

regarding the roles and responsibilities of sponsors, investigators, healthcare institutions, and local healthcare providers and addresses using a quality by design approach to facilitate the conduct of trials in the clinical practice setting.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Integrating Randomized Controlled Trials for Drug and Biological Products Into Routine Clinical Practice." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

## III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information/biologics/biologics-guidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: September 12, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024–21077 Filed 9–17–24; 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 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 on Drug Abuse Special Emphasis Panel; Cohort Studies of HIV/AIDS and Substance Use.

*Date:* November 4, 2024.

*Time:* 10:00 a.m. to 5:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Soyoun Cho, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 594–9460, [Soyoun.cho@nih.gov](mailto:Soyoun.cho@nih.gov).

*Name of Committee:* National Institute on Drug Abuse Special Emphasis Panel; Engaging Survivors of Sexual Violence and Trafficking in HIV and Substance Use Disorder Services.

*Date:* November 6, 2024.

*Time:* 11:30 a.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Marisa Srivareerat, Ph.D., Scientific Review Officer, Scientific Review Branch, Office of Extramural Policy, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 435–1258, [marisa.srivareerat@nih.gov](mailto:marisa.srivareerat@nih.gov).

*Name of Committee:* National Institute on Drug Abuse Special Emphasis Panel; Harnessing Artificial Intelligence and Polypharmacology to Discover Pharmacotherapeutics for Substance Use Disorders.

*Date:* November 13, 2024.

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

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Devon Rene Oskvig, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 402–6965, [devon.oskvig@nih.gov](mailto:devon.oskvig@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: September 12, 2024.

**Lauren A. Fleck,**

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

[FR Doc. 2024–21152 Filed 9–17–24; 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 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:* Oncology 1—Basic Translational Integrated Review Group; Basic Mechanisms of Cancer Health Disparities Study Section.

*Date:* October 15–16, 2024.

*Time:* 10:00 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 (Virtual Meeting).

*Contact Person:* Amy L Rubinstein, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5152, MSC 7844, Bethesda, MD 20892, 301–408–9754, email: [rubinsteinal@csr.nih.gov](mailto:rubinsteinal@csr.nih.gov).

*Name of Committee:* Oncology 2—Translational Clinical Integrated Review

Group; Translational Immuno-oncology Study Section.

*Date:* October 16–17, 2024.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency, Bethesda, One Bethesda Metro Center, Bethesda, MD 20814 (In Person).

*Contact Person:* Maria Elena Cardenas-Corona, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20817, 301–867–5309, email: [maria.cardenas-corona@nih.gov](mailto:maria.cardenas-corona@nih.gov).

*Name of Committee:* Bioengineering Sciences & Technologies Integrated Review Group; Drug and Biologic Therapeutic Delivery Study Section.

*Date:* October 16–17, 2024.

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

*Agenda:* To review and evaluate grant applications.

*Place:* St. Gregory Hotel, 2033 M Street NW, Washington, DC 20036 (In Person).

*Contact Person:* Janice Duy, Ph.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 301–594–3139, email: [janice.duy@nih.gov](mailto:janice.duy@nih.gov).

*Name of Committee:* Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Musculoskeletal Rehabilitation Sciences Study Section.

*Date:* October 16–17, 2024.

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

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Richard Michael Lovering, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1000J, Bethesda, MD 20892, (301) 867–5309, email: [loveringrm@mail.nih.gov](mailto:loveringrm@mail.nih.gov).

*Name of Committee:* Population Sciences and Epidemiology Integrated Review Group; Social and Environmental Determinants of Health Study Section.

*Date:* October 16–17, 2024.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814 (In Person).

*Contact Person:* Ananya Paria, MPH, MS, DHSC, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1007H, Bethesda, MD 20892, (301) 827–6513, email: [pariaa@mail.nih.gov](mailto:pariaa@mail.nih.gov).

*Name of Committee:* Social and Community Influences on Health Integrated Review Group; Health Promotion in Communities Study Section.

*Date:* October 16–17, 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 (Virtual Meeting).

*Contact Person:* Helena Eryam Dagadu, MPH, Ph.D., Scientific Review Officer, Center

for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3137, Bethesda, MD 20892, (301) 435–1266, email: [dagadu@csr.nih.gov](mailto:dagadu@csr.nih.gov).

*Name of Committee:* Interdisciplinary Molecular Sciences and Training Integrated Review Group; Cellular and Molecular Technologies Study Section.

*Date:* October 16–17, 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 (Virtual Meeting).

*Contact Person:* Tatiana V Cohen, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5213, Bethesda, MD 20892, 301–455–2364, email: [tatiana.cohen@nih.gov](mailto:tatiana.cohen@nih.gov).

*Name of Committee:* Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Biochemistry and Biophysics of Membranes Study Section.

*Date:* October 16–17, 2024.

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

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* James W Mack, Ph.D., Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4154, MSC 7806, Bethesda, MD 20892, (301) 435–2037, email: [mackj2@csr.nih.gov](mailto:mackj2@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR Panel: Academic-Industrial Partnerships for Translation of Technologies.

*Date:* October 16, 2024.

*Time:* 10:00 a.m. to 7:00 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Jennifer Ann Sanders, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 496–3553, email: [jennifer.sanders@nih.gov](mailto:jennifer.sanders@nih.gov).

*Name of Committee:* Cell Biology Integrated Review Group; Biology and Development of the Eye Study Section.

*Date:* October 16–17, 2024.

*Time:* 10:00 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 (Virtual Meeting).

*Contact Person:* Robert O'Hagan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (240) 909–6378, email: [ohaganr2@csr.nih.gov](mailto:ohaganr2@csr.nih.gov).

*Name of Committee:* Infectious Diseases and Immunology A Integrated Review Group; Bacterial Virulence Study Section.

*Date:* October 16–17, 2024.

*Time:* 10:00 a.m. to 9:00 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Susan Daum, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3202, Bethesda, MD 20892, 301–827–7233, email: [susan.boyle-vavra@nih.gov](mailto:susan.boyle-vavra@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; BRAIN Initiative: Preclinical Proof of Concept for Novel Recording and Modulation Technologies in the Human CNS.

*Date:* October 16, 2024.

*Time:* 1:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Aurea D De Sousa, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5186, Bethesda, MD 20892, (301) 827–6829, email: [aurea.desousa@nih.gov](mailto:aurea.desousa@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 12, 2024.

**Bruce A. George,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Environmental Health 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:* Environmental Health Sciences Review Committee.