

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN—BIOLOGICAL PRODUCTS <sup>1</sup>

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper (in hours)	Total hours
600.12; <sup>2</sup> Maintenance of Records .....	131	40.145	5,259	32	168,288
600.12(b)(2); Recall Records .....	216	3,4028	735	24	17,640
600.80(c)(1) and 600.80(k); AER Records .....	109	7,503.95	817,931	1	817,931
Total .....					1,003,859

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

<sup>2</sup> The recordkeeping requirements in § 610.18(b) are included in the estimate for § 600.12.

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN—COMBINATION PRODUCTS <sup>1</sup>

21 CFR section; activity	Number of respondents	Number of disclosures per respondents	Total annual disclosures	Average burden per disclosure (in hours)	Total hours
4.102, 4.103, 4.104, 4.105; Postmarketing Safety Reporting for Combination Products, including associated reports and sharing information with other constituent part applicants.	11	18	198	0.35 (21 minutes) ...	69

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

The burden for this information collection has changed since the last OMB approval. The reporting and recordkeeping burden has increased mostly due to an increase in the number of AER reports submitted to FDA and the associated recordkeeping with these reports. We have also added burden we believe attributable to post marketing safety reporting and attendant recordkeeping and disclosures, as required under part 4, subpart B.

Dated: September 23, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023–21252 Filed 9–27–23; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute of General Medical Sciences; Notice of Closed Meetings**

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, 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 Institute of General Medical Sciences Special Emphasis Panel; Renewal of Centers of Biomedical Research Excellence (COBRE) (Phase 2).

*Date:* November 7–8, 2023.

*Time:* 9:30 a.m. to 1:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, National Institute of General Medical Sciences, Natcher Building, 45 Center Drive, Bethesda, Maryland 20892 (Virtual Meeting).

*Contact Person:* Nina Sidorova, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, MSC 6200, Room 3AN18–01, Bethesda, Maryland 20892, 301–594–3663, [sidorova@nigms.nih.gov](mailto:sidorova@nigms.nih.gov).

*Name of Committee:* National Institute of General Medical Sciences Special Emphasis Panel; Review of MOSAIC K99/R00 applications.

*Date:* November 9, 2023.

*Time:* 10:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, National Institute of General Medical Sciences, Natcher Building, 45 Center Drive, Bethesda, Maryland 20892 (Virtual Meeting).

*Contact Person:* Rebecca H. Johnson, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, MSC 6200, Room 3AN12B, Bethesda, Maryland 20892, 301–594–2771, [johnsonrh@nigms.nih.gov](mailto:johnsonrh@nigms.nih.gov).

*Name of Committee:* National Institute of General Medical Sciences Special Emphasis Panel; Review of Support for Research Excellence (SuRE) Program (R16).

*Date:* November 17, 2023.

*Time:* 10:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, National Institute of General Medical Sciences, Natcher Building, 45 Center Drive, Bethesda, Maryland 20892 (Virtual Meeting).

*Contact Person:* Rebecca H. Johnson, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, MSC 6200, Room 3AN12B, Bethesda, Maryland 20892, 301–594–2771, [johnsonrh@nigms.nih.gov](mailto:johnsonrh@nigms.nih.gov).

(Catalogue of Federal Domestic Assistance Program No. 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: September 22, 2023.

**Miguelina Perez,**

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

[FR Doc. 2023–21154 Filed 9–27–23; 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 Meeting**

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, 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:* Heart, Lung, and Blood Initial Review Group; NHLBI

Institutional Training Mechanism Study Section.

*Date:* December 1, 2023.

*Time:* 10:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge I, 6705 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Michael P. Reilly, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6705 Rockledge Drive, Room 208-Z, Bethesda, MD 20892, 301-827-7975, [reillymp@nhlbi.nih.gov](mailto:reillymp@nhlbi.nih.gov).

(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 22, 2023.

**Melanie J. Pantoja,**

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

[FR Doc. 2023-21145 Filed 9-27-23; 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 Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, 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:* Heart, Lung, and Blood Initial Review Group; Heart, Lung, and Blood Program Project Study Section.

*Date:* December 1, 2023.

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

*Agenda:* To review and evaluate grant applications.

*Place:* DoubleTree by Hilton McLean Tysons, 1960 Chain Bridge Rd., McLean, VA 22102.

*Contact Person:* Melissa H. Nagelin, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 208-R, Bethesda, MD 20892, (301) 827-7951, [nagelinmh2@nhlbi.nih.gov](mailto:nagelinmh2@nhlbi.nih.gov).

(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 22, 2023.

**Melanie J. Pantoja,**

*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 Dental and Craniofacial Research; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, 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 Institute of Dental and Craniofacial Research Special Emphasis Panel; Review of NIDCR R03 and DSR Member-Conflict Applications.

*Date:* November 2, 2023.

*Time:* 10:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute of Dental and Craniofacial Research, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Yun Mei, MD, Scientific Review Officer, Scientific Review Branch, National Institute of Dental and Craniofacial Research, National Institutes of Health, 6701 Democracy Boulevard, Bethesda, MD 20892, (301) 827-4639, [yun.mei@nih.gov](mailto:yun.mei@nih.gov).

*Name of Committee:* National Institute of Dental and Craniofacial Research Special Emphasis Panel; Review of RFA-DE-24-001 and RFA-DE-24-002.

*Date:* November 15, 2023.

*Time:* 9:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute of Dental and Craniofacial Research, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Christopher T. Campbell, Ph.D., MD, Scientific Review Officer,

Scientific Review Branch, National Institute of Dental and Craniofacial Research, National Institutes of Health, 6701 Democracy Boulevard, Bethesda, MD 20892, (301) 594-5593, [christopher.campbell@nih.gov](mailto:christopher.campbell@nih.gov).

(Catalogue of Federal Domestic Assistance Program No. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: September 22, 2023.

**Melanie J. Pantoja,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Establishment of the Applied Therapeutics for Cancer Integrated Review Group

Pursuant to the Federal Advisory Committee Act, as amended (5 U.S.C. 1001-1014), the Director, National Institutes of Health (NIH) announces the establishment of the Applied Therapeutics for Cancer Integrated Review Group (IRG) as authorized by 42 U.S.C. 282(b)(16), section 402(b)(16) of the Public Health Service Act, as amended.

The Director, NIH, has determined that the Applied Therapeutics for Cancer IRG is in the public interest in connection with the performance of duties imposed on NIH by law, and that these duties can best be performed through the advice and counsel of the committee.

The committee provides advice and recommendations on funding applications and proposals, including but not limited to, the scientific and technical merit of applications for grants-in-aid for research, research training, or research-related grants and cooperative agreements, or contract proposals relating to scientific areas relevant to translational and clinical investigations that encompass cancer therapeutic development and cancer treatment.

Inquiries may be directed to Claire Harris, Director, Office of Federal Advisory Committee Policy, Office of the Director, National Institutes of Health, 6701 Democracy Boulevard, Suite 1000, Bethesda, Maryland 20892 (Mail code 4875), Telephone (301) 496-2123, or [Claire.Harris@nih.gov](mailto:Claire.Harris@nih.gov).