

[ucm251696.htm](#). There is no fee to attend the public workshop, but attendees must register in advance. Registration will be on a first-come, first-served basis. Non-U.S. citizens are subject to additional security screening, and they should register as soon as possible. Registration ends May 5, 2011.

If you need special accommodations because of a disability, please contact Susan Monahan at susan.monahan@fda.hhs.gov at least 7 days in advance of the public workshop.

SUPPLEMENTARY INFORMATION:

I. Why are we holding this public workshop?

The purpose of the public workshop is to facilitate discussion among FDA, governmental Agencies, academia, physicians, and the key stakeholders in the scientific community on issues related to the studies and methodological approaches examining diagnostics in the postmarket settings. We aim to create a dialogue between professionals with epidemiologic, statistical, and clinically relevant expertise in diagnostic devices to determine the evidence gaps and questions, datasets and approaches for conducting postmarket surveillance and robust analytic studies to improve our understanding of the performance of diagnostics at the postmarket settings.

II. Who is the target audience for this public workshop? Who should attend this public workshop?

This public workshop is open to all interested parties. The target audience is professionals in the scientific community with experience in epidemiology, diagnostics, or biomedical research with an interest in diagnostic devices and epidemiologic study methodology.

III. What are the topics we intend to address at the public workshop?

We intend to discuss a large number of methodological concerns at the workshop, including, but not limited to the following:

- Gaps and challenges in postmarket studies of diagnostics,
- Identifying and verifying emerging data sources and methodologies, and
- Fostering interdisciplinary collaboration towards identifying new opportunities in methodologies for diagnostic devices.

IV. Where can I find out more about this public workshop?

Background information on the public workshop, registration information, the agenda, information about lodging, transcripts, and other relevant

information will be posted, as it becomes available, on the Internet at <http://www.fda.gov/cdrh/meetings.html>.

Dated: April 22, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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 Mental Health Initial Review Group; Interventions Committee for Adult Disorders.

Date: June 1, 2011.

Time: 8:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: St. Gregory Hotel, 2033 M Street, NW., Washington, DC 20036.

Contact Person: David I. Sommers, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Blvd., Room 6154, MSC 9606, Bethesda, MD 20892-9606, 301-443-7861, dsommers@mail.nih.gov.

Name of Committee: National Institute of Mental Health Initial Review Group; Interventions Committee for Disorders Involving Children and Their Families.

Date: June 6, 2011.

Time: 8:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: The Dupont Hotel, 1500 New Hampshire Avenue, NW., Washington, DC 20036.

Contact Person: David I. Sommers, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Blvd., Room 6154, MSC 9606, Bethesda, MD 20892-9606, 301-443-7861, dsommers@mail.nih.gov.

Name of Committee: National Institute of Mental Health Initial Review Group; Mental Health Services in Non-Specialty Settings.

Date: June 15, 2011.

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

Agenda: To review and evaluate grant applications.

Place: Melrose Hotel, 2430 Pennsylvania Ave., NW., Washington, DC 20037.

Contact Person: Aileen Schulte, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6140, MSC 9608, Bethesda, MD 20892-9608, 301-443-1225, aschulte@mail.nih.gov.

Name of Committee: National Institute of Mental Health Initial Review Group; Mental Health Services in Specialty Settings.

Date: June 16, 2011.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call)

Contact Person: Marina Broitman, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6153, MSC 9608, Bethesda, MD 20892-9608, 301-402-8152, mbroitma@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: April 21, 2011.

Anna P. Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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 materials, and personal information concerning individuals associated with the grant applications, the disclosure of which