

prospective payment system, capitated rate, or other payment methodology. The updated Bulletin describes how exclusions can be violated and the administrative sanctions OIG can pursue against those who have violated an exclusion. The updated Bulletin also provides guidance to the health care industry on the scope and frequency of screening employees and contractors to determine whether they are excluded persons.

OIG has posted the full revision of the Special Advisory Bulletin on its Web site: <http://oig.hhs.gov/exclusions/advisories.asp>.

**FOR FURTHER INFORMATION CONTACT:** Patrice S. Drew, Congressional and Regulatory Affairs, Office of Inspector General, (202) 619-1368.

**Daniel R. Levinson,**  
*Inspector General.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Proposed Collection; 60-Day Comment Request: Interactive Informed Consent for Pediatric Clinical Trials**

**SUMMARY:** In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) will publish periodic summaries of proposed

projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

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.

*To Submit Comments and for Further Information:* To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Ms. Victoria Pemberton, Clinical Trials Specialist, National Heart, Lung, and Blood Institute, NIH, 6701 Rockledge Drive, Room 8102, MSC 7940, Bethesda, MD, or call non-toll-free number 301-435-0510, or Email your request, including your address to: [pembertonv@nhlbi.nih.gov](mailto:pembertonv@nhlbi.nih.gov). Formal requests for additional plans and instruments must be requested in writing.

**DATES: Comment Due Date:** Comments regarding this information collection are

best assured of having their full effect if received within 60 days of the date of this publication.

*Proposed Collection:* Interactive Informed Consent for Pediatric Clinical Trials, 0925-New, National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH).

*Need and Use of Information Collection:* This study will compare parents' and children's understanding of information about a hypothetical clinical trial presented using either a standard paper consent document or an interactive computer-based consent program. Parents' and children's understanding, regardless of whether they received the standard consent or the interactive computer-based program, will be assessed by face-to-face interview. In addition, parents' and children's perceptions of, and satisfaction with, the information presented will be evaluated by completion of a short questionnaire. The primary hypothesis to be tested is that interactive computer-based research consent information is better understood and accepted by parents and children compared with the standard paper consent document. Given that many individuals have difficulty reading and interpreting standard written consent documents, this technology holds promise as a means to optimize the consent and assent process particularly among individuals with low literacy and numeracy skills.

OMB approval is requested for 18 months. There are no costs to respondents other than their time. The total estimated annualized burden hours are 201.

Type of respondents	Number of respondents	Number of responses per response	Average burden per response (in hour)	Total annual burden hours
Parents .....	148	1	40/60	99
Children .....	136	1	45/60	102

Dated: April 29, 2013.

**Lynn Susulske,**

*NHLBI Project Clearance Liaison, National Institutes of Health.*

**Michael S. Lauer,**

*Director, DCVS, National Institutes of Health.*

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**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; RFA Panel: Systems Science and Health in the Behavioral and Social Sciences.

*Date:* June 6, 2013.

*Time:* 8:00 a.m. to 5:00 p.m.