

for those products intended to be licensed under section 351(k) of the PHS Act and being developed as a

proposed biosimilar to a reference product.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

FDA form; survey	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Biosimilar User Fee Cover Sheet (Form FDA 3792)	30	2	60	0.5 (30 minutes)	30
Request for discontinuation from BPD program or to move products to discontinued section of Biosimilar List.	6	1	6	1	6
Biosimilar product & interchangeable product applications (351(k)); patent infringement notifications (351(l)).	16	~1.94	31	~610.90	18,938
Formal meeting requests as recommended in FDA guidance.	135	2.30	311	21.42	6,661
Submission of Pediatric Assessment; iPSP template information, including deferrals of pediatric assessments for proposed biosimilar products; iPSP amendments as recommended in FDA guidance.	11	1	11	~38.18	420
Total	419	26,055

Our estimated burden for the information collection reflects an overall increase of 13,069 hours and 105 responses annually. Although part of the increase may be attributed to the inclusion of burden associated with the submission of pediatric study plans, we regard the majority of adjustments as nominal fluctuations consistent with the number of applications and submissions we are receiving.

Dated: September 18, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–21671 Filed 9–20–24; 8:45 am]

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 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: Biobehavioral and Behavioral Processes Integrated Review

Group; Adult Lifespan Psychopathology Study Section.

Date: October 17–18, 2024.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

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

Meeting Format: Virtual Meeting.

Contact Person: Benjamin G. Shaper, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3182, MSC 7848, Bethesda, MD 20892, (301) 402–4786, shaperobg@mail.nih.gov.

Name of Committee: Oncology 1—Basic Translational Integrated Review Group; Gene Regulation in Cancer Study Section.

Date: October 21–22, 2024.

Time: 9:30 a.m. to 7:30 p.m.

Agenda: To review and evaluate grant applications.

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

Meeting Format: Virtual Meeting.

Contact Person: Manzoor A. Zarger, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6208, MSC 7804, Bethesda, MD 20892, (301) 435–2477, zargerma@csr.nih.gov.

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Biobehavioral Regulation, Learning and Ethology Study Section.

Date: October 21–22, 2024.

Time: 9:30 a.m. to 7:30 p.m.

Agenda: To review and evaluate grant applications.

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

Meeting Format: Virtual Meeting.

Contact Person: Sara Louise Hargrave, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 3170,

Bethesda, MD 20892, (301) 443–7193, hargravesl@mail.nih.gov.

Name of Committee: Oncology 1—Basic Translational Integrated Review Group; Basic Cancer Immunobiology Study Section.

Date: October 22–23, 2024.

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

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Meeting Format: In Person.

Contact Person: Sarita Kandula Sastry, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20782, 301–402–4788, sarita.sastry@nih.gov.

Name of Committee: Applied Therapeutics for Cancer Integrated Review Group; Mechanisms of Cancer Therapeutics C Study Section.

Date: October 22–23, 2024.

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

Agenda: To review and evaluate grant applications.

Place: The Darcy Hotel, 1515 Rhode Island Ave, NW, Washington, DC 20005.

Meeting Format: In Person.

Contact Person: Gloria Huei-Ting Su, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–496–0465, gloria.su@nih.gov.

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Skeletal Muscle and Exercise Physiology Study Section.

Date: October 22–23, 2024.

Time: 8:00 a.m. to 10:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015.

Meeting Format: In Person.

Contact Person: Carmen Bertoni, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 805B,

Bethesda, MD 20892, (301) 867–5309, bertonic2@csr.nih.gov.

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

Date: October 22–23, 2024.

Time: 8:30 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

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

Meeting Format: In Person and Virtual Meeting.

Contact Person: Alexei A. Yeliseev, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 443–0552, yeliseeva@mail.nih.gov.

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Analytics and Statistics for Population Research Panel; A Study Section.

Date: October 22–23, 2024.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

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

Meeting Format: Virtual Meeting.

Contact Person: Lisa Steele, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892, (301) 257–2638, steeleln@csr.nih.gov.

Name of Committee: Social and Community Influences on Health Integrated Review Group; Social Sciences and Population Studies A Study Section.

Date: October 22–23, 2024.

Time: 9:00 a.m. to 7:30 p.m.

Agenda: To review and evaluate grant applications.

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

Meeting Format: In Person.

Contact Person: Suzanne Ryan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892, (301) 435–1712, ryansj@csr.nih.gov.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Neurodifferentiation, Plasticity, Regeneration and Rhythmicity Study Section.

Date: October 22–23, 2024.

Time: 9:00 a.m. to 8:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Meeting Format: In Person.

Contact Person: Jacek Topczewski, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1002A1, Bethesda, MD 20892, (301) 594–7574, topczewskij2@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 17, 2024.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–21617 Filed 9–20–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Eunice Kennedy Shriver National Institute of Child Health and Human Development Initial Review Group, Population Sciences Study Section, October 25, 2024, 09:00 a.m. to 05:00 p.m., Hyatt Regency Bethesda, 7400 Wisconsin Avenue, Bethesda, MD 20814, which was published in the **Federal Register** on June 17, 2024, FR Doc. No. 2024–13310, 89 FR 51537.

This notice is being amended to change the start time of the meeting from 9:00 a.m. to 10:00 a.m. E.T. The meeting is closed to the public.

Dated: September 18, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–21662 Filed 9–20–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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: National Institute of Mental Health Initial Review Group; Mental Health Services Study Section.

Date: October 21–22, 2024.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency, Bethesda, One Bethesda Metro Center, Bethesda, MD 20814 (Hybrid Meeting).

Contact Person: Aileen Schulte, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, Neuroscience Center, 6001 Executive Blvd., Bethesda, MD 20852, 301–443–1225, email: aschulte@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: September 18, 2024.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–21663 Filed 9–20–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; National Institutes of Health NeuroBioBank Tissue Access Request and Progress Report Forms (National Institute of Mental Health)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request more information on the