

current good manufacturing practices for medical devices regulation (21 CFR part 820) may be relevant to a PMA review and may be submitted as part of an application. In individual instances,

records may be required as conditions of approval to ensure the device's continuing safety and effectiveness.

In the **Federal Register** of October 19, 2016 (81 FR 72063), FDA published a 60-day notice requesting public

comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity/21 CFR or FD&C Act section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Research conducted outside the United States (814.15(b))	25	1	25	2	50
PMA application (814.20)	35	1	35	668	23,380
PMA amendments and resubmitted PMAs (814.37(a)–(c) and (e))	1,222	1	1,222	167	204,074
PMA supplements (814.39(a))	695	1	695	60	41,700
Special PMA supplement—changes being affected (814.39(d))	88	1	88	6	528
30-day notice (814.39(f))	1,710	1	1,710	16	27,360
Postapproval requirements (814.82(a)(9))	340	1	340	135	45,900
Periodic reports (814.84(b))	695	1	695	10	6,950
Agreement meeting (520(g)(7))	1	1	1	50	50
Expedited review request (515(d)(5) of the FD&C Act)	6	1	6	10	60
Determination Meeting (513(1)(3)(D) of the FD&C Act)	1	1	1	50	50
Panel meeting (515(c)(3) of the FD&C Act)	9	1	9	30	270
Day 100 meeting (515(d)(3) of the FD&C Act)	19	1	19	10	190
Total					350,562

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual responses	Average burden per response	Total hours
Maintenance of records (814.82(a)(5) and (a)(6))	422	1	422	17	7,174

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: January 13, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017–01188 Filed 1–19–17; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Drug Abuse; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which

would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute on Drug Abuse Special Emphasis Panel; Virtual Reality Tools to Enhance Evidence-Based Treatment of Substance Use Disorders (5583).

*Date:* February 1, 2017.

*Time:* 8:00 a.m. to 4:00 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* Gerald L. McLaughlin, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Blvd., Room 4238, MSC 9550, Bethesda, MD 20892–9550, 301–827–5819, [gm145a@nih.gov](mailto:gm145a@nih.gov).

(Catalogue of Federal Domestic Assistance Program No.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: January 13, 2017.

**Natasha M. Copeland,**

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

[FR Doc. 2017–01253 Filed 1–19–17; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Biomedical Imaging and Bioengineering; 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 Biomedical Imaging and Bioengineering Special Emphasis Panel; P41 BTRC Review (2017/05).

*Date:* March 16, 2017.

*Time:* 08:00 a.m. to 8:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, Suite 920, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Dennis Hlasta, Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Blvd., Bethesda, MD 20892, (301) 451-4794, [dennis.hlasta@nih.gov](mailto:dennis.hlasta@nih.gov).

Dated: January 12, 2016.

**David Clary,**

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

[FR Doc. 2017-01252 Filed 1-19-17; 8:45 am]

**BILLING CODE 4140-01-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; SBIB Clinical Pediatric and Fetal Applications.

*Date:* February 15, 2017.

*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:* Songtao Liu, M.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5108, Bethesda, MD 20817, 301-435-3578, [songtao.liu@nih.gov](mailto:songtao.liu@nih.gov).

*Name of Committee:* Musculoskeletal, Oral and Skin Sciences Integrated Review Group;

Oral, Dental and Craniofacial Sciences Study Section.

*Date:* February 16-17, 2017.

*Time:* 7:30 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Doubletree by Hilton Los Angeles Westside Hotel, 6161 W. Centinela Avenue, Culver City, CA 90230.

*Contact Person:* Yi-Hsin Liu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, 301-435-1781, [liuyh@csr.nih.gov](mailto:liuyh@csr.nih.gov).

*Name of Committee:* Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Macromolecular Structure and Function A Study Section.

*Date:* February 16-17, 2017.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Pier 2620 Hotel, 2620 Jones Street, San Francisco, CA 94133.

*Contact Person:* Nitsa Rosenzweig, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4152, MSC 7760, Bethesda, MD 20892, (301) 404-7419, [rosenzweig@csr.nih.gov](mailto:rosenzweig@csr.nih.gov).

*Name of Committee:* Immunology Integrated Review Group; Innate Immunity and Inflammation Study Section.

*Date:* February 16-17, 2017.

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

*Agenda:* To review and evaluate grant applications.

*Place:* The Ritz-Carlton, Pentagon City, 1250 South Hayes St., Arlington, VA 22202.

*Contact Person:* Tina McIntyre, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4202, MSC 7812, Bethesda, MD 20892, 301-594-6375, [mcintyrt@csr.nih.gov](mailto:mcintyrt@csr.nih.gov).

*Name of Committee:* Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Cellular, Molecular and Integrative Reproduction Study Section.

*Date:* February 16-17, 2017.

*Time:* 8:00 a.m. to 12:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* The Westgate Hotel, 1055 Second Avenue, San Diego, CA 92101.

*Contact Person:* Gary Hunnicutt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6164, MSC 7892, Bethesda, MD 20892, 301-435-0229, [hunnicuttgr@csr.nih.gov](mailto:hunnicuttgr@csr.nih.gov).

*Name of Committee:* Cardiovascular and Respiratory Sciences Integrated Review Group; Myocardial Ischemia and Metabolism Study Section.

*Date:* February 16-17, 2017.

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

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Kimm Hamann, Ph.D., Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118A, MSC 7814, Bethesda, MD 20892, 301-435-5575, [hamannkj@csr.nih.gov](mailto:hamannkj@csr.nih.gov).

*Name of Committee:* Genes, Genomes, and Genetics Integrated Review Group; Genetic Variation and Evolution Study Section.

*Date:* February 16-17, 2017.

*Time:* 8:00 a.m. to 7:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Renaissance M Street Hotel, 1143 New Hampshire Avenue NW., Washington, DC 20037.

*Contact Person:* Ronald Adkins, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2206, MSC 7890, Bethesda, MD 20892, 301-435-4511, [ronald.adkins@nih.gov](mailto:ronald.adkins@nih.gov).

*Name of Committee:* Emerging Technologies and Training Neurosciences Integrated Review Group; Molecular Neurogenetics Study Section.

*Date:* February 16-17, 2017.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Mary G Schueler, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5214, MSC 7846, Bethesda, MD 20892, 301-915-6301, [marygs@csr.nih.gov](mailto:marygs@csr.nih.gov).

*Name of Committee:* Brain Disorders and Clinical Neuroscience Integrated Review Group, Diseases and Pathophysiology of the Visual System Study Section.

*Date:* February 16-17, 2017.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Bahia Resort Hotel, 998 West Mission Bay Drive, San Diego, CA 92109.

*Contact Person:* Nataliya Gordiyenko, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5202, MSC 7846, Bethesda, MD 20892, 301.435.1265, [gordiyenkon@csr.nih.gov](mailto:gordiyenkon@csr.nih.gov).

*Name of Committee:* Biobehavioral and Behavioral Processes Integrated Review Group; Child Psychopathology and Developmental Disabilities Study Section.

*Date:* February 16-17, 2017.

*Time:* 8:00 a.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Ritz-Carlton Hotel, 1700 Tysons Boulevard, McLean, VA 22102.

*Contact Person:* Jane A Doussard-Roosevelt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, MSC 7848, Bethesda, MD 20892, (301) 435-4445, [doussarj@csr.nih.gov](mailto:doussarj@csr.nih.gov).

*Name of Committee:* Healthcare Delivery and Methodologies Integrated Review Group, Community Influences on Health Behavior Study Section.

*Date:* February 16-17, 2017.

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

*Agenda:* To review and evaluate grant applications.