

handle the hazardous material used in studies of TSEs. A goal of the NIH is to address these needs by mounting a coordinated effort among the Institutes at NIH as well as with other Federal agencies to achieve these objectives:

A. Establish a repository for research reagents by the next fiscal year;

B. Double the laboratory facilities available over the next two years;

C. Triple the number of investigators involved in TSE research over the next five years;

D. Double or if possible triple current spending for TSE research by the end of FY 2002. To do this, the NIH will convene a special meeting to identify the major needs and opportunities for research in this field. The product of this workshop will form the basis of a Request for Applications. The scientific quality of the applications received will determine the total funding committed to this initiative. The Acting Director, NIH, has agreed to provide funding as needed for this purpose from the Director's Discretionary Fund.

E. Consider, in consultation with OS, the establishment of a "prize" of about \$1 million for the first person(s) or organization(s) to provide proof of principle for the development of a minimally invasive test that would be sufficiently sensitive and specific for screening random populations for presymptomatic infection with CJD or vCJD, and a "prize" of about \$5 million to the first person(s) or institution(s) to obtain FDA approval and to place into commercial distribution a minimally invasive screening test that would be sufficiently sensitive and specific for screening random populations for presymptomatic infection with CJD or vCJD.

4. Oversight—OS

The foundations of OS oversight activities are the statutory obligations of the Secretary, and the lessons that have been learned from experience with the HIV and hepatitis C epidemics.

In 1995, at the request of the Department, the Institute of Medicine (IOM) issued a report titled "HIV and the Blood Supply: An Analysis of Crisis Decisionmaking." The IOM recommended that the Secretary establish a Public Health Service (PHS) Blood Safety Committee (BSC). The Secretary designated the Assistant Secretary for Health to be the chair of this committee and to be the Blood Safety Director for the Department. Other BSC members are the directors of CDC, FDA, and NIH; the Assistant Secretary for Planning and Evaluation; and the Associate General Counsel for Public Health. This committee exists so

that threats to the safety or availability of the blood supply can be brought immediately to the highest levels of the Department. The BSC has met on the issue of deferring blood donors at risk of transmitting BSE by virtue of prior residence in the United Kingdom. The BSC also met on issues relating to the development of CJD at an unusually young age in a hunter who had been a long time plasma donor, and on issues related to the discovery of a poorly characterized TSE that recently appeared in two flocks of East Freisian sheep which had been imported to Vermont from Belgium. The group stands ready to be convened for similar matters in the future.

The Department has also established an Interdepartmental Steering Committee for BSE/TSE Affairs. This committee is chaired by the Commissioner of FDA and includes representatives of CDC, FDA, NIH, USDA, the United States Trade Representative, the Office of Management and Budget, the Customs Service, the Department of State, the Department of Defense, the State Association of Feed Control Officials, the National Association of State Departments of Agriculture, and the White House Office of Science and Technology Policy. This committee assures ongoing coordination between agencies; integrated contingency planning in case BSE or of vCJD is found in the United States; identification of and response to potential vulnerabilities in the United States to BSE and vCJD; and coordination of risk communication plans by the various agencies. A summary of each meeting of this group will be forwarded through the Assistant Secretary of Health to the Secretary within thirty days of each meeting, and on a more expedited basis as necessary.

The Department must assure timely, accurate, thorough, and clear communication to the public about the nature and extent of the threats posed by BSE/TSE and about the actions that each agency of government is taking to protect the public from these threats. In addition, each agency must anticipate the worst case scenarios of a case of BSE or of vCJD being recognized in the United States, and each agency must have a plan not only for dealing with this contingency but also for communicating the event itself, and the agency response to the event, to the public. Furthermore, the communications of the various agencies must be consistent with each other. For this reason, the BSE/TSE Steering Committee will establish a communications workgroup to develop

an interdepartmental communications strategy and plan for dealing with a potential occurrence of BSE and/or vCJD and serve as a public affairs/communications resource in dealing with BSE/TSE issues.

Also, the FDA TSE Advisory Committee meets publicly on at least a semi-annual basis. One standing agenda item of this committee is review of current regulations and guidance to prevent exposure of the United States population to the agent(s) of BSE/TSE through blood, tissues, and other regulated products. A summary of this meeting, with particular attention to this agenda item and to public comment about it, will be forwarded through the Assistant Secretary for Health to the Secretary within thirty days of each meeting, and on a more expedited basis as necessary.

Issues that warrant OS oversight at this time include the following:

A. Assurance of adequate program support to enhance TSE surveillance by CDC as planned.

B. Assurance of adequate program support for FDA regulatory and research activities related to TSEs.

C. Assurance of adequate program support for the TSE research initiatives proposed by NIH.

D. Assurance and coordination of integrated risk communication messages to the public and to industry regarding the true nature of threats posed by BSE/TSEs, particularly in the event of a confirmed case within the United States.

E. Assurance of a seamless collaboration with USDA and other federal and state agencies on BSE/TSE issues.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Statement of Organization, Functions, and Delegations of Authority

Part E, Chapter E (Agency for Healthcare Research and Quality), of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (61 FR 15955-58, April 10, 1996, most recently amended at 65 FR 16395 on March 28, 2000) is further amended to reflect organizational changes necessitated by section 902 of the Public Health Service (PHS) Act as amended by the Healthcare Research

and Quality Act of 1999, Public Law 106-129. The specific organizational amendment is as follows:

Under *Section E-20, Functions*, after the statement for the Office of Health Care Information (EAF), insert the following title and statement:

Office of Priority Populations Research (EAG). Coordinates, supports, manages and conducts health services research on priority populations. Specifically, the Office: (1) Advises the Agency leadership on matters pertaining to the health needs and health care of priority populations, including scientific, ethical, legal and policy issues; (2) prepares the agenda for priority populations research through the Agency's strategic planning process, needs assessment, and user input; (3) serves as an expert resource within the Agency on priority populations to assist program development and participates in the development of policies and programs to implement the Agency's priority populations agenda; (4) fosters new knowledge, tool, and talent development related to priority populations by recommending, leading, coordinating and conducting new initiatives; (5) assists in the translation, dissemination, and application of Agency initiatives and programs to improve health care for priority populations; (6) evaluates the degree to which the Agency is meeting its goals for priority populations research; (7) provides national expertise to Agency staff and Agency partners on priority populations issues, establishing and maintaining liaison with other knowledgeable or concerned agencies, governments and organizations; (8) establishes new contacts and cultivates present ones with external groups (a) to spur increased awareness and emphasis on priority populations within the health services research community, (b) to partner with organizations and

agencies to expand research on priority populations, thereby securing additional resources for these activities, and (c) to build the research capacity on priority populations; and (9) enhances the visibility of the Agency in priority populations research.

These changes are effective upon date of signature.

Dated: July 12, 2001.

Tommy G. Thompson,
Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443-1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the

agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Web-based Semi Annual Report (SAR): NEW

The Health Resources and Services Administration (HRSA), Bureau of Primary Health Care (BPHC) plans to collect the annual reporting requirements for the primary care grantees funded by BPHC using a web-based Semi Annual Report (SAR). The SAR includes reporting requirements for grantees of the following primary care programs: State Primary Care Associations and State Primary Care Offices. Authorizing legislation is found in Public Law 104-299, Health Center Consolidation Act of 1996, enacting Section 330 of the Public Health Service Act.

BPHC collects data on its programs to ensure compliance with legislative mandates and to report to Congress and policymakers on program accomplishments. To meet these objectives, BPHC requires a core set of information collected semi-annually that is appropriate for monitoring and evaluating performance and reporting on annual trends. The SAR, completed by all grantees, provides data on services, characteristics of populations, leveraged funds, and services that fall within the scope of the grant.

The pilot test for the first web-based SAR was conducted in December 2000, and analysis of the data indicates that the SAR is an invaluable tool for collecting data from our grantees.

The estimated burden is as follows:

Form	Number of respondents	Responses per respondent	Hours per response	Total burden hours
SAR	103	1	18	1854

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14-22, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: August 15, 2001.

Jane M. Harrison,
Director, Division of Policy Review and Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), announcement is made of the following National