

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.

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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