

office in the Office of Public Health and Science, Department of Health and Human Services (HHS), is seeking nominations of qualified candidates to be considered for appointment as members of the Secretary's Advisory Committee on Human Research Protections (SACHRP). SACHRP provides advice and recommendations to the Secretary, HHS, and the Assistant Secretary for Health on matters pertaining to the continuance and improvement of functions within the authority of HHS directed toward protections for human subjects in research. SACHRP was established by the Secretary, HHS, on October 1, 2002. OHRP is seeking nominations of qualified candidates to fill two positions on the Committee membership that will be vacated in June of 2009.

**DATES:** Nominations for membership on the Committee must be received no later than January 23, 2009.

**ADDRESSES:** Nominations should be mailed or delivered to Dr. Jerry Menikoff, Director, Office for Human Research Protections, Department of Health and Human Services, 1101 Wootton Parkway, Suite 200; Rockville, MD 20852. Nominations also may be sent via e-mail to [sachrp@hhs.gov](mailto:sachrp@hhs.gov) or via facsimile at 240-453-6909.

**FOR FURTHER INFORMATION CONTACT:** Julia Gorey, Executive Director, SACHRP, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, telephone: 240-453-8141. A copy of the Committee charter and list of the current members can be obtained by contacting Ms. Gorey, accessing the SACHRP Web site at <http://www.hhs.gov/ohrp/sachrp>, or requesting via e-mail at [sachrp@hhs.gov](mailto:sachrp@hhs.gov).

**SUPPLEMENTARY INFORMATION:** The Committee provides advice 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 provides advice relating to the responsible conduct of research involving human subjects with particular emphasis on special populations such as neonates and children, prisoners, the decisionally impaired, pregnant women, embryos and fetuses, individuals and populations in international studies, investigator conflicts of interest and populations in which there are individually identifiable samples, data, or information.

In addition, the Committee is responsible for reviewing selected ongoing work and planned activities of the 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 and the institutions that sponsor research.

**Nominations:** The Office for Human Research Protections is requesting nominations to fill two positions for voting members of SACHRP. The two positions will become vacant in June of 2009. 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, and 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 individuals selected for appointment to the Committee can be invited to serve a term of up to four years. Committee members receive a stipend and reimbursement for per diem and any travel expenses incurred for attending Committee meetings and/or conducting other business in the interest of the Committee.

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 email address of the individual being nominated; and (3) a current copy of the nominee's curriculum vitae. Federal employees should not be nominated for consideration of appointment to this Committee.

The Department makes every effort to ensure that the membership of HHS 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 individuals from a broad representation of geographic areas, women and men, ethnic and minority

groups, and the disabled are given consideration for membership on HHS 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.

Documentation must be included in the nomination to indicate that the nominated individual is willing to serve as a member of SACHRP. Individuals who are selected to be considered for appointment will be required to provide detailed information regarding their financial holdings, consultancies, and research grants or contracts. Disclosure of this information is necessary in order to determine if the selected candidate is involved in any activity that may pose a potential conflict with the official duties to be performed as a member of SACHRP.

Dated: November 18, 2008.

**Jerry Menikoff,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Agency Recordkeeping/Reporting Requirements Under Emergency Review by the Office of Management and Budget (OMB)

**Title:** Indian Tribes, Tribal Organizations or Tribal Consortia Letter of Intent to Operate a Title IV-E Program.

**OMB No.:** New Collection.

**Description:** The Fostering Connections to Success and Increasing Adoptions Act of 2008 (Pub. L. 110-351) added section 479B to the Social Security Act (the Act), which allows Indian Tribes the option to apply to the Secretary to receive Federal funding to support the administration of their own foster care, adoption assistance and relative guardianship programs under title IV-E of the Act. The law also amended the Act at section 476(c)(2)(ii) to allow Indian Tribes to receive one-time development grants of up to \$300,000 to be used to offset the cost of developing a title IV-E plan to carry out the requirements of section 479B of the Act, and required ACF to provide technical assistance and

implementation services to Indian Tribes regarding the title IV–E program.  
 In order to plan for the review of Tribal title IV–E plans and technical assistance needs, the Administration for Children and Families (ACF) is requesting that all Federally recognized Indian Tribes, Tribal organizations or Tribal consortia (hereafter, “Tribes”)

that plan to operate a title IV–E program send a letter of intent to their ACF Regional Program Manager by December 31, 2008.  
 ACF will ask Tribes to include in the letter of intent the following information:  
 1. The Federal fiscal year (FY) in which the Tribe expects to begin

operation of a title IV–E program. (According to the law, the earliest possible implementation period is FY 2010.)  
 2. Information on the intended Tribal service area for the Tribal title IV–E program.  
*Respondents:* Indian Tribes, Tribal organizations and Tribal consortia.

ANNUAL BURDEN ESTIMATES

Information collection	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Letter of Intent .....	562	1	1	562

*Estimated Total Annual Burden Hours:* 562.

*Additional Information:* ACF is requesting that OMB grant a 90-day approval for this information collection under procedures for emergency processing by November 28, 2008. A copy of this information collection, with applicable supporting documentation, may be obtained by calling the Administration for Children and Families, Reports Clearance Officer, Robert Sargis at (202) 690–7275 or e-mailing to [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

Comments and questions about the information collection described above should be directed to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for ACF, Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, (202) 395–7316.

Dated: November 13, 2008.

**Robert Sargis,**

*Reports Clearance Officer.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2008–N–0589]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Mental Models Study of Health Care Providers’ Understanding of Prescription Drug Effectiveness**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain

information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of the Mental Models Study of Health Care Providers’ Understanding of Prescription Drug Effectiveness. Together with other information being collected, the results from this study will be used to help inform FDA about how health care providers conceptualize the drug effectiveness portion of the risk/benefit tradeoff and how that conceptualization differs from how agency experts think about drug effectiveness. The information gathered in this study will be used to focus and strengthen future planned quantitative research. It will also contribute to FDA’s ability to communicate drug effectiveness information to health care providers in labeling and other communications.

**DATES:** Submit written or electronic comments on the collection of information by January 23, 2009.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Berbakos, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3792.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Mental Models Study of Health Care Providers’ Understanding of Prescription Drug Effectiveness**

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information.