretation.

d. 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. 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 10 double-spaced pages, printed on one side, with one-inch margins, and unreduced font.

F. Submission and Deadline*Application*

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 available at the following Internet address: <http://www.cdc.gov/...Forms>, or in the application kit.

On or before May 30, 2001, submit the application to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

G. Evaluation Criteria

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

1. Plan (10 points)

Extent to which the applicant presents a detailed operational plan for continuing and conducting the project, and which clearly and appropriately addresses all Recipient Activities.

2. Objectives (15 points)

Extent to which the applicant describes specific objectives for the continuation of the project which are consistent with the purpose of this program, and which are measurable and time-phased.

3. Methods (30 points)

Extent to which the applicant clearly identifies specific assigned responsibilities for all key professional personnel. Extent to which the plan clearly describes the applicant's technical approach/methods for conducting the proposed study and extent to which the plan is adequate to accomplish the purpose. Extent to which the applicant describes specific study protocols, or plans for the continuation of study protocols that are appropriate for the purpose of the project. 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 minorities, (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.

4. Capacity (30 points)

Extent to which the applicant can document past experience and achievement in successfully completing the types of recipient activities necessary for achieving the purpose of this project, and the extent to which the applicant demonstrates the ability to successfully collaborate with many blood banks in the United States on blood safety issues, such as those related to CJD.

5. Evaluation (15 points)

Extent to which the applicant provides a detailed and adequate plan for evaluating study results and for evaluating progress toward achieving the purpose of the project.

6. Budget (not scored)

Extent to which the line-item budget is detailed, clearly justified, and consistent with the purpose and objectives of this program.

7. Human Subjects (not scored)

Does the application adequately address the requirements of Title 45 CFS Part 46 for the protection of human subjects?

H. Other Requirements*Technical Reporting Requirements*

Provide CDC with an original plus two copies of the following:

1. Progress reports (annual);
2. Financial status report, no more than 90 days after the end of the budget period; and
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 in the application kit.

- 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 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) and 317(k)(2) of the

Public Health Service Act, [42 U.S.C. Sections 241(a) and 247b(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 additional information, contact: Andrea Wooddall, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, Room 3000, 2920 Brandywine Road, Atlanta, GA 30341-4146, Telephone number (770) 488-2749, Email address ayw3@cdc.gov.

For program technical assistance, contact: Dr. Larry Schonberger, Division of Viral and Rickettsial Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Atlanta, GA 30333, Telephone number 404-639-3091, Email address lbs1@cdc.gov.

Dated: April 4, 2001.

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****Proposed Information Collection Activity; Comment Request**

Title: Low Income Home Energy Assistance Program (LIHEAP) Grantee Survey.

OMB No.: 0970-0076.

Description: The LIHEAP Grantee Survey is an annual data collection activity, which is sent to the 50 States and the District of Columbia grantees administering the Low Income Home Energy Assistance Program (LIHEAP). The survey requests estimates on sources and uses of funds under LIHEAP—preliminary estimates for the current fiscal year and final estimates for the previous fiscal year. We are proposing changes in the collection of data using the Grantee Survey, generally to reduce the burden on grantees. In addition, the annual submission of the Grantee Survey will be changed from