

2010); however, current testing procedures (16 CFR 1500.42) do not provide criteria to classify results obtained from a three-animal test. NICEATM, in collaboration with ICCVAM, conducted an analysis to determine classification criteria based on results from a three-animal test that would maintain hazard classification equivalent to that provided by current testing procedures (16 CFR 1500.42).

The process for developing the ICCVAM recommendations began with a critical review of the analysis (Haseman *et al.*, 2011) and existing data by the ICCVAM Interagency Ocular Toxicity Working Group (OTWG). As part of ICCVAM's ongoing international collaborations, scientists from the European Union Reference Laboratory for Alternatives to Animal Testing and the Japanese Center for the Validation of Alternative Methods served as liaisons to the OTWG. The analysis (Haseman *et al.*, 2011) was provided to the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) at the June 17–18, 2010 meeting (75 FR 26758, May 12, 2010) for comment. The public was also given an opportunity to comment at that meeting. The OTWG then developed draft ICCVAM recommendations regarding classification criteria based on results from a three-animal test that would maintain hazard classification equivalent to that provided by current testing procedures (16 CFR 1500.42). The draft ICCVAM recommendations and supporting analysis (Haseman *et al.*, 2011) were made available on the NICEATM–ICCVAM Web site (<http://iccvam.niehs.nih.gov/methods/ocutox/reducenum.htm>) for comment by the broad stakeholder community (76 FR 50220, August 12, 2011).

ICCVAM considered the analysis (Haseman *et al.*, 2011), all public comments, and the SACATM comments in preparing the final ICCVAM test method recommendations. The recommendations are provided in the *ICCVAM Test Method Evaluation Report: Identifying Chemical Eye Hazards with Fewer Animals* (NIH Publication No. 12–7930), which is available on the NICEATM–ICCVAM Web site (<http://iccvam.niehs.nih.gov/methods/ocutox/reducenum-TMER.htm>). ICCVAM concludes that using a classification criterion of one or more positive animals in a three-animal test to identify chemicals and products that are eye hazards will maintain hazard classification equivalent to that provided by current testing procedures (16 CFR 1500.42 [CPSC, 2010]), while using up to 50% to 83% fewer animals. ICCVAM, therefore, recommends

consideration of this classification together with eye safety testing procedures that use a maximum of three animals per test substance. Consistent with ICCVAM's duty to foster interagency and international harmonization (42 U.S.C. 285l-3), this recommendation harmonizes the number of animals used for eye safety testing across U.S. regulatory agencies and international test guidelines. The ICCVAM TMER includes relevant ocular toxicity regulations and guidelines, applicable **Federal Register** notices, public comments, and SACATM meeting minutes.

#### **Background Information on ICCVAM, NICEATM, and SACATM**

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that require, use, generate, or disseminate toxicological and safety testing information. ICCVAM conducts technical evaluations of new, revised, and alternative safety testing methods and integrated testing strategies with regulatory applicability and promotes the scientific validation and regulatory acceptance of testing methods that more accurately assess the safety and hazards of chemicals and products and that reduce, refine (enhance animal well-being and lessen or avoid pain and distress), or replace animal use. The ICCVAM Authorization Act of 2000 (42 U.S.C. 285l-3) established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM. NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and conducts independent validation studies to assess the usefulness and limitations of new, revised, and alternative test methods and strategies. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative test methods and strategies for validation studies and technical evaluations. Additional information about NICEATM and ICCVAM can be found on the NICEATM–ICCVAM Web site (<http://iccvam.niehs.nih.gov>).

SACATM was established in response to the ICCVAM Authorization Act (Section 285l-3[d]) and is composed of scientists from the public and private sectors. SACATM advises ICCVAM, NICEATM, and the Director of the NIEHS and NTP regarding statutorily mandated duties of ICCVAM and activities of NICEATM. SACATM provides advice on priorities and activities related to the development, validation, scientific review, regulatory acceptance, implementation, and national and international

harmonization of new, revised, and alternative toxicological test methods. Additional information about SACATM, including the charter, roster, and records of past meetings, can be found at <http://ntp.niehs.nih.gov/go/167>.

#### **References**

CPSC. 2010. Federal Hazardous Substances Act Regulations. 16 CFR 1500. Available: <http://www.gpo.gov/fdsys/pkg/CFR-2011-title16-vol2/pdf/CFR-2011-title16-vol2-chapII-subchapC.pdf>.

Haseman J.K., Allen D.G., Lipscomb E.A., Truax J.F., Stokes WS. 2011. Using fewer animals to identify chemical eye hazards: revised criteria necessary to maintain equivalent hazard classification. *Regul Toxicol Pharmacol* 61: 98–104.

Dated: October 3, 2012.

**John R. Bucher,**

*Associate Director, National Toxicology Program.*

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**BILLING CODE 4140-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **National Institute on Minority Health and Health Disparities; 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 would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute on Minority Health and Health Disparities Special Emphasis Panel; NIMHD Social, Behavioral, Health Services, and Policy Research on Minority Health and Health Disparities (R01).

*Date:* November 7–9, 2012.

*Time:* 8 a.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton Rockville Hotel, 1750 Rockville Pike, Rockville, MD 20852.

*Contact Person:* Maryline Laude-Sharp, Ph.D., Scientific Review Officer, National Institute on Minority Health and Health

Disparities, National Institutes of Health, 6707 Democracy Blvd., Suite 800, Bethesda, MD 20892, (301) 451-9536, [mlaudesharp@mail.nih.gov](mailto:mlaudesharp@mail.nih.gov).

*Name of Committee:* National Institute on Minority Health and Health Disparities Special Emphasis Panel; NIMHD Basic and Applied Biomedical Research on Minority Health and Health Disparities (R01).

*Date:* November 15-16, 2012.

*Time:* 8 a.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton Rockville Hotel, 1750 Rockville Pike, Rockville, MD 20852.

*Contact Person:* Maryline Laude-Sharp, Ph.D., Scientific Review Officer, National Institute on Minority Health, and Health Disparities, National Institutes of Health, 6707 Democracy Blvd., Suite 800, Bethesda, MD 20892, (301) 451-9536, [mlaudesharp@mail.nih.gov](mailto:mlaudesharp@mail.nih.gov).

Dated: October 3, 2012.

**David Clary,**

*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

#### National Institute of General Medical Sciences; 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 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 General Medical Sciences Special Emphasis Panel; Peer Review of R01 Grant Applications.

*Date:* November 14-15, 2012.

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

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Natcher Building, 45 Center Drive, Room 3An18, Bethesda, MD 20892, (Virtual Meeting).

*Contact Person:* Margaret J. Weidman, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An18B,

Bethesda, MD 20892, 301-594-3663, [weidmanma@nigms.nih.gov](mailto:weidmanma@nigms.nih.gov). (Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: October 3, 2012.

**Melanie J. Gray,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2012-24870 Filed 10-9-12; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of General Medical Sciences; 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 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 General Medical Sciences Initial Review Group; Training and Workforce Development Subcommittee—A.

*Date:* November 14, 2012.

*Time:* 8 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:* Carole H. Latker, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.18, Bethesda, MD 20892, 301-594-2848, [latker@nigms.nih.gov](mailto:latker@nigms.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: October 3, 2012.

**Melanie J. Gray,**

*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

#### National Institute of General Medical Sciences; 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 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 General Medical Sciences Special Emphasis Panel; MBRS SCORE.

*Date:* November 13, 2012.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Doubletree Hotel Bethesda, (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Robert Horowitz, Ph.D., Scientific Review Officer, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.18, Bethesda, MD 20892-6200, 301-594-6904, [horowitz@mail.nih.gov](mailto:horowitz@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: October 2, 2012.

**Melanie J. Gray,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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