

**III. Listing of New Entries**

In table 2, FDA provides the listing of new entries and consensus standards

added as modifications to the list of recognized standards under Recognition List Number: 045.

TABLE 2—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS

Recognition No.	Title of standard <sup>1</sup>	Reference No. and date
<b>A. General I (Quality Systems/Risk Management) (QS/RM)</b>		
5-110 .....	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less.	ISTA 3A 2008.
5-111 .....	Packaged-Products for Less-Than-Truckload (LTL) Shipment .....	ISTA 3B 2012.
5-112 .....	Unitized Loads of Same Product .....	ISTA 3E 2009.
<b>B. In Vitro Diagnostics (IVD)</b>		
7-265 .....	Liquid Chromatography-Mass Spectrometry Methods; Approved Guideline.	C62-A: 2014.
7-266 .....	A Framework for Using CLSI Documents to Evaluate Clinical Laboratory Measurement Procedures.	EP19 Second Edition: 2015.
<b>C. Ophthalmic</b>		
10-101 .....	Ophthalmic optics—Contact lenses and contact lens care products—Cytotoxicity testing of contact lenses in combination with lens care solution to evaluate lens/solution interactions.	ISO 18189 First edition 2016-06-01.
10-102 .....	American National Standard for Ophthalmics—Light Hazard Protection for Ophthalmic Instruments.	ANSI Z80.36—2016.

<sup>1</sup> All standard titles in this table conform to the style requirements of the respective organizations.

**IV. List of Recognized Standards**

FDA maintains the Agency’s current list of FDA Recognized Consensus Standards in a searchable database that may be accessed directly at FDA’s Internet site at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>. FDA will incorporate the modifications and revisions described in this notice into the database and, upon publication in the **Federal Register**, this recognition of consensus standards will be effective. FDA will announce additional modifications and revisions to the list of recognized consensus standards, as needed, in the **Federal Register** once a year, or more often if necessary. Beginning with Recognition List 033, FDA no longer announces minor revisions to the list of recognized consensus standards such as technical contact person, devices affected, processes affected, Code of Federal Regulations citations, and product codes.

**V. Recommendation of Standards for Recognition by FDA**

Any person may recommend consensus standards as candidates for recognition under section 514 of the FD&C Act by submitting such recommendations, with reasons for the recommendation, to [standards@cdrh.fda.gov](mailto:standards@cdrh.fda.gov). To be properly considered, such recommendations should contain, at a minimum, the following

information: (1) Title of the standard, (2) any reference number and date, (3) name and address of the national or international standards development organization, (4) a proposed list of devices for which a declaration of conformity to this standard should routinely apply, and (5) a brief identification of the testing or performance or other characteristics of the device(s) that would be addressed by a declaration of conformity.

**VI. Electronic Access**

You may obtain a copy of “Guidance on the Recognition and Use of Consensus Standards” by using the Internet. The Center for Devices and Radiological Health (CDRH) maintains a site on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page, <http://www.fda.gov/MedicalDevices>, includes a link to standards-related documents including the guidance and the current list of recognized standards. After publication in the **Federal Register**, this notice announcing “Modification to the List of Recognized Standards, Recognition List Number: 045” will be available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm>. You may access “Guidance on the Recognition and Use of Consensus Standards,” and

the searchable database for “FDA Recognized Consensus Standards” at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards>.

Dated: September 15, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-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; Prokaryotic Gene Expression.

*Date:* October 5, 2016.

*Time:* 9:00 a.m. to 11:00 a.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 A. Currie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1108, MSC 7890, Bethesda, MD 20892, (301) 435-1219, [currieri@csr.nih.gov](mailto:currieri@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:* Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Musculoskeletal Rehabilitation Sciences Study Section.

*Date:* October 17, 2016.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Westin BWI, 1110 Old Elkridge Landing Road, Linthicum, MD 21090.

*Contact Person:* Maria Nurminskaya, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, Bethesda, MD 20892, (301) 435-1222, [nurminskaya@csr.nih.gov](mailto:nurminskaya@csr.nih.gov).

*Name of Committee:* Infectious Diseases and Microbiology Integrated Review Group; Virology—B Study Section.

*Date:* October 17–18, 2016.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Residence Inn Alexandria Old Town, 1456 Duke St, Alexandria, VA 22314.

*Contact Person:* John C. Pugh, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1206, MSC 7808, Bethesda, MD 20892, (301) 435-2398, [pughjohn@csr.nih.gov](mailto:pughjohn@csr.nih.gov).

*Name of Committee:* Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Mechanisms of Sensory, Perceptual, and Cognitive Processes Study Section.

*Date:* October 17–18, 2016.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Washington Plaza Hotel, 10 Thomas Circle NW., Washington, DC 20005.

*Contact Person:* Kirk Thompson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5184, MSC 7844, Bethesda, MD 20892, 301-435-1242, [kgt@mail.nih.gov](mailto:kgt@mail.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Vaccine Related Immune Activation and Immunoregulation.

*Date:* October 18, 2016.

*Time:* 8:00 a.m. to 5:00 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:* Liying Guo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4016F, Bethesda, MD 20892, 301-435-0908, [lguo@mail.nih.gov](mailto:lguo@mail.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR-16-114: Spermatogenic Stem Cell Culture Systems to Preserve and Restore Reproductive Capacity in Males.

*Date:* October 19, 2016.

*Time:* 2:00 p.m. to 6:00 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:* Clara M. Cheng, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6170, MSC 7892, Bethesda, MD 20892, 301-435-1041, [chengc@csr.nih.gov](mailto:chengc@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: September 15, 2016.

**Carolyn Baum,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Heart, Lung, and Blood Institute; 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 a meeting of the Board of Scientific Counselors, NHLBI. The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the NATIONAL HEART, LUNG, AND BLOOD INSTITUTE, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Board of Scientific Counselors, NHLBI.

*Date:* October 25, 2016.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate programmatic and personnel issues.

*Place:* Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

*Contact Person:* Robert S. Balaban, Ph.D., Scientific Director, National Heart, Lung, and Blood Institute, National Institutes of Health, Building 10, 10 Center Drive, CRC, 4th Floor, Room 1581, Bethesda, MD 20892, 301-496-2116, [balabanr@nhlbi.nih.gov](mailto:balabanr@nhlbi.nih.gov).

Information is also available on the Institute's/Center's home page:

[www.nhlbi.nih.gov/meetings/index.htm](http://www.nhlbi.nih.gov/meetings/index.htm),

where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: September 15, 2016.

**Michelle Trout,**

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

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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. 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:* Oncology 1-Basic Translational Integrated Review Group; Tumor Microenvironment Study Section.

*Date:* October 13–14, 2016.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

*Contact Person:* Angela Y. Ng, MBA, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6200, MSC 7804, Bethesda, MD 20892, 301-435-1715, [ngan@mail.nih.gov](mailto:ngan@mail.nih.gov).