

III. Paperwork Reduction Act of 1995

This revised final guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this guidance was approved under OMB control number 0910–0509. The approval expires on December 31, 2006. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this revised guidance at any time. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The revised guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with access to the Internet may obtain the revised guidance document at <http://www.cfsan.fda.gov/guidance.html>.

Dated: June 13, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–12234 Filed 6–21–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children (ACHDGDNC).

Dates and Times: July 21, 2005, 9 a.m. to 5 p.m., and July 22, 2005, 9 a.m. to 3 p.m.

Place: Ronald Reagan Building and International Trade Center, Rotunda Room,

1300 Pennsylvania Avenue, NW., Washington, DC 20004.

Status: The meeting will be open to the public with attendance limited to space availability.

Purpose: The Advisory Committee provides advice and recommendations concerning the grants and projects authorized under the Heritable Disorders Program and technical information to develop policies and priorities for this program that will enhance the ability of the State and local health agencies to provide for newborn and child screening, counseling and health care services for newborns and children having or at risk for heritable disorders. Specifically, the Advisory Committee shall advise and guide the Secretary regarding the most appropriate application of universal newborn screening tests, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having or at risk for heritable disorders.

Agenda: Presentations and discussions will include: an update on the American College of Medical Genetics report; the role of evidence and other factors in decisionmaking; the status of newborn screening in States; the newborn screening policy of the American College of Obstetrics and Gynecology; and reports from the Subcommittees on Education and Training, Treatment and Follow-up, and Laboratory Standards and Procedures.

Proposed agenda items are subject to change as priorities indicate.

Public Comments: Time will be provided each day for public comment. Written comments should be submitted no later than July 14, 2005. Individuals who wish to provide public comment or who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the ACHDGDNC Executive Secretary, Michele A. Lloyd-Puryear, M.D., Ph.D., Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18A–19, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–1080.

For Further Information Contact: Anyone interested in obtaining a roster of members or other relevant information should write or contact Jill Shuger, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18A–19, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–1080. Information on the Advisory Committee is available at <http://mchb.hrsa.gov/programs/genetics/committee>.

Dated: June 16, 2005.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 05–12233 Filed 6–21–05; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institutes on Aging; 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 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 institute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Aging Special Emphasis Panel HRS.

Date: June 29–30, 2005.

Time: 6:15 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814.

Contact Person: Alfonso R. Latoni, PhD, Health Scientist Administrator, Scientific Review Office, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Room 2C212, Bethesda, MD 20892, 301–402–7707, latonia@nia.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: National Institute on Aging Special Emphasis Panel; Alzheimer Trials.

Date: July 8, 2005.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Gateway Building, 7201 Wisconsin Ave, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Ramesh Vemuri, PhD, Health Scientist Administrator, Scientific Review Office, National Institute on Aging, National Institutes of Health, Room 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–402–7700, rv23r@nih.gov.

Name of Committee: National Institute on Aging Special Emphasis Panel; Long Term Care.

Care: July 10–11, 2005.

Time: 6 p.m. to 5 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: Jon Rolf, PhD, Health Scientist Administrator, Scientific Review

Office, National Institutes of Health, National Institute on Aging, 7201 Wisconsin Avenue, Room 2C212, Bethesda, MD 20814, (301) 402-7703, rolfj@nia.nih.gov.

Name of Committee: National Institute on Aging Special Emphasis Panel; Calcium and Muscle Aging.

Date: July 11-12, 2005.

Time: 6:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Ramesh Vemuri, PhD, Health Scientist Administrator, Scientific Review Office, National Institute on Aging, National Institutes of Health, Room 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301-402-7700, rv23r@nih.gov.

Name of Committee: National Institute on Aging Special Emphasis Panel, Alzheimer's Disease Cellular Models.

Date: July 19, 2005.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Ave, Bethesda, MD 20814, (Telephone Conference Call).

Contact Person: William Cruce, PhD, Health Scientist Administrator, Scientific Review Office, National Institute on Aging, National Institutes of Health, Room 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20814, 301-402-7704, crucew@nia.nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: June 14, 2005.

LaVerne J. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05-12269 Filed 6-21-05; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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)(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 Neurological Disorders and Stroke Special Emphasis Panel; Huntington's Disease: Development of Novel Therapeutics.

Date: June 20, 2005.

Time: 1 p.m. to 2 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: W. Ernest Lyons, PhD, Scientific Review Administrator, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892-9529, (301) 496-4056.

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: National Institute of Neurological Disorders and Stroke Special Emphasis Panel MRI Review.

Date: June 21, 2005.

Time: 12 p.m. to 2 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: Joann McConnell, PhD, Scientific Review Administrator, Scientific Review Branch, NIH/NINDS/Neuroscience Center, 6001 Executive Blvd., Suite 3208, Msc 9529, Bethesda, MD 20892-9529, (301) 496-5324, mcconnej@nids.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: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Huntington's Disease Review.

Date: June 23, 2005.

Time: 2:30 p.m. to 4:30 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: Joann McConnell, PhD, Scientific Review Administrator, Scientific Review Branch, NIH/NINDS/Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892-9529, (301) 496-5324, mcconnej@nids.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: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Molecular Libraries HTS Assay Development RFA.

Date: June 29-30, 2005.

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

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, DC, 2401 M Street NW., Washington, DC 20037.

Contact Person: Shantadurga Rajaram, PhD, Scientific Review Administrator, Scientific Review Branch, NIH/NINDS/Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20852, (301) 435-6033, 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 14, 2005.

LaVerne Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05-12271 Filed 6-21-05; 8:45 am]

BILLING CODE 4140-01-M

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. 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: National Institute of Mental Health Special Emphasis Panel, ITV COI.

Date: July 8, 2005.

Time: 12 p.m. to 3 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: Henry J. Haigler, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Rm. 6150, MSC 9608, Bethesda, MD 20892-9608, (301) 443-7216, hhaigler@mail.nih.gov.

Name of Committee: National Institute of Mental Health Special Emphasis Panel, Review of HIV/AIDS applications.

Date: July 13, 2005.

Time: 9 a.m. to 3 p.m.