

blood or blood components from donors who subsequently tested positive for antibody to hepatitis C virus (anti-HCV) using a licensed multiantigen assay.¹ Blood collection establishments will identify potentially HCV-contaminated blood products and inform transfusion services of these units. The transfusion services will then attempt to notify the recipients of these products and encourage these recipients to be tested for HCV infection. CDC, in collaboration with the Agency for Health Care Policy and Research (AHCPR) and the FDA, has been charged with the responsibility of evaluating this nationwide notification process. The objective of this study is to evaluate the effectiveness of the targeted lookback for identifying persons infected with HCV, obtaining appropriate medical follow-up, and promoting healthy lifestyles and behaviors. The evaluation has three specific aims:

1. Determine the effectiveness of targeted lookback for identifying prior transfusion recipients with HCV infection, including the proportion of recipients identified who are ultimately tested, the proportion of those tested who are HCV positive, the reasons persons do not receive notification, and the reasons persons do not avail themselves of testing.
2. Determine the effectiveness of targeted lookback for encouraging and obtaining appropriate medical follow-up and promoting healthy lifestyles and behaviors among persons found positive for HCV infection, including proportion of HCV-positive persons who seek medical evaluation and outcome of that evaluation (severity of liver disease, anti-viral therapy, quality of counseling), and reactions/impact of notification on HCV-negative persons.
3. Determine the cost-effectiveness of targeted lookback, including resources

(cost, personnel, etc.) utilized by blood collection groups and transfusion services for implementation and costs of medical evaluation and management.

The evaluation will comprise the following components:

1. A nationwide survey of blood collection establishments.
2. A nationwide survey of transfusion services.
3. A follow-up study of transfusion recipients presumed to have been notified of their potential HCV exposure. This detailed study will involve contacting and interviewing transfusion recipients from a sample of transfusion services in defined geographic areas.
4. A follow-up study of notified transfusion recipients who obtain HCV testing offered by blood collection centers.

The total cost to respondents is estimated to be \$346,063.

Respondents	Number of respondents	Number of responses/respondents	Avg. burden/response (in hours)	Total burden (in hours)
Blood collection establishments	140	1	5	700
Transfusion services	5,000	1	5	25,000
Transfusion recipients (first telephone contact)	5,000	1	0.2	1,000
Transfusion recipients (second telephone contact)	2,000	1	0.5	1,000
Transfusion recipients (follow-up interview and study)	200	3	0.5	300
Transfusion recipients (first interview of recipients tested at ARC/ABC)	500	1	0.2	100
Transfusion recipients (follow-up interview and study of recipients tested at ARC/ABC)	100	3	0.5	150
Total	28,250

Dated: April 30, 1999.

Nancy Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99-11339 Filed 5-5-99; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 99119]

Centers for Excellence in Health Statistics; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC), through the Office of Prevention Research and the National

Center for Health Statistics (NCHS) invites applications to establish Centers for Excellence in Health Statistics (CEHS). The goal of these cooperative agreements is to support research to enhance the capability of the statistical sciences to meet the rapidly changing needs of health surveillance, public health research, and in particular prevention research. This program addresses the "Healthy People 2000" priority area(s) of Surveillance and Data.

The purposes of this program are to:

1. Build Infrastructure (Administrative Core): Provide an organizational setting to promote research on methods for health statistics, drawing upon multiple disciplines and involving collaboration with multiple partners. Serve as a model for outreach, input, and collaboration that helps assure that research can be applied to solving priority problems nationally or in the local community.

2. Research Component: Support methodological and analytic research projects aimed at advancing the state of the art of collection, analysis, and interpretation of health statistics to inform prevention research and evaluation. Integrate the fields of statistics, health services research, survey research, public health, epidemiology, behavioral and social sciences, computer science and technology among others. Through such multi-disciplinary research, explore new approaches to enhance the capability of the statistical system to meet the rapidly changing needs of health surveillance, public health research, and prevention research.

3. Recruitment and Outreach (Promote Training): Enhance opportunities for research training, career development, and mentoring.

¹ Food and Drug Administration. Guidance For Industry. Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Units from Prior Collections from

Donors with Repeatedly Reactive Screening Tests for Antibody to Hepatitis C Virus (Anti-HCV); (2) Supplemental Testing, and the Notification of Consignees and Blood Recipients of Donor Test

Results for Anti-HCV. Rockville, MD: Center for Biologics Evaluation and Research, FDA; September 1998.

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, hospitals, other public and private nonprofit organizations, State and local governments or their bona fide agents, and federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations.

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 \$750,000 is available in FY 1999 to fund approximately two awards. It is expected that the average award will be \$375,000 in total costs, ranging from \$250,000 to \$500,000. It is anticipated that the awards will begin on or about September 30, 1999 and will be made for a 12-month budget period within a project period of up to three years. Funding estimates may change. Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by progress reports and the availability of funds.

D. Use of Funds

Applicants should include sufficient travel funds within their budgets to travel to NCHS, Hyattsville, Maryland facility for an annual meeting of all awarded research center principal investigators.

E. Programmatic Interests

There is programmatic interest in developing CEHS that would conduct a wide range of research, analytic and implementation activities pertaining to health statistics and information systems for health promotion and disease prevention research and application. Examples of relevant research topics include but are not limited to those listed below:

1. Survey methodology: New sampling approaches, new designs for hard to reach populations, new approaches for linking and integrating health surveys, improved capabilities for conducting longitudinal and cross sectional studies, improved methods for addressing language and cognitive issues in conducting surveys.

2. Health Promotion and Disease Prevention: Development of standards in terms, definitions and methods; development of health status indicators

for within population group comparison; examination of protective or wellness factors and health seeking behaviors particular to population groups.

3. Data linkages: Improved use of existing administrative data sets (e.g., Medicare, Medicaid, Veterans Administration, National Death Index, hospital discharges, and employer health files), expanded use of data sources from outside the public health arena, approaches to tracking patient health episodes across different providers, and methods for linking or matching different data sources to move toward broader population coverage.

4. Data analysis: Analytic approaches to interpreting poverty and socioeconomic status and their effect on population subgroups, analytic approaches to assessing the impact of managed care on health as well as impact of other changes in health care systems, and enhancement of epidemiological studies of disease and illness including the impact of behavior and environmental exposures, improved strategies for combining qualitative data to enhance insight into statistical research, examination of demographic aspects of health, morbidity, disability, and mortality—including issues related to the influence of early life on later life, algorithms for measuring health outcomes and quality of care, and validation of aggregated variables.

5. Information technology: Expanded research and development of automation technologies, including the development of new electronic methods for data collection, improved analytic tools, and new approaches to electronic data dissemination.

6. Special populations: Improved data on populations particularly vulnerable to changes in the health care system and those with unique health problems (racial/ethnic minorities, poor, disabled, elderly, highly mobile populations) of particular interest is the reliability of race and ethnic information on vital and medical records (self-report versus proxy) with a focus on mortality statistics and misreporting.

7. Medical informatics: Approaches to defining, accessing and using computerized patient records, the development of uniform data elements and definitions, developing methods for greater linkage between medical informatics and population-based health information, developing standardized instruments for recording utilization (especially preventive services) for illness episodes that can be used by primary care service providers in a variety of settings.

8. Measurement: Improved techniques for describing and measuring health status, functional status, health outcomes, and the impact of care and the environment, behavior, family, and community on health status.

9. Non-sampling error: Examination of biases associated with the sampling frame, mode of survey, non-response, and measurement bias.

10. Confidentiality and data sharing: Development of innovative methods and techniques to ensure the confidentiality of information provided by respondents, while at the same time maximizing the sharing of micro-data for analysis, e.g., employing random transformations and imputed synthetic variables and evaluating the resulting analytic losses; development and evaluation of alternative approaches to obtain informed consent.

F. 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. Build Infrastructure (Administrative Core)

- (1) Establish an appropriate organizational setting and institutional infrastructure (administrative core) that is supportive of a set of research projects. This setting must facilitate collaboration between multiple disciplines and involve multiple partners.

- (2) Establish relationship(s) with organizations relevant to the success of the Center's research agenda, demonstrated by letters of agreement. Cooperation with private-sector programs is encouraged.

- (3) Establish relationship(s) with organizations or individuals that can help assure that research can be applied to solving priority problems nationally or (if appropriate) in the local community.

b. Research Component

- (1) Develop and organize a prevention/promotion research theme (or set of themes) and a research agenda. For example, themes and research agendas can address Programmatic Interests research topics outlined in that section of the announcement, or can be focused on problems unique to the community in which the CEHS would be located.

- (2) Design and conduct one or more research projects within the research agenda developed by the particular CEHS that involves specialists or experts in sophisticated methodology

and individuals or organizations from the community, if appropriate, to identify priorities and link research activities to important public health, prevention and health statistics research issues.

(3) Develop a plan to disseminate research findings as widely as is practicable.

c. Recruitment and Outreach (Promote Training): Establish program for enhancing opportunities, career development and training including mentoring of junior researchers, and programs for training mid-career or transitional professionals who have not previously worked in the specialties of health statistics and prevention research.

2. CDC/NCHS Activities:

a. Provide technical assistance on projects as necessary.

b. If needed, assist in the development of controlled access environment which allows micro-data applications.

c. If needed, assist in the development of a research protocol for IRB review by all cooperating institutions participating in the research.

d. The CDC Institutional Review Board (IRB) will review and approve the protocol initially and on at least an annual basis until the research project is completed.

G. Application Content

In developing the application, applicants should follow the information in the Program Requirements, the Other Requirements, and Evaluation Criteria sections.

H. Submission and Deadline

1. Letter of Intent (LOI)

The letter of intent should be submitted to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement by June 2, 1999. The letter of intent should not exceed two pages and include the following information.

a. Name, address, telephone and fax numbers, and E-mail address of the proposed Principal Investigator and the identities of other key personnel and participation institutions.

b. A descriptive title of the proposed research.

Although the letter of intent is required, it is not binding, and does not enter into the review of a subsequent application, the information that it contains allows NCHS staff to estimate the potential review workload and avoid conflicts of interest in the review process.

2. Application

Submit the original and five copies of PHS-398 (OMB Number 2420925-0001) (adhere to the instructions on the Errata Instruction Sheet for PHS 398). Forms are in the application kit.

On or before deadline date of July 6, 1999, submit the application to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

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

(a) Received on or before the deadline date; or

(b) Sent on or before the deadline date and received in time for orderly processing. (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 which do not meet the criteria in (a) or (b) above are considered late applications, will not be considered, and will be returned to the applicant.

I. Evaluation Criteria

Applications may be subjected to a preliminary evaluation by a peer review group to determine if the application is of sufficient technical and scientific merit to warrant further review (triage); the CDC will withdraw from further consideration applications judged to be noncompetitive 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. Each competitive application will be evaluated individually against the following criteria by a Special Emphasis Panel (SEP) appointed by CDC. The SEP will score each proposal based on scientific and technical merit. Factors to be considered by the SEP include:

1. Build Infrastructure (Administrative Core)

a. Organizational Infrastructure: Does the applicant demonstrate a multi-disciplinary approach to achieve the mission? Will the approach lead to the development of a body of knowledge that can yield results beyond that accomplished with individual projects alone? Will the CEHS attract established investigators and develop genuine collaboration among investigators with diverse backgrounds and areas of expertise.

b. Environment: Does the scientific, technical and administrative environment of the center contribute to excellence and the probability of success? Does the center take advantage of unique features of the scientific and public health environments or employ useful collaborative arrangements? Is there evidence of a high level of institutional commitment and support? Does the Center Director (Principal Investigator) have specific authority and responsibility to carry out the project? Is the Center Director located organizationally at a level to garner the support needed for the center (i.e., report to an appropriate institutional official, e.g., dean of a school, vice president of a university, or commissioner of health)? Is the time and effort indicated for the Center Director adequate (minimum of 25 percent effort devoted solely to this project with an anticipated range of 25 to 50 percent)?

c. Community Collaboration: Ability to build coalitions and partnerships with critical organizations and individuals (such as distinguished scientists as well as potential researchers in training, universities, colleges, research institutions, state and local governments, hospitals and academic health centers, managed care organizations, and other public and private nonprofit organizations) and to facilitate collaboration and coordination to assure the accomplishment of CEHS goals.

d. Organization: The quality and appropriateness of the organizational structure, the quality and experience of the administrative staff, the plans for quality control through in-house consultation and outside review (e.g., Scientific Advisory Board), and the quality of the plans for the allocating and monitoring of resources.

e. Budget: Reasonableness of proposed budget and time frame for the project in relation to the work proposed.

2. Research Component

a. Research Theme: Is the concept of a center fulfilled, i.e., is there an organizing prevention/promotion research theme (or set of themes) and a research agenda that defines the mission of the particular CEHS?

b. Public Health Significance: Does the center address an important public health problem? If the aims of the application are achieved, how will the field or health statistics and prevention research benefit? What will be the effect of the center and its affiliated studies on fundamental advances in the development, testing, and dissemination of health statistics and prevention

research and on informing public health policy?

c. Leadership: Are the center director and other senior investigators at the forefront of their respective fields? Do they have the experience and authority to organize, administer and direct the center?

d. Research projects: Are the specific research projects of exceptional scientific merit?

e. Innovation: Does the Center propose to develop novel concepts, approaches, measures or methods in basic research that will inform and guide health promotion and disease prevention? Are the aims original and innovative? Do the projects extend existing approaches or develop new methodologies or technologies?

f. Study Populations: 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.

g. Human Subjects: When applicable, the adequacy of the proposed means for protecting human subjects.

h. Budget: Reasonableness of proposed budget.

3. Recruitment and Outreach (Promote Training)

a. Does the applicant include a research development component for new, mid-career or transitional professionals through research training and career development mechanisms?

b. To what extent are special efforts made to recruit minority professionals and students to the CEHS?

A second-level review will be conducted by a panel of senior Federal officials. The following will be considered in making funding decisions: (1) Results of the initial review, (2) program balance, and (3) availability of funds.

J. Other Requirements

Technical Reporting Requirements

Provide CDC with the original plus two copies of:

1. Annual progress reports due 30 days after the end of the budget period;
2. Financial status report, no more than 90 days after the end of the budget period, and;

3. Final financial report and performance report, no more than 90 days of the project.

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. (See Addendum I)

AR-1 Human Subjects Requirements

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

AR-9 Paperwork Reduction Act Requirements

AR-10 Smoke-Free Workplace Requirements

AR-11 Healthy People 2000

AR-12 Lobbying Restrictions

K. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 306 of the Public Health Service Act, 42 U.S.C. section 242k as amended. The Catalog of Federal Domestic Assistance number is 93.283.

L. Where to Obtain Additional Information

The application kit and program announcement can be downloaded from the CDC home page on the Internet: <http://www.cdc.gov>. (Click on funding).

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, address, and phone number and will need to refer to Announcement 99119. You will receive a complete program description, information on application procedures, and application forms. CDC will not send application kits by facsimile or express mail. Please refer to Program Announcement 99119 when you request information.

If you have questions after reviewing the contents of all documents business management and technical assistance may be obtained from: Victoria Sepe, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99119, Centers for Disease Control and Prevention, Room 3000, 2920 Brandywine Road, Atlanta, GA 30341, telephone (770) 488-2721, Email address: vxw1@cdc.gov.

For programmatic technical assistance, contact: Jennifer Madans,

Ph.D. and/or Audrey Burwell, MS, National Center for Health Statistics, 6525 Belcrest Road, Room 1140, Hyattsville, MD 20782, Phone: 301-436-7016, Phone: 301-436-7062, Email: JHM4@cdc.gov, Email: AZB2@cdc.gov.

For additional programmatic information, see also the NCHS home page on the Internet: <http://www.cdc.gov/nchswwww>.

Dated: April 30, 1999.

John L. Williams,

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

[FR Doc. 99-11338 Filed 5-5-99; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

President's Committee on Mental Retardation; Notice of Meeting

AGENCY HOLDING THE MEETING:

President's Committee on Mental Retardation.

TIME AND DATE: May 23, 1999—9:30 a.m.—5 p.m.

PLACE: Hilton New Orleans Riverside Hotel, New Orleans, Louisiana.

STATUS: Full Committee Meetings are open to the public. An interpreter for the deaf will be available upon advance request. All meeting sites are barrier free.

TO BE CONSIDERED: The Committee plans to discuss critical issues concerning Federal Policy, Federal Research and Demonstration, State Policy Collaboration, Minority and Cultural Diversity and Mission and Public Awareness, relating to individuals with mental retardation.

The PCMR acts in an advisory capacity to the President and the Secretary of the U.S. Department of Health and Human Services on a broad range of topics relating to programs, services, and supports for persons with mental retardation. The Committee, by Executive Order, is responsible for evaluating the adequacy of current practices in programs and supports for persons with mental retardation, and for reviewing legislative proposals that impact the quality of life that is experienced by citizens with mental retardation and their families.

CONTACT PERSON FOR MORE INFORMATION:

Jane L. Browning, Room 701 Aerospace Building, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, (202) 619-0634.