

for both class II and class III CADe devices applied to radiology images and radiology device data. These clinical performance studies may be part of a premarket submission to FDA, whether it is a 510(k) submission, an application for PMA, an application for a humanitarian device exemption, or an application for an investigational device exemption.

In the **Federal Register** of October 21, 2009 (74 FR 54053), FDA announced the availability of the draft guidance documents. Interested persons were invited to comment by January 19, 2010. Six comments were received with multiple recommendations about changes to the content of the documents. FDA also received comments during the public meetings of the Radiology Devices Panel, an FDA advisory committee, on March 4–5, 2008, and November 17–18, 2009. In response to all of these comments, FDA revised both guidance documents to clarify the level of detail the Agency would like to see regarding the description and operation of the CADe device and about test data reuse. In response to the comments, the new guidance documents also clarify that digitized film is within the scope of radiological data and that FDA intends to create new product codes as necessary to identify and track new types of CADe products.

FDA's revisions, based on comments on the CADe 510(k) guidance, also include updated recommendations on the scoring process and when a clinical performance assessment may be necessary. The Generalizability Testing subsection was extensively modified, including removing recommendations on algorithm stability testing. In response to comments on the CADe clinical performance assessment guidance, FDA limited the postmarket section to outlining the basic postapproval study process.

## II. Significance of Guidance

These guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidances represent the Agency's current thinking on premarket notification (510(k)) submissions of certain CADe devices applied to radiology images and radiology device data and on clinical performance studies for CADe devices applied to radiology images and radiology device data. The guidance documents do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies

the requirements of the applicable statute and regulations.

## III. Electronic Access

Persons interested in obtaining a copy of either guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. To receive "Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data—Premarket Notification (510(k)) Submissions," or "Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data—Premarket Approval (PMA) and Premarket Notification (510(k)) Submissions," you may either send an email request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number (1697) to identify the CADe 510(k) guidance or the document number (1698) to identify the CADe clinical performance assessment guidance.

## IV. Paperwork Reduction Act of 1995

These guidance documents refer to currently approved collections of information found in FDA regulations. These collections of information 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 collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; and the collections of information in 21 CFR part 814 have been approved under OMB control numbers 0910–0231 and 0910–0332.

## V. 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. 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.

Dated: June 27, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2012–16227 Filed 7–2–12; 8:45 am]

**BILLING CODE 4160–01–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 Revisions on the Protections for Human Subjects Study Section.

*Date:* July 30, 2012.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Lorian Hotel and Spa, 1600 King Street, Alexandria, VA 22314.

*Contact Person:* Karin F. Helmers, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3166, MSC 7770, Bethesda, MD 20892, 301–254–9975, [helmersk@csr.nih.gov](mailto:helmersk@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Member Conflict: Motor Function, Speech and Rehabilitation.

*Date:* July 30, 2012.

*Time:* 1:00 p.m. to 2:30 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:* Weijia Ni, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, MSC 7848, Bethesda, MD 20892, (301) 237–9918, [niw@csr.nih.gov](mailto:niw@csr.nih.gov).

*Name of Committee:* Biology of Development and Aging Integrated Review Group, International and Cooperative Projects—1 Study Section.

*Date:* August 2, 2012.

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

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

*Contact Person:* Hilary D. Sigmon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5222, MSC 7852, Bethesda, MD 20892, (301) 594-6377, [sigmonh@csr.nih.gov](mailto:sigmonh@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Member Conflict: Biobehavioral and Behavioral Processes.

*Date:* August 2, 2012.

*Time:* 11:00 a.m. to 12:30 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:* Melissa Gerald, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3172, MSC 7848, Bethesda, MD 20892, (301) 408-9107, [geraldmel@csr.nih.gov](mailto:geraldmel@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: June 27, 2012.

**Jennifer S. Spaeth,**

*Director, 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

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*Name of Committee:* Center for Scientific Review Special Emphasis Panel Program Project: Support of NIGMS.

*Date:* July 23-24, 2012.

*Time:* 11:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

*Contact Person:* Noni Byrnes, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5130, MSC 7840, Bethesda, MD 20892, (301) 435-1023, [byrnesn@csr.nih.gov](mailto:byrnesn@csr.nih.gov).

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

*Date:* July 24-25, 2012.

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

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

*Contact Person:* Wei-Qin Zhao, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5181, MSC 7846, Bethesda, MD 20892-7846, (301) 435-1236, [zhaow@csr.nih.gov](mailto:zhaow@csr.nih.gov).

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

*Date:* July 24, 2012.

*Time:* 2:00 p.m. to 5:00 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:* Rass M. Shaiyq, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 2182, MSC 7818, Bethesda, MD 20892, (301) 435-2359, [shaiyqr@csr.nih.gov](mailto:shaiyqr@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, PAR12-017: Shared NMR Spectrometers.

*Date:* July 25-26, 2012.

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

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

*Contact Person:* David R. Jollie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4150, MSC 7806, Bethesda, MD 20892, (301) 435-1722, [jollieda@csr.nih.gov](mailto:jollieda@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, PAR12-010: Research Relevant to the Family Smoking Prevention and Tobacco Control Act.

*Date:* July 25, 2012.

*Time:* 4:00 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:* Everett E. Sinnett, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2178, MSC 7818, Bethesda, MD 20892, (301) 435-1016, [sinnett@nih.gov](mailto:sinnett@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 27, 2012.

**Jennifer S. Spaeth,**

*Director, 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

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*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Member Conflict: AIDS and AIDS Related Research.

*Date:* July 20, 2012.

*Time:* 12:30 p.m. to 7:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* St Gregory Hotel and Suites, 2033 M Street NW., Washington, DC 20817, (Telephone Conference Call).

*Contact Person:* Jose H. Guerrier, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301-435-1137, [guerriej@csr.nih.gov](mailto:guerriej@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Program Project: Neurobiology of Behavior in Model Organisms.

*Date:* July 30-31, 2012.

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

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

*Contact Person:* Elena Smirnova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5187, MSC 7840, Bethesda, MD 20892, 301-435-1236, [smirnove@csr.nih.gov](mailto:smirnove@csr.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine;