

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: Topics in Digestive Disease.

Date: November 23, 2015.

Time: 2:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Aiping Zhao, MD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm 2188 MSC7818, Bethesda, MD 20892-7818, (301) 435-0682, zhaoa2@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Oncology 2—Translational Clinical Applications.

Date: November 24, 2015.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Sharon K. Gubanich, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6195D, MSC 7804, Bethesda, MD 20892, (301) 408-9512, gubanics@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(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)

Dated: November 10, 2015.

Natasha Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-29243 Filed 11-16-15; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day 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 Cancer Therapy Evaluation Program (CTEP)/Division of Cancer Therapy and Diagnostics (DCTD), 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 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 to be 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.

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, Charles Hall, RPh, M.S.,

Chief, Pharmaceutical Management Branch, Cancer Therapy Evaluation Program, National Cancer Institute, 9609 Medical Center Drive, RM 5W240, MSC 9725, Bethesda, Maryland 20892. Or call non-toll-free number (240) 276-6575, or email your request, include your address to: hallch@mail.nih.gov.

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: Title: Drug Accountability Report Form and Investigator Registration Procedure in the Conduct of Investigational Trials for the Treatment of Cancer, 0925-0613, Expiration Date 03/31/2016, Revision, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: Revision. 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. The frequency of Response is up to 16 times per year. The affected public is private sector including businesses, other for-profit organizations, and non-profit institutions. The type of respondents are investigators, pharmacists, nurses, pharmacy technicians, and data managers.

OMB approval is requested for 3 years. There are no capital costs, operating costs or maintenance costs. The total estimated annualized burden hours are 22,645 hours.

Estimated Annualized Burden Hours

TABLE 1—ESTIMATES OF ANNUAL BURDEN

Type of respondents	Form	Number of respondents	Frequency of response	Average time per response (in hours)	Total hour burden
Investigators and Designee for Investigator Registration and DARF.	Statement of Investigator (Attachments 3A, 3B or 10).	22,283	1	15/60	5,571
	NCI/DCTD/CTEP Supplemental Investigator (Attachment 4).	22,283	1	10/60	3,721
	Financial Disclosure Forms (Attachment 5A or 5B).	22,283	1	5/60	1,849
	NCI/DCTD/CTEP Drug Accountability Record Form (DARF and DARF-Oral) (Attachments 1 & 2).	3,288	16	4/60	3,525

Dated: November 9, 2015.

Karla Bailey,

Project Clearance Liaison, National Cancer Institute, NIH.

[FR Doc. 2015–29246 Filed 11–16–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases: 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 Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID SBIR Phase II Clinical Trial Implementation Cooperative Agreement (U44).

Date: December 9, 2015.

Time: 9:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 4C100, 5601 Fishers Lane, Rockville, MD 20892.

Contact Person: Zhuqing (Charlie) Li, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room # 3G41B, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC9823, Bethesda, MD 20892–9823, (240) 669–5068, zhuqing.li@nih.gov.

Name of Committee: National Institute of Allergy and Infectious Diseases Special

Emphasis Panel; NIAID Resource-Related Research Projects (R24) and NIAID Investigator Initiated Program Project Applications (P01).

Date: January 12–13, 2016.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 3F100, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Quirijn Vos, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G31A, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–9823, (240) 669–5059, qv@niaid.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 9, 2015.

Natasha Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–29247 Filed 11–16–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2); 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 purpose of this meeting is to evaluate requests for preclinical development resources for potential new therapeutics for the treatment of cancer. The outcome of the evaluation will provide information to internal NCI committees that will

decide whether NCI should support requests and make available contract resources for development of the potential therapeutic to improve the treatment of various forms of cancer. The research proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the proposed research projects, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; Dec 2015 Cycle 21 NExT SEP Committee Meeting.

Date: December 16, 2015.

Time: 8:30 a.m. to 4:30 p.m.

Agenda: To evaluate the NCI Experimental Therapeutics Program Portfolio.

Place: National Institutes of Health, 9000 Rockville Pike, Campus Building 31, Conference Room 6C6, Bethesda, MD 20892.

Contact Person: Barbara Mroczkowski, Ph.D., Executive Secretary, Discovery Experimental Therapeutics Program National Cancer Institute, NIH, 31 Center Drive, Room 3A44, Bethesda, MD 20817, (301) 496–4291, mroczkoskib@mail.nih.gov.

Toby Hecht, Ph.D., Executive Secretary, Development Experimental Therapeutics Program, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 3W110, Rockville, MD 20850, (240) 276–5683 toby.hecht2@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: November 10, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–29245 Filed 11–16–15; 8:45 am]

BILLING CODE 4140–01–P