

indication of nosocomial pneumonia (pneumonia contracted by hospitalized patients), including ventilator-associated pneumonia, caused by susceptible isolates of the following Gram-positive bacteria: *Staphylococcus aureus* (including methicillin-susceptible and -resistant isolates) or *Streptococcus pneumoniae* (penicillin susceptible strains).

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 meeting 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 November 13, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. 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 November 2, 2012. 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 November 5, 2012.

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 Diane Goyette 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: September 13, 2012.

**Jill Hartzler Warner,**  
*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2012-23185 Filed 9-19-12; 8:45 am]

**BILLING CODE 4160-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Proposed Collection: Comment Request: Drug Accountability Report Form and Investigator Registration Procedure in the Conduct of Investigational Trials for the Treatment of Cancer (NCI)**

**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 Cancer Institute (NCI), 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.

**Proposed Collection:** *Title:* Drug Accountability Report Form and Investigator Registration Procedure in the Conduct of Investigational Trials for the Treatment of Cancer (NCI) (OMB No. 0925-0613). *Type of Information Collection Request:* Revision. **Need and Use of Information Collection:** The U.S. Food and Drug Administration (FDA) holds the National Cancer Institute (NCI) responsible, as a sponsor of investigational drug trials, for the collection of information about the clinical investigators who participate in these trials and to assure the FDA that systems for accountability are being maintained by investigators in its clinical trials program. The information collected is used to identify qualified investigators and to facilitate the submission and distribution of important information relative to the investigational drug and the response of the patient to that drug. Investigators are physicians who specialize in the treatment of patients with cancer. Data obtained from the Drug Accountability Record is used to track the dispensing of investigational anticancer agents from receipt from the NCI to dispensing or administration to patients. NCI and/or its auditors use this information for compliance purposes. *Frequency of Response:* Up to 16 times per year. *Affected Public:* Private sector including businesses, other for-profit organizations, and non-profit institutions. *Type of Respondents:* Investigators, pharmacists, nurses, pharmacy technicians, and data managers. The annualized respondents' burden for record keeping is estimated to require 14,223 hours (see Table 1). There are no capital costs, operating costs, or maintenance costs.

TABLE 1—ESTIMATES OF ANNUAL BURDEN

Type of respondents	Form	Number of respondents	Frequency of response	Average time per response (hours)	Total hour burden
Investigators and Designee for Investigator Registration and DARF.	Statement of Investigator .....	20,112	1	15/60	5,028
	Supplemental Investigator .....	20,112	1	10/60	3,352
	Financial Disclosure .....	20,112	1	5/60	1,676
	Drug Accountability Record Form (DARF and DARF-Oral).	3,907	16	4/60	4,167
Totals .....	.....	.....	.....	.....	14,223

**Request for Comments**

Written comments and/or suggestions from the public and affected agencies are invited to address 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) The quality, utility, and clarity of the information collected; and (4) 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.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Charles, Hall, RPh, M.S., Chief, Pharmaceutical Management Branch, Cancer Therapy Evaluation Program, National Cancer Institute, Executive Plaza North, Room 7149, 9000 Rockville Pike, Bethesda, Maryland 20891. Or call non-toll-free number 301-496-5725 or email your request, include your address to: [halch@mail.nih.gov](mailto:halch@mail.nih.gov).

Comments 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.

Dated: September 14, 2012.

**Vivian Horovitch-Kelley,**

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

[FR Doc. 2012-23243 Filed 9-19-12; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****National Human Genome Research Institute; 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:* National Human Genome Research Institute Special Emphasis Panel; R25 DAP Sept. 2012.

*Date:* October 25, 2012.

*Time:* 1 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Human Genome Research Institute, 5635 Fishers Lane, 3rd Floor Conference Room, Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* Keith McKenney, Ph.D., Scientific Review Officer, NHGRI, 5635 Fishers Lane, Suite 4076, Bethesda, MD 20814, 301-594-4280, [mckenneyk@mail.nih.gov](mailto:mckenneyk@mail.nih.gov).

*Name of Committee:* National Human Genome Research Institute Special Emphasis Panel; Genomic Resources.

*Date:* October 29, 2012.

*Time:* 10 a.m. to 1 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Human Genome Research Institute, 5635 Fishers Lane, 4th floor Conference Room, Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* Keith McKenney, Ph.D., Scientific Review Officer, NHGRI, 5635 Fishers Lane, Suite 4076, Bethesda, MD 20814, 301-594-4280, [mckenneyk@mail.nih.gov](mailto:mckenneyk@mail.nih.gov).

*Name of Committee:* National Human Genome Research Institute Initial Review Group; Genome Research Review Committee, GNOM-G (CEGS plus regular load).

*Date:* November 1-2, 2012.

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

*Agenda:* To review and evaluate grant applications.

*Place:* National Human Genome Research Institute, 5635 Fishers Lane, Terrace Suite 9 & 10, Rockville, MD 20852.

*Contact Person:* Ken D. Nakamura, Ph.D., Scientific Review Officer, Office of Scientific Review, National Human Genome Research Institute, National Institutes of Health, Bethesda, MD 20892, 301-402-0838.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: September 14, 2012.

**David Clary,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2012-23128 Filed 9-19-12; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****National Center for Complementary & Alternative Medicine; Notice of Closed Meeting**

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 meeting.

The meeting 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:* National Center for Complementary and Alternative Medicine Special Emphasis Panel; Clinical Research of Complementary Medical Care.

*Date:* October 22, 2012.

*Time:* 1:30 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892.

*Contact Person:* Hungyi Shau, Ph.D., Scientific Review Officer, National Center For Complementary and Alternative Medicine, National Institutes of Health, 6707 Democracy Boulevard, Suite 401, Bethesda, MD 20892, 301-402-1030, [Hungyi.Shau@nih.gov](mailto:Hungyi.Shau@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Alternative Medicine, National Institutes of Health, HHS)

Dated: September 13, 2012.

**Michelle Trout,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2012-23129 Filed 9-19-12; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****National Heart, Lung, and Blood Institute; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Board of Scientific Counselors, NHLBI.

The meeting will be closed to the public as indicated below in accordance