

guidance may also inform the development of any future actions, as needed.

## II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

## IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/RegulatoryInformation/Guidances/ucm257698.htm> or <http://www.regulations.gov>.

Dated: June 2, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-14643 Filed 6-13-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Neurological Disorders and Stroke; 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 materials, 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 Neurological Disorders and Stroke Initial Review Group, Neurological Sciences and Disorders K.

*Date:* June 23-24, 2011.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Shanta Rajaram, PhD, Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-435-6033, [rajarams@mail.nih.gov](mailto:rajarams@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: June 7, 2011.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2011-14718 Filed 6-13-11; 8:45 am]

**BILLING CODE 4140-01-P**

## 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, Radiation Therapy and Biology SBIR/STTR.

*Date:* July 11, 2011.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Doubletree Hotel Washington, 1515 Rhode Island Ave, NW., Washington, DC 20005.

*Contact Person:* Bo Hong, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6194, MSC 7804, Bethesda, MD 20892, 301-435-5879, [hongb@csr.nih.gov](mailto:hongb@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Member Conflict: Vascular Hematology.

*Date:* July 11-12, 2011.

*Time:* 1 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:* Anshumali Chaudhari, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4124, MSC 7802, Bethesda, MD 20892, (301) 435-1210, [chaudhaa@csr.nih.gov](mailto:chaudhaa@csr.nih.gov).

*Name of Committee:* AIDS and Related Research Integrated Review Group, NeuroAIDS and other End-Organ Diseases Study Section.

*Date:* July 12, 2011.

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

*Agenda:* To review and evaluate grant applications.

*Place:* The Westin Seattle, 1900 5th Avenue, Seattle, WA 98101.

*Contact Person:* Eduardo A Montalvo, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5108, MSC 7852, Bethesda, MD 20892, (301) 435-1168, [montalve@csr.nih.gov](mailto:montalve@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, RFA Panel: Indo-US Program on Reproductive Health.

*Date:* July 13, 2011.

*Time:* 8 a.m. to 12 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Gary Hunnicutt, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6164, MSC 7892, Bethesda, MD 20892, 301-435-0229, [gary.hunnicutt@nih.gov](mailto:gary.hunnicutt@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Fellowship: Chemical and Bioanalytical Sciences,

*Date:* July 13, 2011.

*Time:* 8:30 a.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Courtyard by Marriott, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

*Contact Person:* Sergei Ruvins, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4158, MSC 7806, Bethesda, MD 20892, 301-435-1180, [ruvins@csr.nih.gov](mailto:ruvins@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Small Business: Skeletal Muscle and Exercise Physiology.

*Date:* July 13, 2011.

*Time:* 1 p.m. to 3:30 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:* Richard Ingraham, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4116, MSC 7814, Bethesda, MD 20892, 301-496-8551, [ingrahamrh@mail.nih.gov](mailto:ingrahamrh@mail.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, RFA Panel: Indo-US Program on Reproductive Health.

*Date:* July 13, 2011.

*Time:* 12:30 p.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Dianne Hardy, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6175, Bethesda, MD 20892, 301-435-1154, [dianne.hardy@nih.gov](mailto:dianne.hardy@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: June 7, 2011.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2011-14716 Filed 6-13-11; 8:45 am]

**BILLING CODE 4140-01-P**

## 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 Special Emphasis Panel, NIH Pathway to Independence (PI) Award.

*Date:* July 12, 2011.

*Time:* 12 p.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:* Megan Libbey, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6148, MSC 9609, Rockville, MD 20852-9609, 301-402-6807, [libbeym@mail.nih.gov](mailto:libbeym@mail.nih.gov).

*Name of Committee:* National Institute of Mental Health Special Emphasis Panel, Fellowships and Dissertation Grants.

*Date:* July 20, 2011.

*Time:* 1 p.m. to 4 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:* David W. Miller, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Boulevard, Room 6140, MSC 9608, Bethesda, MD 20892-9608, 301-443-9734, [millerda@mail.nih.gov](mailto:millerda@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: June 7, 2011.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2011-14714 Filed 6-13-11; 8:45 am]

**BILLING CODE 4140-01-P**

## 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 Special Emphasis Panel, National Cooperative Drug Discovery and Development Group.

*Date:* June 29, 2011.

*Time:* 1 p.m. to 4 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:* Vinod Charles, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6151, MSC 9606, Bethesda, MD 20892-9606, 301-443-1606, [charlesvi@mail.nih.gov](mailto:charlesvi@mail.nih.gov).

*Name of Committee:* National Institute of Mental Health Special Emphasis Panel, Conflicts and Eating Disorders 2011.

*Date:* July 7, 2011.

*Time:* 12:30 p.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:* Francois Boller, MD, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6142, MSC 9606, Bethesda, MD 20892-9606, 301-443-1513, [bollefr@mail.nih.gov](mailto:bollefr@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: June 7, 2011.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2011-14712 Filed 6-13-11; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Diabetes and Digestive and Kidney 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