

Explanation for Burden Estimates:

The burden estimates for tables I and II of this document are based on FDA's experience with voluntary recalls under part 810 of the regulations. FDA expects no more than two mandatory recalls per year, as most recalls are done voluntarily. Since the last time this collection of information was submitted to OMB for renewal/approval, there have been no mandatory recalls.

Dated: February 18, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9-4137 Filed 2-25-09; 8:45 am]

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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. Appendix 2), 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 Oral and Dental: Small Business.

Date: March 5-6, 2009.

Time: 9 a.m. to 12 a.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Tamizchelvi Thyagarajan, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4016K, MSC 7814, Bethesda, MD 20892, 301-451-1327, tthyagar@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, Pathogens and their Vectors.

Date: March 12, 2009.

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: Richard G. Kostriken, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3192, MSC 7808, Bethesda, MD 20892, 301-402-4454, kostrikr@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 Quick Trials on Imaging and Image-guided Intervention.

Date: March 12, 2009.

Time: 11 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: John Firrell, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5213, MSC 7854, Bethesda, MD 20892, 301-435-2598, firrellj@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, Infectious Agent Detection/Diagnosis, Food Safety, Sterilization/Disinfection and Bioremediation.

Date: March 13, 2009.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Guest Suites Santa Monica, 1707 Fourth Street, Santa Monica, CA 90401.

Contact Person: Fouad A. El-Zaatari, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3206, MSC 7808, Bethesda, MD 20814-9692, (301) 435-1149, elzaataf@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, Specials of Genes, Genomes, and Genetics.

Date: March 13, 2009.

Time: 1 p.m. to 3 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: Michael A. Marino, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2216, MSC 7890, Bethesda, MD 20892, (301) 435-0601, marinomi@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, BTSS Member Conflict.

Date: March 16, 2009.

Time: 2 p.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: Roberto J. Matus, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5108, MSC 7854, Bethesda, MD 20892, (301) 435-2204, matusr@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: Immune Mechanisms.

Date: March 19, 2009.

Time: 1 p.m. to 4 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: Jian, Wang, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4095D, MSC 7812, Bethesda, MD 20892, (301) 435-2778, wangjia@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Health of the Population SBIR-2.

Date: March 23, 2009.

Time: 12 p.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: Karin F. Helmers, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3148, MSC 7770, Bethesda, MD 20892, 301-435-1017, helmersk@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel Data Ontologies and Sharing Data and Tools.

Date: March 24-25, 2009.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Alexander Gubin, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm 5144, MSC 7812, Bethesda, MD 20892, 301-435-2902, gubina@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Small Business: Digestive Sciences.

Date: March 24-25, 2009.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Bonnie L. Burgess-Beusse, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2182, MSC 7818, Bethesda, MD 20892, 301-435-1783, beusseb@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel Diversity Fellowships: Division of Translational and Clinical Sciences.

Date: March 24–25, 2009.

Time: 8 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: John Firrell, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5213, MSC 7854, Bethesda, MD 20892, 301-435-2598, firrellj@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Technologies in Cell Biology.

Date: March 24–25, 2009.

Time: 9 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: Noni Byrnes, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5130, MSC 7840, Bethesda, MD 20892, (301) 435-1023, byrnesn@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)

Dated: February 18, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-3944 Filed 2-25-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the

Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Rapid HIV Testing Clinical Information Form for the Minority AIDS Initiative (MAI) for Ethnic and Racial Minorities at Risk for Substance Use and HIV/AIDS—In Use Without OMB Approval

The Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Treatment (CSAT), is requesting an OMB review and approval of the Minority AIDS Initiative (MAI) Rapid HIV Testing Clinical Information Form that will be utilized for ethnic and racial minority groups at risk for substance use and HIV/AIDS that are served by CSAT's TCE—HIV grantees. The MAI HIV Rapid Testing Clinical Information Form would allow SAMHSA/CSAT to collect essential clinical information that will be used for quality assurance, quality performance, and product monitoring on approximately 30,000 rapid HIV test kits to be provided to ethnic and racial minority communities at no cost to the recipient provider organizations. The MAI Rapid HIV Testing Clinical Information Form would support quality of care, provide adequate clinical and product monitoring, and provide appropriate safeguards against fraud, waste and abuse of Federal funds. SAMHSA's approach would avoid unnecessary delay in informing any person potentially adversely affected by a test kit recall or public health advisory. This program is authorized under Section 509 of the Public Health Service (PHS) Act [42 U.S.C. 290bb-2].

The goals of SAMHSA's MAI initiative are to: (1) Increase the access

by racial and ethnic minority communities to HIV testing, prevention, care, and treatment services; (2) implement strategies and activities specifically targeted to the highest risk and hardest-to-serve populations; (3) reduce the stigma associated with HIV/AIDS screening through outreach and education, and (4) establish collaborations or opportunities for programs and/or activities to be integrated.

The target populations for the initiative are African Americans, Hispanic/Latinos, and other racial and ethnic minorities that are disproportionately impacted by the twin epidemics of HIV/AIDS and substance abuse. Since 1981 approximately 1.7 million people are estimated to have been infected with HIV in the U.S., and more than 1.1 million are estimated to be living with HIV/AIDS today. Racial and ethnic minorities have been disproportionately affected by HIV/AIDS, and represent the majority of new AIDS cases (70%), new HIV infections (54%), prevalent HIV/AIDS cases (65%), and AIDS deaths (72%) (CDC, 2006). African Americans have been especially affected by HIV/AIDS. More than half of all new HIV infections and half of new AIDS diagnoses occur in African Americans despite their accounting for approximately 12% of the U.S. population. A similar impact exists among Latinos, who represent 14% of the U.S. population but account for 20% of estimated AIDS diagnoses. Together, Asian/Pacific Islanders and American Indian/Alaska Natives represent 1%–2% of new AIDS diagnoses.

The spread of HIV disease in the United States has been partly fueled by the use of illicit drugs. Injection drug use (IDU) is directly related to HIV transmission through the sharing of drug equipment. According to CDC's latest report on 2006 rates, IDUs accounted for 12 percent of estimated new HIV infections. CDC's historical trend analysis indicates that new infections have declined dramatically in this population over time and confirm the substantial evidence to date of success in reducing HIV infections among IDUs. Despite these declines, rates of HIV and AIDS continue to rise among certain groups including men who have sex with men, high risk heterosexual women and ethnic and racial minority groups due to non-IDU drugs and alcohol that interfere with judgment about sexual and other types of behaviors.

The estimated hour burden is presented in the following table: