

Dated: April 9, 2002.

Eve E. Slater,

Assistant Secretary for Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 02046]

Cooperative Agreement for a Research Program To Determine the Incidence of Emerging Human Transmissible Spongiform Encephalopathies in the United States; 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 to determine the incidence of emerging human transmissible spongiform encephalopathies (TSE) in the United States. This program addresses the "Healthy People 2010" focus area of Immunization and Infectious Diseases.

The purpose of the program is to enhance national surveillance for TSE or prion diseases. The objectives are to (1) develop new diagnostic techniques; (2) facilitate laboratory investigation of new emerging TSE and (3) develop a research program to determine the incidence of potential TSE or prion diseases in the United States. Go to the website in Part J. of this announcement for more background information.

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, 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. Faith-Based organizations are eligible for this award.

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 experiences in neuropathology.

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 \$750,000 is available in FY 2002 to fund one award. 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 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. Develop a collaborative network of medical professionals (i.e. pathologists, neuropathologists, etc.) to report suspected variant Creutzfeldt-Jakob Disease (CJD) cases and collect data on physician-diagnosed TSE.

b. Develop a plan to confirm the diagnosis of TSE and characterize infecting prions to monitor the emergence of novel types of TSE such as variant (CJD).

c. Collaborate with state and local health departments and other centers to establish effective ways of increasing state-of-the art diagnoses, including autopsy rates among physician-diagnosed cases of TSE.

d. Develop a system for the collection of critical epidemiologic information on the cases confirmed with TSE.

e. Develop research methodologies to assess the relationship, if any, of chronic wasting disease of deer and elk to human TSE.

f. Provide training on TSE, as needed, such as clinical and neuropathologic manifestations of variant CJD, to medical professionals (i.e. neurologists, pathologists, etc.).

g. Disseminate the results of research findings.

2. CDC Activities

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

b. 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

Letter of Intent (LOI)

An LOI is required for this program. The narrative should be no more than two 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 02046 (2) name and address of institution and (3) name, address and telephone number of contact person. Notification can be provided by facsimile, postal mail, or electronic mail (e-mail).

Application

Use the information in the Program Requirements (particularly in the Recipient Activities), 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 un-reduced fonts.

F. Submission and Deadline

Letter of Intent (LOI)

On or before May 30, 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 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: www.cdc.gov/od/pgo/forminfo.htm, or in the application kit.

On or before June 15, 2002, 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 submission to the Objective Review Panel. (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.

G. Evaluation Criteria

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

1. Plan (30 points)

The 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. Extent to which the applicant demonstrates existing collaborations with a network of neuropathologists and general pathologists in the United States and experience in testing brain tissues from a large number of confirmed CJD cases reported each year in the United States.

2. Objectives (10 points)

The 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 (15 points)

The extent to which the applicant clearly identifies specific assigned responsibilities for all key professional personnel assigned to carry out each of the recipient activities. Extent to which the plan clearly describes the applicant's technical approach/methods for ensuring the completeness and reporting of epidemiologic information on the cases evaluated at the Pathology Center and extent to which the plan is adequate to accomplish the purpose. Extent to which the applicant describes specific plans for the continuation of activities 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 or communities and recognition of mutual benefits.

4. Capacity (25 points)

The degree to which the applicant demonstrates existing laboratory capacity to perform state-of-the-art diagnostic tests for human TSE and characterize infecting prions. 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. The degree to which the applicant demonstrates the ability to successfully collaborate with state and local health departments and professional associations whose members are involved in the care and diagnosis of CJD patients such as the American Academy of Neurology, the American Association of Neuropathologists, and the United States and Canadian Academy of Pathologists.

5. Evaluation (10 points)

The 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. Measures of Effectiveness (10 points)

The extent the applicant provides Measures of Effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. Are the measures objective/quantitative and do they measure the intended outcome?

7. Budget (not scored)

The extent to which the line-item budget is detailed, clearly justified, consistent with the purpose and objectives of this program, and outlines how the budget relates to the Recipient Activities as listed under the "Program Requirements" section of this program announcement.

8. Human Subjects (not scored)

Does the application adequately address the requirements of Title 45 CFR part 46 for the protection of human subjects?

H. Other Requirements

Technical Reporting Requirement

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

1. Progress report (annually)
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
- AR-22 Research Integrity

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: Merlin Williams, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, Room 3000, 2920 Brandywine Road, M/S K75, Atlanta, GA 30341-4146. Telephone number: (770)488-2765. Fax number: (770)488-2670. E-mail address: mqw6@cdc.gov.

For program technical assistance, contact: Dr. Ermias Belay, Division of Viral and Rickettsial Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Mailstop A-39, Atlanta, GA 30333. Telephone number:

404-639-3091. Fax Number: 404-639-3838. E-mail address: EBelay@cdc.gov.

Dated: April 8, 2002.

Sandra R. Manning,

CFM, Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Availability of Draft Technical Report of a Feasibility Study of the Health Consequences to the American Population of Nuclear Weapons Tests Conducted by the United States and Other Nations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of availability and request for comments.

SUMMARY: In 1998, the Congress requested that the Department of Health and Human Services (HHS) conduct an initial assessment of the feasibility and public health implications of a detailed study of the health impact on the American people of radioactive fallout from the testing of nuclear weapons. This request resulted in a joint project by scientists at the Centers for Disease Control and Prevention (CDC) and at the National Cancer Institute (NCI).

This notice announces that a 2-volume Technical Report providing details on the scientific methods and conclusions of this feasibility project is now available for public comment. This project has, for the first time, estimated preliminary doses to representative persons in all counties of the contiguous United States for a set of important radionuclides produced as a result of nuclear weapons testing from 1951 through 1962 by the United States and other nations. The work that has now been completed demonstrates that it is feasible to conduct a more detailed study of the health impact on the American population as a result of exposure to radioactive fallout from the testing of nuclear weapons in the United States and abroad.

However, significant resources would be required to implement this project, and careful consideration should be given to public health priorities before embarking on this path. To assist in the process of deciding about future fallout-

related work, this report contains five different options for consideration.

DATES: To be considered, comments on this draft Technical Report must be received August 13, 2002. Comments received after the close of the public comment period will be considered at the discretion of CDC on the basis of what is deemed to be in the best interest of the general public.

ADDRESSES: Requests for copies of the draft Technical Report should be sent to the Radiation Studies Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, Centers for Disease Control and Prevention, Mail Stop E-39, 1600 Clifton Road, NE, Atlanta, Georgia 30333, telephone (404) 498-1800, e-mail NTS and Global Fallout Report@cdc.gov. Written comments regarding the draft Technical Report should be sent to the same address. Because of its large size, CDC reserves the right to provide only one copy of the draft Technical Report free of charge to a requester. The document may also be accessed via the Internet at <http://www.cdc.gov/nceh/radiation/default.htm>.

Written comments submitted in response to this notice should bear the title of the report, "A Feasibility Study of the Health Consequences to the American Population of Nuclear Weapons Tests Conducted by the United States and Other Nations." Because all public comments regarding this draft Technical Report will be available for inspection, no confidential business information or personal medical information should be submitted in response to this notice.

FOR FURTHER INFORMATION CONTACT: Radiation Studies Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, Centers for Disease Control and Prevention, Mail Stop E-39, 1600 Clifton Road, NE, Atlanta, Georgia 30333.

SUPPLEMENTARY INFORMATION: Before 1963, the United States and other countries tested more than 500 nuclear weapons in the atmosphere. Each of these tests inserted radioactive debris, commonly known as fallout, into the atmosphere. Depending on the size and type of weapon detonated, some of this fallout traveled great distances before depositing on the earth and exposing people to radiation. Any person living in the contiguous United States since 1951 has been exposed to radioactive fallout, and all organs and tissues of the body have received some radiation exposure. On the basis of the preliminary estimates of dose and risk

developed in this feasibility study, fallout radiation appears to have the greatest impact on risks for thyroid tumors. Risks for leukemia would be lower. Risk for cancers of other organs or tissues could be assessed as well, but because of the smaller amount of information available about radiation-associated health effects and the lower doses to most organs, the uncertainties associated with these estimates would be extremely large.

Dated: April 8, 2002.

Joseph R. Carter,

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 Medicare & Medicaid Services

[CMS-4042-N]

RIN 0938-ZA32

Medicare Program; Solicitation for Proposals for Medicare Preferred Provider Organization (PPO) Demonstrations in the Medicare+Choice Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice for solicitation of proposals.

SUMMARY: This notice informs interested parties of an opportunity to apply for a cooperative agreement to develop a Medicare Preferred Provider Organization (PPO) Demonstration. We are interested in making the PPO health care option, which has been successful in non-Medicare markets, more widely available to people with Medicare. Our objective is to introduce more variety into the Medicare+Choice program so that Medicare beneficiaries have broader choice and more options available. We intend to use a competitive application process to select several organizations to develop PPO demonstrations beginning January 1, 2003.

DATES: Applications will be considered timely if we receive them on or before May 30, 2002.

ADDRESSES: Applications should be mailed to the following address: Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Beneficiary Choices, Demonstration and Data Analysis Group, Division of Demonstration Programs, Attn: Ron