DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS), Subcommittee on Privacy and Confidentiality.

Time and Date: 9:00 a.m.-5:00 p.m., May 20, 1990.

Place: Room 405A, Hubert Humphrey Building, 200 Independence Avenue, SW, Washington, D.C. 20201.

Status: Open.

Purpose: At this meeting, the Subcommittee will hear panel presentations on selected confidentiality issues. On the first day, a panel discussion is planned on the flow of health information between employers and insurers and related issues of the flow of health information between employers. Thus, persons without a federal identification card will need to have the guard call for an escort to the Humphrey building by non-government employees. Therefore, the Subcommittee will discuss their views on these topics. On the second day, the Subcommittee will hear a panel discussion of pharmacy benefit management of health and their information practices.

Notice: In the interest of security, the Department has instituted stringent procedures for entrance to the Hubert H. Humphrey building by non-government employees. Thus, persons without a government identification card will need to have the guard call for an escort to the meeting.

Contact Person for More Information: Substantive program information as well as summaries of meetings and a roster of committee members may be obtained from Gail Horlick, M.S.W., J.D., Lead Staff Person for the NCVHS Subcommittee on Privacy and Confidentiality, Office of Research and Demonstrations, Health Care Financing Administration, M5–C4–13–01, 7500 Security Boulevard, Baltimore, Maryland 21244–1850, telephone (410) 786–6620; or Marjorie S. Greenberg, Executive Secretary, NCVHS, NCHS, CDC, Room 1100, Presidential Building, 5625 Belcrest Road, Hyattsville, Maryland 20782, telephone (301) 436–7050. Information also is available on the NCVHS home page of the HHS website: http://aspe.os.dhhs.gov/ncvhs, where an agenda for the meeting will be posted when available.


Ida M. Ustad,
Deputy Associate Administrator for Acquisition Policy.

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BILLING CODE 6820–61–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Scientific Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has made a final finding of scientific misconduct in the following case:

Chang-Fen Huang, Ph.D., State University of New York at Stony Brook (SUNY – SB): based on an investigation conducted by SUNY – SB dated December 18, 1997, ORI finds that Dr. Huang, former graduate student, Department of Biochemistry, SUNY – SB, engaged in scientific misconduct in the reporting and conducting of research supported by a grant from the National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health (NIH).

Specifically, ORI finds that:

(1) Dr. Huang falsified and misrepresented six autoradiographs of Northern blots (ARG) that she had obtained from earlier unrelated experiments to make them appear to have come from several different and separate experiments.

(2) For one of the sets noted in (1) above, Dr. Huang falsified and misrepresented the ARG in panel B of figure 1, in C.F. Huang et al. “Depolarization-transcription signals in skeletal muscle use calcium flux through L channels, but bypass the sarcoplasmic reticulum,” Neuron 13:167–177, 1994. Figure 1B purported to show the effect of electrical activity on the expression of genes for subunits of the acetyl choline receptor, but actually used data derived from a separate and unrelated experiment showing the effect of phorbol esters on the expression of the myogenin gene that had been previously reported in an unrelated publication. The publication was retracted at Neuron 13(1):1294, 1998.

(3) For one of the sets noted in (1) above, Dr. Huang falsified and misrepresented Figure VII/7, an aggregate ARG, on page 159 of her dissertation, “Studies of the Signaling Pathway Coupling Membrane Depolarization and AchR Gene Inactivation in Chick Skeletal Muscle,” December 1993. The figure reported the effect of a set of calcium-active agents on the sarcoplasmic reticulum that were different from those studied for the original ARG.

Dr. Huang has accepted the ORI finding and has entered into a Voluntary Exclusion Agreement with ORI in which she has voluntarily agreed, for the three (3) year period beginning April 20, 1999:

(1) To exclude herself from any contracting or subcontracting with any agency of the United States Government and from eligibility for, or involvement in, nonprocurement transactions (e.g., grants and cooperative agreements) of the United States Government as defined in 45 C.F.R. Part 76 (Debarment Regulations); and

(2) To exclude herself from serving in any advisory capacity to the Public Health Service (PHS), including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

FOR FURTHER INFORMATION CONTACT:

Acting Director, Division of Research Investigations, Office of Research Integrity 5515 Security Lane, Suite 700, Rockville, MD 20852, (301) 443–5330.

Chris B. Pascal,
Acting Director, Office of Research Integrity.

[FR Doc. 99–11120 Filed 5–3–99; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Health Care Policy and Research

Nomination of Topics for Evidence-based Practice Centers (EPCs)

The Agency for Health Care Policy and Research (AHCPR) invites a third round of nominations of topics for evidence reports and technology assessments relating to the prevention, diagnosis, treatment and management of common diseases and clinical conditions. AHCPR’s first request for topic nominations was published in the Federal Register on December 23, 1996. AHCPR’s second request was published in the Federal Register on November 28, 1997.

With this third round of nominations, AHCPR is expanding the range of topics that may be submitted. In addition to nominations of topics for assessments and evidence reports on specific health care technologies and medical
procedures, including alternative or complementary therapies, AHCPR is, for the first time, inviting nominations of topics for assessments and evidence reports relating to organization and financing of health care. Section A of this announcement describes the nomination process and selection criteria for clinical topics. Section B of this announcement describes the nomination process and selection criteria for organizational and financial topics.

AHCPR serves as a science partner with private-sector and other public organizations in their efforts to improve the quality, effectiveness, and appropriateness of health care delivery in the United States, and to speed the translation of evidence-based research findings into improved health care. AHCPR awards task order contracts to its Evidence-based Practice Centers (EPCs) to undertake scientific analyses and evidence syntheses on high-priority topics. The EPCs produce science syntheses—evidence reports and technology assessments—that provide to public and private organizations the foundation for developing and implementing their own practice guidelines, performance measures, and other strategies to improve the quality of health care and make decisions related to the effectiveness or appropriateness of specific health care technologies.

As the body of scientific studies related to the organization and financing of health care grows, evidence reports and scientific syntheses of these studies can provide health system organizations with a scientific foundation for developing system-wide policies and practices. These reports might, for example, address and evaluate innovations in the delivery of care, the organization of health care systems, or provide payment mechanisms.

As a result of nominations received in response to AHCPR's December 1996 Federal Register notice, EPCs developed evidence reports or technology assessments on: (1) testosterone suppression treatment of prostatic cancer; (2) evaluation of cervical cytology; (3) diagnosis and treatment of dysphagia/swallowing problems in the elderly; (4) evaluation and treatment of new onset of atrial fibrillation in the elderly; (5) diagnosis of sleep apnea; (6) treatment of attention deficit and hyperactivity disorder; (7) diagnosis and treatment of acute sinusitis; (8) rehabilitation of persons with traumatic brain injury; (9) prevention and management of urinary tract infections in patients with chronic renal disease; (10) pharmacotherapy for alcohol dependence; (11) management of stable angina; and, (12) treatment of depression with new drugs.

As a result of nominations received in response to the November 1997 Federal Register notice, the EPCs are developing evidence reports or technology assessments on: (1) use of erythropoietin in oncology and hematology; (2) management of chronic obstructive pulmonary disease; (3) criteria to determine disability for patients with chronic renal disease; (4) treatment of acne; (5) management of anesthesia during cataract surgery; (6) criteria for weaning from mechanical ventilation; (7) management of cancer pain; (8) evaluation of technologies for identifying acute cardiac ischemia in emergency departments; (9) management of hypertension during pregnancy; (10) management of acute otitis media; (11) management of preterm labor; (12) prevention of venous thromboembolism after injury; (13) management of unstable angina; (14) criteria for referral of patients with epilepsy; and, (15) alternative and complementary medicine: use of garlic in prevention of cardiovascular disease and cancer; and use of silybum marianum in treatment of liver disease and cirrhosis.

Background

Under Title IX of the Public Health Service Act, AHCPR is charged with enhancing the quality, appropriateness, and effectiveness of health care services and access to such services. AHCPR accomplishes these goals through scientific research and through promotion of improvements in clinical practice (including the prevention of diseases and other health conditions) and promotion of improvements in the organization, financing, and delivery of health care services (42 U.S.C. 299–299c–6 and 1320b–12).

Evidence-based Practice Centers (EPCs)

The EPCs prepare evidence reports and technology assessments on topics for which there is significant demand for information by health care providers, insurers, purchasers, health-related societies, patient advocacy groups, and consumer organizations. Such topics may include the prevention, diagnosis and/or treatment of particular diseases or health conditions including, where appropriate, the use of alternative/complementary therapies, as well as the appropriate use of more commonly provided services, procedures, or technologies. Topics also may include issues related to the organization and financing of care. AHCPR widely disseminates the evidence reports and technology assessments produced by the EPCs, both electronically and in print.

The AHCPR will review topic nominations and supporting information and determine final topics, seeking additional information as appropriate. Nominators of selected topics are expected to serve as resources to EPCs as they develop evidence reports and technology assessments. Nominators may also serve as peer reviewers of draft evidence reports and assessments.

The processes that AHCPR employs to select topics nominated for analyses by the EPCs are described below. The topics selected will complement AHCPR's efforts to build a balanced portfolio of evidence reports. Section A addresses AHCPR's nomination process and selection criteria for clinical topics. Section B addresses AHCPR's nomination process and selection criteria for organization and financing topics.

Section A: Clinical Topics

Nomination Process for Clinical Topics

Nominations of clinical topics for AHCPR evidence reports and technology assessments should focus on specific aspects of prevention, diagnosis, treatment and/or management of a particular condition, or on an individual procedure, device, treatment, or technology. Potential topics should be carefully defined and circumscribed so that within 12 months databases can be searched, the evidence reviewed, supplemental analyses performed, draft reports and assessments circulated for external peer review, and final evidence reports or technology assessments produced. Topics selected will not duplicate current and widely available clinical practice guidelines or technology assessments, unless new evidence is available that suggests the need for revisions or updates.

For each topic, nominators should provide a rationale and supporting evidence on the importance and clinical relevance of the topic. Nominators also should indicate how the evidence report or technology assessment will be utilized by their professional practices or organizations. Nominations should include:

- Defined condition, target population, and three to five specific questions to be answered.
- Incidence or prevalence, and indication of the disease burden (e.g., mortality, morbidity, functional impairment, diminution of quality or life) in the U.S. general population or in subpopulations (e.g., Medicare or...
Medicaid populations, minorities, women or children). For prevalence, the number of cases in the U.S. and the number affected per 1,000 persons in the general U.S. population should be provided. For incidence, the number of new cases per 100,000 a year should be provided.

- Costs associated with the clinical condition, procedure, treatment, or technology, including the number of people needing care, high unit cost of care, high indirect costs, or average reimbursed amounts for diagnostic and therapeutic interventions (e.g., average U.S. costs and number of persons who receive care for diagnosis or treatment in a year, citing ICD9–CM and CPT codes if possible).
- Potential of the evidence report or technology assessment to decrease health care costs or to improve health status or clinical outcomes.
- Availability of scientific data and bibliographies of studies on the topic.
- Significant variations in practice patterns and/or results.
- Indication by nominator’s organization and/or relevant professional organizations of intended use of the report or assessment (e.g., rapid use of the report or assessment to develop or update clinical practice guidelines, educational programs, and other quality improvement tools, or payment or coverage policies about a particular condition).

Selection Criteria for Clinical Topics

Selection criteria for AHCPR evidence report and technology assessment topics include: (1) High incidence or prevalence in the general population or in subpopulations, including racial and ethnic minorities, as well as pediatric and elderly populations; (2) significance for the needs of the Medicare, Medicaid and other Federal health programs; (3) high costs associated with a condition, procedure, treatment, or technology, whether due to the number of people needing care, high unit cost of care, or high indirect costs; (4) controversy or uncertainty about the effectiveness or relative effectiveness of available clinical strategies or technologies; (5) potential to inform and improve patient or provider decisionmaking; (6) potential to reduce clinically significant variations in the prevention, diagnosis, treatment, or clinical management of a disease or condition, or in the use of a procedure or technology, or in the health outcomes achieved; (7) availability of scientific data to support the study or analysis of the topic; (8) potential opportunities for rapid implementation; (9) complementarity to other evidence reports to support AHCPR’s effort to build a balanced portfolio of evidence reports and technology assessments; and (10) indication that the nominating organization and/or relevant professional organizations would use the report or assessment on the topic nominated to develop or update a clinical practice guideline, other quality improvement tools, or coverage decision policies.

Section B: Organization and Financing Topics

Nomination Process for Organization and Financing Topics

Nominations of organization and financing topics for AHCPR research syntheses and evidence reports should focus on specific aspects of health care organization and finance, particularly with regard to their impact on health care outcomes and quality. Potential topics should be carefully defined and circumscribed so that within 12 months databases can be searched, the evidence reviewed, supplemental analyses performed, draft reports circulated for external peer review, and final evidence reports produced. Topics selected will not duplicate current and widely available research syntheses, unless new evidence suggests the need for revisions or updates.

For each topic, nominators should provide a rationale and supporting evidence on the importance and relevance of the topic. Nominators also should indicate how the evidence report could be used by public and private decision-makers to improve clinical care delivery and health outcomes.

Nomination information should include:

- Defined organizational/financial arrangement or structure impacting quality, outcomes, cost, access or use, along with three to five specific questions to be answered.
- If appropriate, description of how the organizational or financial arrangement or structure is particularly relevant to delivery of care for specific vulnerable populations (e.g., children, persons with chronic disease) or certain communities (e.g., rural areas).
- Costs potentially affected by the organizational or financial arrangement, to the extent they can be quantified.
- Potential of the evidence report to decrease health care costs or to improve health status or outcomes.
- Availability of scientific data and bibliographies of studies on the topic.
- References to significant variation in delivery and financing patterns and/or results.
- Indication by nominator’s organization or of intended use of an evidence report on this topic.

Selection Criteria for Organization and Financing Topics

Topics for AHCPR evidence reports related to the organization and financing of care that will be of greatest interest are those that have one or more of the following characteristics: (1) Uncertainty about the impact of the subject organizational or financing strategy; (2) potential for the organizational or financing strategy or the proposed research synthesis to significantly affect aggregate health care costs, outcomes, or quality; (3) policy-relevant to Medicare, Medicaid, and/or other Federal and State health programs; (4) relevant to vulnerable populations, including racial and ethnic minorities, and particular communities, such as rural areas; (5) available scientific data to support the study or analysis of the topic; and, (6) potential for rapid incorporation into managerial or policy decisionmaking.

Examples of topics related to the organization and financing of care include: (1) Use of formulas by hospitals and MCO’s; (2) impact of pre-hospital care for coronary disease; (3) impact of gatekeeper systems; (4) effect of stepdown units on quality and cost of care; (5) effect of risk-sharing payment schemes for physicians; (6) effect of co-payment and deductibles on care sought and received.

Materials Submission and Deadline

Nominations may be in the form of a letter. To be considered for the next group of evidence reports and technology assessments, topic nominations should be submitted by July 6, 1999 to: Douglas B. Kamerow, M.D., M.P.H., Director, Center for Practice and Technology Assessment, Agency for Health Care Policy and Research, 6010 Executive Boulevard, Suite 300, Rockville, Maryland 20852.

AHCPR encourages topic nominations from professional societies and organizations comprised of members of minority populations, as well as nomination of topics that have significant impact on the health status of women, children, ethnic and racial populations.

In addition to publication of requests for topic nominations in the Federal Register, AHCPR also accepts nominations on an ongoing basis at the above address for EPC evidence reports and technology assessments.
A. Purpose

The Centers for Disease Control and Prevention (CDC) announces that grant applications are being accepted to establish a National Sexual Violence Resource Center (NSVRC) for fiscal year (FY) 1999. This program addresses the priority area of Violent and Abusive Behavior. The purposes of the program are to:

1. Strengthen the existing support system serving sexual assault survivors;
2. Provide leadership in the prevention of sexual violence;
3. Provide comprehensive information and resources, policy analysis and development; and
4. Provide technical assistance and professional consultation to sexual assault programs, national, State and local organizations, community volunteers, and the media designed to enhance community response to and prevention of sexual violence.

B. Eligible Applicants

Applications may be submitted by National sexual assault coalitions and State sexual assault coalitions. National sexual assault coalitions are membership organizations of State sexual assault coalitions which work to end sexual violence through public awareness, education, and public policy advocacy. State sexual assault coalitions are State level organizations that represent and are supported by the majority of the rape crisis centers and sexual assault programs in a given state. National and State coalitions both have a 501(c)(3) designation and work with State and national systems (e.g., criminal justice, health, etc.) for sexual assault survivors.

Competition is limited to National and State sexual assault coalitions because:
1. The resource center will provide an infrastructure that supports the field of prevention of sexual violence that has been characterized by a lack of resources to adequately address the issue;
2. The resource center will provide immediate access to information and resources needed by people who work with women who are victims of violence;
3. The Senate appropriation committee encourages CDC to supplement state sexual assault coalitions’ rape prevention and education efforts and to support state sexual assault coalitions focused on ending sexual violence; and
4. State sexual assault coalitions have a long history of providing victim services, educating students, training various groups including professionals and increasing public awareness of sexual violence.

Note: Pub. L. 104–65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities shall not be eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

C. Availability of Funds

Approximately $700,000 is available in FY 1999 to fund one award. It is expected that the award will begin on or about September 1, 1999 and will be made for a 12-month budget period within a project period of up to five (5) years. Funding estimates may change. Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

Applications with year 1 annual budgets that exceed $700,000 (total direct and indirect costs) will be determined as ineligible and returned to the applicant.

Use of Funds

a. Allowable Uses of Funds:

Funds may be used for planning, developing, implementing, and evaluating projects. Accordingly, funds can be used to support personnel, purchase furniture appropriate to the establishment of this center, and to purchase hardware and software required to implement the project. Applicants may enter into contractual agreements to purchase goods and services, or to support collaborative activities, but the applicant must retain proper stewardship over funds and responsibility for tasks associated with the project.

b. Prohibited Uses of Funds:

Funds for this project may not be used for construction, renovation, the lease of passenger vehicles, or supplanting current applicant expenditures.

D. Program Requirements

The applicant requirements:

1. Provide technical assistance and training to assist organizations, programs and communities to adapt available resources to meet local needs.
2. Establish and maintain (for public use) a central resource of materials that addresses a wide range of sexual violence issues.
3. Develop systems for providing an assortment of information relative to sexual violence prevention.
4. Establish and maintain a full working partnership with an academic institution, research institution, or a consultant with demonstrated scientific expertise in the area of sexual violence programs.
5. Establish and maintain a full working partnership with appropriate National/State Sexual Assault Coalitions.
6. Provide a full-time manager and other staff as appropriate.
7. Develop and implement a mechanism(s) for assessing the informational and data needs of the diverse populations working in the field of sexual violence prevention.
8. Provide a detailed evaluation plan that will document program process, effectiveness, impact, or outcomes.

E. Application Content

Use the information in the Program Requirements, 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 40 pages, excluding the abstract, budget justification, and attachments.