SUPPLEMENTARY INFORMATION:

1. The Committee shall advise on matters pertaining to the continuance and improvement of functions within the authority of HHS directed toward protections for human subjects in research. Specifically, the committee will provide advice relating to the responsible conduct of research involving human subjects with particular emphasis on: Special populations, such as neonates and children, prisoners, and the decisionally impaired; pregnant women, embryos, and fetuses; individuals and populations in international studies; populations in which there are individually identifiable samples, data, or information; and investigator conflicts of interest.

In addition, the Committee is responsible for reviewing selected ongoing work and planned activities of the Office for Human Research Protections (OHRP) and other offices/agencies within HHS responsible for human subjects protection. These evaluations may include but are not limited to a review of assurance systems, the application of minimal research risk standards, the granting of waivers, education programs sponsored by OHRP, and the ongoing monitoring and oversight of institutional review boards (IRBs) and the institutions that sponsor research.

2. Nominations. The Office for Human Research Protections is requesting nominations to fill one position for a voting member of SACHRP. The position will become vacant on September 1, 2004. Nominations of potential candidates for consideration are being sought from a wide array of fields, including but not limited to: public health and medicine; behavioral and social sciences; health administration; biomedical ethics. To qualify for consideration of appointment to the Committee, an individual must possess demonstrated experience and expertise in any of the several disciplines and fields pertinent to human subjects protection and/or clinical research.

The individual selected for appointment to the Committee will serve as a voting member. The individual selected for appointment to the Committee can be invited to serve a term of up to four years. Committee members receive stipend for attending Committee meetings and conducting other business in the interest of the Committee, including per diem and reimbursement for travel expenses incurred.

Nominations should be typewritten. The following information should be included in the package of material submitted for each individual being nominated for consideration (1) A letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination (*i.e.,* specific attributes which qualify the nominee for service in this capacity), and a statement that the nominee is willing to serve as a member of the Committee; (2) the nominator's name, address and daytime telephone number, and the home and/or work address, telephone number, and e-mail address of the individual being nominated; and (3) a current copy of the nominee's curriculum vitae. The names of Federal employees should not be nominated for consideration of appointment to this Committee.

The Department makes every effort to ensure that the membership of DHHS Federal advisory committees is fairly balanced in terms of points of view represented and the committee's function. Every effort is made to ensure that a broad representation of geographic areas, females, ethnic and minority groups, and the disabled are given consideration for membership on DHHS Federal advisory committees. Appointment to this Committee shall be made without discrimination on the basis of age, race, ethnicity, gender sexual orientation, disability, and cultural, religious, or socioeconomic status. Nominations must state that the nominee is willing to serve as a member of SACHRP and appears to have no conflict of interest that would preclude membership. Potential candidates are required to provide detailed information concerning such matters as financial holdings, consultancies, and research grants or contracts to permit evaluation of possible sources of conflict of interest.

Dated: February 5, 2004.

Bernard A. Schwetz,

Executive Secretary, Secretary's Advisory Committee on Human Research Protections, Acting Director, Office for Human Research Protections.

[FR Doc. 04–3602 Filed 2–18–04; 8:45 am]

BILLING CODE 4150–36–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Secretary's Advisory Committee on Human Research Protections

AGENCY: Office of the Secretary, Office of Public Health and Science.

ACTION: Notice of meeting.

Authority: 42 U.S.C. 217a, section 222 of the Public Health Services (PHS) Act, as amended. The Committee is governed by the provisions of Public Law 92–463, as amended (5 U.S.C. appendix 2), which sets forth standards for the formation and use of advisory committees.

SUMMARY: Pursuant to section 10(A) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice is hereby given of the third meeting of the Secretary's Advisory Committee on Human Research Protections (SACHRP). The meeting will be open to the public.

DATES: The meeting will be held on Monday, March 29, 2004, from 8:30 a.m. to 4:30 p.m. e.s.t., and Tuesday, March 30, 2004, from 8:30 a.m. to 4:30 p.m. e.s.t.

ADDRESSES: Holiday Inn Hotel and Suites, The Commonwealth Center, 625 First Street, Alexandria, VA 22314.

FOR FURTHER INFORMATION CONTACT: Bernard Schwetz, D.V.M., Ph.D., Acting Director, Office for Human Research Protections, Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852, (301) 496–7005, fax: (301) 402–0527, e-mail address: *sachrp@osophs.dhhs.gov* or Catherine Slatinshek, Executive Director, SACHRP Office for Human Research Protections, 1101 Wooton Parkway, Suite 200; Rockville, Maryland 20852, (301) 496–7005, fax: (301) 496–0527, e-mail address: *sachrp@osophs.dhhs.gov*.

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. 217a, section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services and the Assistant Secretary for Health on issues and topics pertaining to or associated with the protection of human research subjects.

On March 29, SACHRP will receive and discuss preliminary reports from its three subcommittees. The three subcommittees were created by SACHRP at its meeting held on July 22, 2003, to address issues related to the following three topic areas: HHS regulations and policies for research involving prisoners, HHS regulations and policies for research involving children, and the accreditation of human research protection programs by non-federal accrediting bodies. On March 30, SACHRP will hold follow-up discussions on adverse events reporting issues under HHS and FDA regulations. This topic was discussed at the Committee meeting held on December 11–12, 2003. In addition, discussions will be held to review human subjects research in international settings. These will be followed by panel discussions related to HIPAA regulations, and will

conclude with a presentation on litigation issues affecting the clinical research enterprise. The Committee also will discuss future tasks for the remainder of the year.

Public attendance at the meeting is limited to space available. Individuals must provide a photo ID for entry into the meeting. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the designated contact person. Members of the public will have the opportunity to provide comments at the meeting on March 29 and 30, 2004. Public comment will be limited to five minutes per speaker. Any members of the public who wish to have printed material distributed to SACHRP members for this scheduled meeting should submit materials to the Executive Director, SACHRP (contact information listed above) prior to close of business March 16, 2004.

Information about SACHRP and the draft meeting agenda will be posted on the SACHRP Web site at: *http://ohrp.osophs.dhhs.gov/sachrp/sachrp.htm*.

Dated: February 12, 2004.

Bernard A. Schwetz

Acting Director, Office for Human Research Protections, and Acting Executive Secretary, Secretary's Advisory Committee on Human Research Protections.

[FR Doc. 04–3603 Filed 2–18–04; 8:45 am]

BILLING CODE 4150–36–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) allow the proposed information collection project: ''CAHPS II Reports Laboratory Experiment''. This experiment will assess the impact of improved data displays on consumers' understanding and use of reports of health care quality. In accordance with the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A), AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by April 19, 2004.

ADDRESSES: Written comments should be submitted to: Cynthia D. McMichael, Reports Clearance Officer, AHRQ, 540 Gaither Road, Suite 5022, Rockville, MD 20850.

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from AHRQ's Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Cynthia D. McMichael, AHRQ, Reports Clearance Officer, (301) 427–1651.

SUPPLEMENTARY INFORMATION:

Proposed Project—''CAHPS II Reports Laboratory Experiment''

CAHPS II Reports Laboratory Experiment is designed to assess the impact of improved data displays on consumers' understanding and use of reports of health care quality and tests the impact of alternative design features. Getting consumers to pay attention to and use comparative quality information continues to be a major challenge to CAHPS and other quality reporting efforts, including efforts by the Centers for Medicare & Medicaid Services (CMS) and the National Committee for Quality Assurance (NCQA), and others. We need to learn more about ways to maximize the likelihood that consumers of health services will look at and pay attention to quality information, understand and interpret it accurately, use the information appropriately, and make ''effective'' choices based on the information.

This study will test the impact of alternative design features on user comprehension of available health care quality information and on its saliency to user decision-making. The study will assess ease of navigation of alternative approaches and consumers' stated preferences among the choices offered.

Study participants will be persons between 25–70 years old who have health insurance and have had a visit to a doctor in the last 12 months. The quality information presented to study participants in this laboratory experiment evaluating design alternatives will consist of mock data on consumers' assessments of the care provided by their physicians. The quality information will contain measures of physician performance, with candidate measures including how well the doctor scored on (1) listening carefully to patients; (2) giving explanations that are easy to understand; (3) spending enough time with patients; and, (4) treating patients with courtesy and respect. The quality information also will include ratings of the doctor's staff, for example, office staff that are as helpful as they should be and office staff who treat patients with courtesy and respect. Finally, the quality information will include measures of access to care, such as being able to make appointments as soon as needed, a reasonable amount of time waiting in the doctor's office, and access to extended hours of service. The exact quality measures on which we will present information will be determined during preliminary testing.

Data Confidentiality Provisions

To protect subject confidentiality, the following procedures will be employed:

- Upon arriving at the testing location and prior to participation, each subject will receive and sign the consent form, approved by the grantee's Institutional Review Board, that contains information about their rights as a subject and the measures being taken to safeguard confidentiality. A test administrator will verbally repeat and explain the information in the form at the beginning of the testing session. Subjects will be informed that their participation is voluntary and that they have the right to refuse to answer any questions or to stop participating at any point during the testing session.
- All subject materials will be marked with a unique ID number, rather than the subjects' names. Subjects' names will never be linked with their individual answers. Any information linking subject names and ID numbers will be kept in a secure location and will be accessible only to members of the project team. Subject names will not be shared with anyone outside of the project team.
- All information will be aggregated and reported at the group, rather than the individual, level.
- During portions of the testing session that will be video-taped (*i.e.,* the taping of the ''choose a doctor'' and comprehension questions to gather timing data), we will refer to the subjects by first name only. The videotapes will be marked with subject ID numbers and will be stored in a secure location. The tapes will be used only for analysis purposes by project team members.
- Subjects will be informed that participation is voluntary.
- All completed subject materials (*e.g.,* recruitment screeners, questionnaires, tapes, consent forms, incentive receipt forms) will be kept in a secure location accessible only to members of the project team.