

Program Support Center

Under *Part P, Section P-20, Functions*, change the following:

Under *Chapter PF, Information Technology Service (PF)*, delete the title and functional statement for the *Systems Networking Division (PFF)* in its entirety.

Under *Chapter PB, Human Resources Service (PB)*, after the statement for the *Personnel and Pay Systems Division (PBG)*, add the following title and functional statement:

Systems Networking Division (PBH)

(1) Designs, obtains, installs, and maintains automatic data processing systems, including hardware, software, and data communications required to support the IMPACT system and the office automation activities of the HRS; (2) provides automated data processing and distributed configuration management services for human resource computer systems located in the regional offices and the OPDIV personnel offices; (3) provides the personnel offices with technical expertise in such areas as data communications, data center hardware and related equipment, data center operating systems, general purpose software, and data center management; (4) schedules, operates and maintains the production processes in the departmental personnel/payroll systems; and (5) produces and distributes output products including computer files, printed reports and electronic transmissions for both internal, departmental and external customer use.

Dated: June 30, 1997.

Lynnda M. Regan,

Director, Program Support Center.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement Number 793]

Cooperative Agreement for the Development of New Diagnostic Methods and a Research Program To Determine the Incidence of Emerging Human Spongiform Encephalopathies

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1997 funds to provide assistance through a cooperative agreement for developing

new diagnostic methods and a research program to determine the incidence of emerging human spongiform encephalopathies.

CDC is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Immunization and Infectious Diseases. (For ordering a copy of Healthy People 2000, see the section Where to Obtain Additional Information.)

Authority

This program is authorized under sections 301 and 317 (42 U.S.C. 241 and 247b), of the Public Health Service Act, as amended.

Smoke-Free Workplace

CDC encourages all grant recipients to provide a smoke-free workplace and to promote the nonuse of all tobacco products, and Pub. L. 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

Eligible Applicants

Applications may be submitted by public and private non-profit organizations and governments and their agencies. Thus, universities, colleges, research institutions, hospitals, other public and private non-profit organizations are eligible to apply.

Applicant staff must have certification to practice neuropathology (a medical field focusing on examination and study of brain tissues) in the United States or certification to practice pathology (or neurology) in the United States and show, in their curriculum vitae, the extent of their experience in neuropathology.

Note: Effective January 1, 1996, Public Law 104-65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 which engages in lobbying activities will not be eligible for the receipt of Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

Availability of Funds

Approximately \$65,000 is available in FY 1997 to fund one award. It is expected that the award will begin on or about September 20, 1997, and will be made for a 12-month budget period within a project period of up to 5 years. Funding estimates may vary and are subject to change. Continuation awards

within an approved project period will be made on the basis of satisfactory progress and availability of funds.

Use of Funds

Restrictions on Lobbying

Applicants should be aware of restrictions on the use of Department of Health and Human Services (HHS) funds for lobbying of Federal or State legislative bodies. Under the provisions of 31 U.S.C. Section 1352 (which has been in effect since December 23, 1989), recipients (and their subtier contractors) are prohibited from using appropriated Federal funds (other than profits from a Federal contract) for lobbying Congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement or loan. This includes grants/cooperative agreements that, in whole or in part, involve conferences for which Federal funds cannot be used directly or indirectly to encourage participants to lobby or to instruct participants on how to lobby.

In addition, the FY 1997 Departments of Labor, HHS, and Education, and Related Agencies Appropriations Act, which became effective October 1, 1996, expressly prohibits the use of 1997 appropriated funds for indirect or "grass roots" lobbying efforts that are designed to support or defeat legislation pending before State legislatures. Section 503 of this new law, as enacted by the Omnibus Consolidated Appropriations Act, 1997, Division A, title I, Section 101(e), Pub. L. No. 104-208 (September 30, 1996), provides as follows:

Sec. 503(a) No part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress, * * * except in presentation to the Congress or any State legislative body itself.

Sec. 503(b) No part of any appropriation contained in this Act shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

Background

In 1986, a newly recognized cattle disease, bovine spongiform

encephalopathy (BSE, commonly known as "mad cow" disease), was reported in Britain. As of mid-1997, more than 166,000 British cattle have been confirmed with BSE in more than 33,900 herds. The practice of feeding cattle rendered animal protein was shown to be responsible in greatly amplifying the BSE outbreak. Transmission of the BSE agent to domestic cats and other zoo animals, possibly through contaminated feeds, raised concerns that the human population might also be susceptible to this new disease. These concerns were heightened in March 1996 when the Spongiform Encephalopathy Advisory Committee (SAEC) to the government of Britain announced 10 young Creutzfeldt-Jakob disease (CJD) patients with unusual clinical and neuropathological features. In the absence of known recognizable risk factors for CJD or any other plausible explanation for the clustering of these extraordinarily young CJD patients, the British researchers concluded that the patients may represent spread of the BSE agent to the human population.

In addition to the young age at onset, this new variant of CJD has been characterized by atypical clinical features with prominent behavioral changes at the time of clinical presentation and subsequent onset of neurologic abnormalities including ataxia within weeks or months, dementia and myoclonus late in the illness, a duration of illness of at least six months, and nondiagnostic electroencephalographic changes. The specific, uniform neuropathology includes, in both the cerebellum and cerebrum, numerous kuru-type amyloid plaques surrounded by vacuoles and prion protein accumulation at high concentration, indicated by immunocytochemical analysis.

As of May 6, 1997, five additional confirmed and one probable cases of new variant CJD were identified in the United Kingdom and one confirmed case was identified in France. Although a definitive scientific causal association of new variant CJD with BSE has not yet been established, the evidence for a causal link has been accumulating.

Purpose

The purpose of this cooperative agreement is to provide assistance for the development of new diagnostic techniques and a research program to determine the incidence of potentially emerging human spongiform encephalopathies in the United States.

Program Requirements

In conducting activities to achieve the purpose of this program, the recipient shall be responsible for the activities under A., below, and CDC shall be responsible for conducting activities under B., below:

A. Recipient Activities

1. Test the application of novel diagnostic methods to research the incidence of emerging human spongiform encephalopathies.
2. Develop research programs that can be used to monitor the emergence of human spongiform encephalopathies.
3. Identify new cases of human spongiform encephalopathies.
4. Disseminate result of research findings.

B. CDC Activities

Provide assistance in the dissemination of results and other technical assistance as required.

Technical Reporting Requirements

Narrative semiannual progress reports are required and must be submitted no later than 30 days after each semiannual reporting period. The semiannual progress reports must include the following for each program, function, or activity involved: (1) A comparison of actual accomplishments to the goal established for the period; (2) the reasons for failure, if established goals were not met; and (3) other pertinent information including, when appropriate, analysis and explanation of performance costs significantly higher than expected. All manuscripts published as a result of the work supported in part or whole by the cooperative agreement will be submitted with the progress reports.

An annual Financial Status Report (FSR) is required no later than 90 days after the end of each budget period. A final performance report and financial status report are due no later than 90 days after the end of the project period.

An original and two copies of all reports should be submitted to the Grants Management Officer, Grants Management Branch, Procurement and Grants Office, CDC.

Required Format for Application

All applicants must develop their application in accordance with the PHS Form 5161-1 (revised 7/92), information contained in this cooperative agreement announcement, and the instructions outlined below. In order to ensure an objective, impartial, and prompt review, applications which do not conform to these instructions may be disqualified.

1. All pages must be clearly numbered.

2. A complete index to the application and its appendices must be included.

3. The original and two copies of the application must be submitted unstapled and unbound.

4. Any reprints, brochures, or other enclosures must be copied onto 8½" by 11" white paper by the applicant. No bound materials will be accepted.

5. All materials must be typewritten, single spaced, and in unrounded type (no smaller than font size 12) on 8½" by 11" white paper, with at least 1" margins, headers, and footers.

6. All pages must be printed on one side only.

Application Content

The application narrative must not exceed 10 pages (excluding budget and appendices). Unless indicated otherwise, all information requested below must appear in the narrative.

Materials or information that should be part of the narrative will not be accepted if placed in the appendices. The application narrative must contain the following sections in the order presented below:

1. Background

Discuss the background and need for the proposed project. Demonstrate a clear understanding of the purpose and objectives of this cooperative agreement program.

2. Capacity and Personnel

Describe applicant's past experience in conducting projects/studies similar to that being proposed. Describe applicant's resources, facilities, and professional personnel that will be involved in conducting the project. Include in an appendix curriculum vitae for key professional personnel involved with the project. Describe plans for administration of the project and identify administrative resources/personnel that will be assigned to the project.

3. Objectives and Technical Approach

Describe specific objectives for the proposed project which are measurable and time-phased and are consistent with the purpose and goals of this cooperative agreement. Present a detailed operational plan for initiating and conducting the project which clearly and appropriately addresses all Recipient Activities (provide a detailed description of first-year activities and a brief overview of activities in subsequent years. Clearly state the proposed length of the project period). Clearly identify specific assigned

responsibilities for all key professional personnel. Include a clear description of applicant's technical approach/methods which are directly relevant to the study objectives to include obtaining study samples. Describe the nature and extent of collaboration with CDC and/or others during various phases of the project. Describe in detail a plan for evaluating study results and for evaluating progress toward achieving project objectives.

4. Budget

Provide in an appendix a budget and accompanying detailed justification for the first-year of the project that is consistent with the purpose and objectives of this program. Also, provide estimated total budget for each subsequent year. If requesting funds for contracts, provide the following information for each proposed contract: (1) Name of proposed contractor, (2) breakdown and justification for estimated costs, (3) description and scope of activities to be performed by contractor, (4) period of performance, and (5) method of contractor selection (e.g., sole-source or competitive solicitation).

5. Human Subjects

Whether or not exempt from DHHS regulations, if the proposed project involves human subjects, describe in an appendix adequate procedures for the protection of human subjects. Also, ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects by including a description of the composition of the proposed study population (for example, addressing the inclusion of women and members of minority groups and their sub-populations in the section that will describe the research design). Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. See the Other Requirements Section for additional information.

Evaluation Criteria

The applications will be reviewed and evaluated according to the following criteria:

1. Background and Need (5 points)

Extent to which applicant's discussion of the background for the proposed project demonstrates a clear understanding of the purpose and objectives of this cooperative agreement program. Extent to which applicant illustrates and justifies the need for the proposed project that is consistent with

the purpose and objectives of this cooperative agreement program.

2. Capacity (70 points total)

a. Extent to which applicant describes adequate resources and facilities (both technical and administrative) for conducting the project. (10 points)

b. Extent to which applicant documents that professional personnel involved in the project are qualified and have past experience and achievements in research related to transmissible spongiform encephalopathies, particularly in the application of CJD diagnostic methods such as neuropathology, immunocytochemistry, Western blot testing, and genetic analysis in determining the incidence of emerging human spongiform encephalopathies; these qualifications have to be evidenced by curriculum vitae, publications, etc. Applicants must provide curriculum vitae of their program staff and relevant scientific articles published in peer-reviewed journals within the last five years. (40 points)

c. Extent to which applicant demonstrates the ability to collaborate with as many neuropathologists and/or pathologists working in human spongiform encephalopathy research to include how study samples will be collected. (20 points)

3. Objectives and Technical Approach (25 points total)

a. Extent to which applicant describes specific objectives of the proposed project which are consistent with the purpose and goals of this cooperative agreement program and which are measurable and time-phased. (5 points)

b. Extent to which applicant presents a detailed operational plan for initiating and conducting the project, which clearly and appropriately addresses all Recipient Activities. Extent to which applicant clearly identifies specific assigned responsibilities for all key professional personnel. Extent to which the plan clearly describes applicant's technical approach/methods for conducting the proposed studies and extent to which the plan is adequate to accomplish the objectives. Extent to which applicant describes specific study protocols or plans for the development of study protocols that are appropriate for achieving project objectives. If the proposed project involves human subjects, whether or not exempt from the DHHS regulations, the extent to which adequate procedures are described for the protection of human subjects. Note: Objective Review Group (ORG) recommendations on the adequacy of protections include: (1)

Protections appear adequate and there are no comments to make or concerns to raise, (2) protections appear adequate, but there are comments regarding the protocol, (3) protections appear inadequate and the ORG has concerns related to human subjects, or (4) disapproval of the application is recommended because the research risks are sufficiently serious and protection against the risks are 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 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; and (4) documentation of plans for recruitment and outreach for study participants that includes the process of establishing partnerships with community(ies) and recognition of mutual benefits. (15 points)

c. Extent to which applicant provides a detailed and adequate plan for evaluating study results and for evaluating progress toward achieving project objectives. (5 points)

4. Budget (not scored)

Extent to which the proposed budget is reasonable, clearly justifiable, and consistent with the intended use of cooperative agreement funds.

Executive Order 12372 Review

This program is not subject to Executive Order 12372 Review.

Public Health System Reporting Requirements

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Number is 93.283.

Other Requirements

Human Subjects

If the proposed project involves research on human subjects, the applicant must comply with the Department of Health and Human Services Regulations (45 CFR part 46) regarding the protection of human subjects. Assurance must be provided to demonstrate that the project will be

subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing evidence of this assurance in accordance with the appropriate guidelines and form provided in the application kit.

Women, Racial and Ethnic Minorities

It is the policy of the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC/ATSDR-supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian, Alaskan Native, Asian, Pacific Islander, Black and Hispanic. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity and/or sex of subjects. Further guidance to this policy is contained in the **Federal Register**, Vol. 60, No. 179, pages 47947-47951, dated Friday, September 15, 1995.

Application Submission and Deadline

The original and two copies of the application PHS Form 5161-1 (revised 7/92, OMB Number 0937-0189) must be submitted to Sharron Orum, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 305, Mailstop E-18, Atlanta, Georgia 30305, on or before August 8, 1997.

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

Received on or before the deadline date; or

b. 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.)

2. **Late Applications:** Applications which do not meet the criteria in 1.a. or 1.b. above are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

Where To Obtain Additional Information

To receive additional written information, call (404) 332-4561. You will be asked to leave your name, address, and telephone number. Please refer to Announcement Number 793. You will receive a complete program description, information on application procedures and application forms. If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Gladys T. Gissentanna, Grant Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 314, Mailstop E-18, Atlanta, GA 30305, telephone: (404) 842-6801. Programmatic technical assistance may be obtained from Lawrence B. Schonberger, MD, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), Atlanta, GA 30333, telephone: (404) 639-3091, Email address: LBS1@CDC.GOV. You may also obtain this announcement from one of two Internet sites on the actual publication date: CDC's homepage at <http://www.cdc.gov> or the Government Printing Office homepage (including free on-line access to the **Federal Register** at <http://www.access.gpo.gov>). Other CDC announcements are also listed on the Internet on the CDC homepage.

Please refer to Announcement Number 793 when requesting information regarding this program.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017-001-00474-0) or Healthy People 2000 (Summary Report, Stock No. 017-001-00473-1) referenced in the Introduction through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, telephone: (202) 512-1800.

Dated: July 1, 1997.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Cooperative Agreements for Competitive Innovations in Syphilis Prevention in the United States: Reconsidering the Epidemiology and Involving Communities, Phase II: Evaluation of a Community Intervention, Program Announcement 523: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Disease, Disability, and Injury Prevention and Control SEP: Cooperative Agreements for Competitive Innovations in Syphilis Prevention in the United States: Reconsidering the Epidemiology and Involving Communities, Phase II: Evaluation of a Community Intervention, Program Announcement 523.

Time and Date: 8:30 a.m.-5 p.m., August 12, 1997.

Place: 11 Corporate Square Boulevard, Conference Room A, Atlanta, Georgia 30329.

Status: Closed.

Matters to be discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement 523.

The meeting will be closed to the public in accordance with provisions set forth in section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Pub. L. 92-463.

Contact Person For More Information: John R. Lehnher, Chief, Prevention Support Office, National Center for HIV, STD, and TB Prevention, CDC, M/S E07, 1600 Clifton Road, NE, Atlanta, Georgia 30333, telephone 404/639-8025.

Dated: July 2, 1997.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

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