reclassification into Class III (premarket approval), labeling improvements and postmarket surveillance studies. The committee will also consider surgical mesh used to treat stress urinary incontinence.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before August 30, 2011. Oral presentations from the public will be scheduled between approximately 10 a.m. and 11 a.m. on September 8 and 9, 2011. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before August 22, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by August 23, 2011.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Committee Management Staff, 301–796–5966 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: *June 30, 2011.*

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2011–17695 Filed 7–13–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Formative Research Methodology Studies for the National Children's Study

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for reinstatement of approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on April 27, 2011, pages 23608–23609, and allowed 60 days for public comment. Two written comments and two verbal comments were received. The verbal comments expressed support for the broad scope of the study. The written comments were identical and questioned the cost and utility of the study. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Formative Research Studies for the National Children's Study (NCS) *Need and Use of Information Collection:* The Children's Health Act of 2000 (Pub. L. 106–310) states:

(a) *Purpose.*—It is the purpose of this section to authorize the National Institute of Child Health and Human Development* to conduct a national longitudinal study of environmental influences (including physical, chemical, biological, and psychosocial) on children's health and development.

(b) *In General.*—The Director of the National Institute of Child Health and Human Development* shall establish a consortium of representatives from appropriate Federal agencies (including the Centers for Disease Control and Prevention, the Environmental Protection Agency) to—

(1) Plan, develop, and implement a prospective cohort study, from birth to adulthood, to evaluate the effects of both chronic and intermittent exposures on child health and human development; and

(2) Investigate basic mechanisms of developmental disorders and environmental factors, both risk and protective, that influence health and developmental processes.

(c) *Requirement.*—The study under subsection (b) shall—

(1) Incorporate behavioral, emotional, educational, and contextual consequences to enable a complete assessment of the physical, chemical, biological, and psychosocial environmental influences on children's well-being;

(2) Gather data on environmental influences and outcomes on diverse populations of children, which may include the consideration of prenatal exposures; and

(3) Consider health disparities among children, which may include the consideration of prenatal exposures.

To fulfill the requirements of the Children's Health Act, the results of formative research and pilot tests will be used to maximize the efficiency of NCS procedures, materials, and methods for outreach, engagement of stakeholders, recruitment and retention of Study subjects, and to ensure scientifically robust data collection methodologies for the National Children's Study (NCS) Vanguard and Main Studies. With this submission, the NCS seeks to obtain OMB's generic approval to conduct survey and instrument design and administration, focus groups, cognitive interviews, and health and social service provider information collection surrounding outreach, engagement, recruitment, consent and questionnaire design, and retention activities.

The results from formative research and pilot tests proposed will inform the feasibility (scientific robustness), acceptability (burden to participants and study logistics) and cost of NCS Vanguard and Main Study recruitment, retention, study visit measures and study logistics. *Type of Review:* Reinstatement of OMB #0925–0590, Expiration June 30, 2011. *Frequency of Response:* Annual [As needed on an on-going and concurrent basis]. *Affected Public:* Members of the public, researchers, practitioners, and other health professionals. *Type of Respondents:* Women of child-bearing age, fathers, community leaders, members, and organizations, health care facilities and professionals, public health, environmental, social and cognitive science professional organizations and practitioners, hospital

administrators, cultural and faith-based centers, and schools and child care organizations. These include both persons enrolled in the NCS Vanguard Study and their peers who are not participating in the NCS Vanguard Study.

Annual reporting burden: See Table 1. The annualized cost to respondents is estimated at: $300,000 (based on $10 per hour).

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN SUMMARY

Data collection activity	Type of respondent	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Small, focused survey and instrument design and administration.	NCS participants	4,000	2	1	8,000
	Members of NCS target population (not NCS participants).	4,000	2	1	8,000
	Health and Social Service Providers	2,000	1	1	2,000
	Community Stakeholders	2,000	1	1	2,000
Focus groups	NCS participants	2,000	1	2	2,000
	Members of NCS target population (not NCS participants).	2,000	1	2	2,000
	Health and Social Service Providers	2,000	1	2	2,000
	Community Stakeholders	2,000	1	2	2,000
Cognitive interviews	NCS participants	500	1	2	1,000
	Members of NCS target population (not NCS participants).	500	1	2	1,000
Total		21,000			30,000

Requests for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency'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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to Office of Management and Budget, Office of Information and Regulatory Affairs, *Attn:* NIH Desk Officer, by e-mail to *OIRA_submission@omb.eop.gov,* or by fax to 202–395–6974. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Ms. Jamelle E. Banks, Public Health Analyst, Office of Science Policy, Analysis and Communication, National Institute of Child Health and Human Development, 31 Center Drive, Room 2A18, Bethesda, Maryland 20892, or call a non-toll free number (301) 496–1877 or E-mail your request, including your address to *banksj@mail.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received *within 30 days* of the date of this publication.

Dated: July 8, 2011.

Jamelle E. Banks,

Public Health Analyst, Office of Science Policy, Analysis and Communications National Institute of Child Health and Human Development.

[FR Doc. 2011–17735 Filed 7–13–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: HIV/AIDS.

Date: August 3, 2011.

Time: 10 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Jose H Guerrier, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301–435–1137, *guerriej@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, AIDS Related Technology Applications.

Date: August 3, 2011.

Time: 2 to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Robert Freund, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5216, MSC 7852, Bethesda, MD 20892, 301–435–1050, *freundr@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)