

Through a combination of plenary presentations and panel discussions, the conference will explore the integration of genetics into primary care and discuss the various roles of healthcare providers in the provision of genetics services. Afternoon focus groups will concentrate on several different areas of genetics education, training, and integration. Conference participants will be asked to consider a number of public policy questions of interest to SACGT, including how are health professions schools responding to changes and challenges brought about by genetics and genetic testing; are future health professionals being taught what they need to know to integrate new health technologies and services into the clinical and public health settings; are current health professionals, who were trained long before the explosion of genetics knowledge, receiving the training they need to continue to practice effectively; are they being taught about the proper use and interpretation of genetic tests and about their ethical, legal, and social implications; are the revolutionary advances in genetics having an equally revolutionary effect on our educational methods; what changes are already underway; are they sufficient; are they occurring quickly enough; is government doing as much as it should do? On the following day during its regular Committee meeting, SACGT will consider these issues and develop its recommendations to the Secretary.

Reviewing the outcomes of the SACGT Education Conference will be the Committee's first order of business at its May 14–15 meeting. In addition, four of the SACGT work groups will be presenting reports to the Committee: The ACCESS Work Group will present a draft report on billing and reimbursement for genetic education and counseling services; the Informed Consent/Institutional Review Board Work Group will present its revised recommendations on decision making and informed consent for clinical and public health genetic tests; the Data Work Group will present three case studies on the development and clinical application of a genetic test; and the Rare Disease Work Group will present a report on genetic testing for rare diseases. Presentations will also be made on the development of a "Frequently Asked Questions" document on Clinical Laboratory Improvement Amendments certification and the Food and Drug Administration's progress in the development in the development of a pre-market review of genetic tests. Time will be provided for

public comment and interested individuals should notify the contact person listed below.

Under authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, the Department of Health and Human Services established SACGT to advise and make recommendations to the Secretary through the Assistant Secretary for Health on all aspects of the development and use of genetic tests. SACGT is directed to (1) recommend policies and procedures for the safe and effective incorporation of genetic technologies into health care; (2) assess the effectiveness of existing and future measures for oversight of genetic tests; and (3) identify research needs related to the Committee's purview.

The draft meeting agenda and other information about SACGT will be available at the following Web site: <http://www4.od.nih.gov/oba/sacgt/htm>. Individuals who wish to provide public comment or who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the SACGT Executive Secretary, Ms. Sarah Carr, by telephone at 301-496-9838 or e-mail at [sc112@nih.gov](mailto:sc112@nih.gov). The SACGT office is located at 6705 Rockledge Drive, Suite 750, Bethesda, Maryland 20892.

Dated: April 5, 2002.

**Sarah Carr,**

*Executive Secretary, Secretary's Advisory Committee on Genetic Testing.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Action Plan To Assure the Appropriate Use of Therapeutic Agents in the Elderly: Notice of Opportunity for Public Comment

**AGENCY:** Department of Health and Human Services, Office of the Secretary, Office of Public Health and Science, Office of Disease Prevention and Health Promotion.

**ACTION:** Notice.

**SUMMARY:** The Department of Health and Human Services (DHHS) solicits written comments on the key elements of a national action plan to assure the appropriate use of therapeutic agents in the elderly.

**DATES:** Written comments may be submitted on or before 5:00 p.m. E.S.T. on May 22, 2002.

**ADDRESSES:** Written comments should be sent to Debra C. Nichols, M.D.,

M.P.H., DHHS Office of Disease Prevention and Health Promotion, Office of Public Health and Science, room 738-G, 200 Independence Ave., SW., Washington, DC 20201, (202) 205-4872 (telephone), 202-205-9478 (facsimile). Comments also may be submitted electronically to [dnichols@osophs.dhhs.gov](mailto:dnichols@osophs.dhhs.gov).

#### FOR FURTHER INFORMATION CONTACT:

Debra Nichols, M.D., M.P.H. DHHS Office of Disease Prevention and Health Promotion, Office of Public Health and Science, room 738-G, 200 Independence Ave., SW., Washington, DC 20201, (202) 205-4872.

#### SUPPLEMENTARY INFORMATION:

##### Background

The Elderly are at increased risk of complications from the effects of therapeutic agents. These risks are caused by the use of multiple, concurrent medications, the use of inappropriate medication and the underuse of needed medication.

Management of this problem will require the coordinated efforts of both federal and private sectors. Provider behavior must be modified through education, the use of monitoring systems and patient and caregiver empowerment. The most important strategies that the nation can use to fight this problem must be identified.

##### Written Comments

In preparation for the development of a national action plan to assure the appropriate use of therapeutic agents in the elderly in the United States, comments are welcome from all interested stakeholders.

Comments will be most useful if they include the following information:

(1) What you consider to be the three to five most important priorities for assuring the appropriate use of therapeutic agents in the elderly in the United States.

(2) How, as a nation, we should pursue these strategies.

(3) Your views on the most effective ways to address disparities among different segments of the population.

(4) (If applicable) A short summary of activities that your organization is engaged in or plans to engage in to assure the appropriate use of therapeutic agents in the elderly. Submitted information may become part of a publicly accessible website information center, or be otherwise made available.

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](http://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: