

manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the CBER Internet site at <http://www.fda.gov/cber/guidelines.htm> or on the Division of Dockets Management Internet site at <http://www.regulations.gov>.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously 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 (the PRA) (44 U.S.C. 3501–3520). The information collection provisions in 21 CFR part 814, subpart B (Pre-market Approval Applications (PMAAs)) in this guidance have been approved under OMB control number 0910–0231. This approval expires November 30, 2010.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

Dated: December 5, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–29330 Filed 12–11–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; 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 Center for Research Resources Special Emphasis Panel CTSA 1.

Date: February 10–11, 2009.

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

Agenda: To review and evaluate grant applications.

Place: Hilton Washington DC/Rockville Hotel, Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Mohan Viswanathan, PhD, Deputy Director, Office of Review, National Center for Research Resources, National Institutes of Health, 6701 Democracy Blvd., Dem. 1, Room 1084, MSC 4874, Bethesda, MD 20892–4874, 301–435–0829, mv10f@nih.gov.

Name of Committee: National Center for Research Resources Special Emphasis Panel; CTSA–2.

Date: February 18–19, 2009.

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

Agenda: To review and evaluate grant applications.

Place: Hilton Washington DC /Rockville Hotel, Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Mohan Viswanathan, PhD, Deputy Director, Office of Review, National Center for Research Resources, National Institutes of Health, 6701 Democracy Blvd., Dem. 1, Room 1084, MSC 4874, Bethesda, MD 20892–4874, 301–435–0829, mv10f@nih.gov.

Name of Committee: National Center for Research Resources Special Emphasis Panel RCM1–COBRE.

Date: February 25–26, 2009.

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

Agenda: To review and evaluate grant applications.

Place: Hilton Wash. DC/Rockville Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Steven Birken, PhD, Scientific Review Officer, Office of Review, National Center for Research Resources, 1

Democracy Plaza, Room 1078, 6701 Democracy Blvd., Bethesda, MD 20892, 301–435–0815, birkens@mail.nih.gov.

Name of Committee: National Center for Research Resources Special Emphasis Panel; RCM1 Infrastructures for Clinical and Translational Research (RCTR).

Date: March 4, 2009.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Carol Lambert, PhD, Scientific Review Officer, Office of Review, National Center for Research Resources, National Institute of Health, 6701 Democracy Boulevard, 1 Democracy Plaza, Room 1076, Bethesda, MD 20892–4874, (301) 435–0814, lambert@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.371, Biomedical Technology; 93.389, Research Infrastructure, 93.306, 93.333, National Institutes of Health, HHS)

Dated: December 4, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–29272 Filed 12–10–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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 Heart, Lung, and Blood Institute Special Emphasis Panel; Research Scientist Development Awards.

Date: December 18, 2008.

Time: 8:30 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westin Arlington Gateway, 801 N. Glebe Road, Arlington, VA 22203.

Contact Person: Mark Roltsch, PhD, Scientific Review Administrator, Review Branch/DERA, National Heart, Lung, and