

bodies, investigators, and other stakeholders.

The revised draft technical specification and template have been left in the original ICH format. The final technical specification and template will be reformatted and edited to conform with FDA's good guidance practices regulation (21 CFR 10.115) and style before publication. The technical specification and template, when finalized, will represent the current thinking of FDA on the topics they address. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. As we develop any final guidance on this topic, FDA will consider comments on the applicability of Executive Order 14192, per OMB guidance M-25-20, and in particular, on any costs or cost savings.

## 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 part 312 pertaining to clinical trial design and protocols have been approved under OMB control number 0910-0014.

## III. Electronic Access

Persons with access to the internet may obtain the draft guidance, template, and technical specification at <https://www.regulations.gov>, <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>, or <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

Dated: June 2, 2025.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2025-10359 Filed 6-5-25; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, Fellowships: Sensory and Motor Neurosciences, Cognition and Perception June 30, 2025, 09:30 a.m. to July 01, 2025, 07:00 p.m., National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on June 02, 2025, 90 FR 23342, Doc. No. 2025-09845.

This meeting is being amended to change the date from June 30, 2025–July 1, 2025, to July 29–July 30, 2025. The meeting is closed to the public.

Dated: June 2, 2025.

**Sterlyn H. Gibson,**

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

[FR Doc. 2025-10337 Filed 6-5-25; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, NIDDK.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting can be accessed from the NIH Videocast at the following link: <https://videocast.nih.gov/>.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended for the review, discussion, and evaluation of individual grant applications conducted by the National Institute Of Diabetes And Digestive And Kidney Diseases, including consideration of personnel qualifications and performance, and the competence of individual investigators,

the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Board of Scientific Counselors, NIDDK.

*Date:* October 8–9, 2025.

*Open:* October 08, 2025, 10:00 a.m. to 5:00 p.m.

*Agenda:* Introductions and Overview.

*Address:* National Institutes of Health, Building 10, 10 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

*Closed:* October 09, 2025, 10:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate personal qualifications and performance, and competence of individual Investigators.

*Address:* National Institutes of Health, Building 10, 10 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Michael W. Krause, Ph.D., Scientific Director, NIDDK, National Institute of Diabetes and Digestive and Kidney Diseases, National Institute of Health, Building 5, Room B104, Bethesda, MD 20892-1818, (301) 402-4633, [mwkrause@helix.nih.gov](mailto:mwkrause@helix.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: June 2, 2025.

**Bruce A. George,**

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

[FR Doc. 2025-10335 Filed 6-5-25; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Pregnancy and Neonatology Study Section, June 26, 2025, 09:00 a.m. to June 27, 2025, 08:00 p.m., National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on May 29, 2025, 90 FR 22746, Doc No. 2025-09612.

This meeting is being amended to change the contact person from Andrew M. Wolfe to Anthony Chan, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 496-9392, [anthony.chan@nih.gov](mailto:anthony.chan@nih.gov). The meeting is closed to the public.

Dated: June 2, 2025.

**Sterlyn H. Gibson,**

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

[FR Doc. 2025–10333 Filed 6–5–25; 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:* Center for Scientific Review Special Emphasis Panel; PAR Panel: Maximizing Investigators' Research Award Review.

*Date:* July 1–2, 2025.

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

*Agenda:* To review and evaluate grant applications.

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

*Meeting Format:* Virtual Meeting.

*Contact Person:* James J. Li, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5148, MSC 7849, Bethesda, MD 20892, 301–806–8065, [lijames@csr.nih.gov](mailto:lijames@csr.nih.gov).

*Name of Committee:* Infectious Diseases and Immunology B Integrated Review Group; HIV Comorbidities and Clinical Studies Study Section.

*Date:* July 8–9, 2025.

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

*Agenda:* To review and evaluate grant applications.

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

*Meeting Format:* Virtual Meeting.

*Contact Person:* Shannon J. Sherman, Ph.D., Scientific Review Officer, The Center for Scientific Review, The National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–594–0715, [shannon.sherman@nih.gov](mailto:shannon.sherman@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Small Business: Informatics tools for the Pangenome.

*Date:* July 8, 2025.

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

*Agenda:* To review and evaluate grant applications.

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

*Meeting Format:* Virtual Meeting.

*Contact Person:* Joonil Seog, SCD Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–402–9791, [joonil.seog@nih.gov](mailto:joonil.seog@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Fellowships: Cell Biology, Developmental Biology, and Bioengineering.

*Date:* July 8–9, 2025.

*Time:* 9:30 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Meeting Format:* Virtual Meeting.

*Contact Person:* Alexander Gubin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4196, MSC 7812, Bethesda, MD 20892, 301–435–2902, [gubina@csr.nih.gov](mailto:gubina@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Fellowships: Infectious Diseases and Immunology C.

*Date:* July 8–9, 2025.

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

*Agenda:* To review and evaluate grant applications.

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

*Meeting Format:* Virtual Meeting.

*Contact Person:* Melinda H. Krick, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr., Room 808G, Bethesda, MD 20892, (301) 435–1199, [krickmh@csr.nih.gov](mailto:krickmh@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; RFA–RM–24–009: Human Virome Program: Developing novel and innovative tools to interrogate and annotate the human virome (U01 Clinical Trial Not Allowed).

*Date:* July 8, 2025.

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

*Agenda:* To review and evaluate grant applications.

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

*Meeting Format:* Virtual Meeting.

*Contact Person:* Anna Babakhanyan, Ph.D., Scientific Review Officer, The Center for Scientific Review, The National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, [anna.babakhanyan@nih.gov](mailto:anna.babakhanyan@nih.gov).

*Name of Committee:* Oncology 1—Basic Translational Integrated Review Group; Basic Mechanisms of Cancer Health Disparities Study Section.

*Date:* July 8–9, 2025.

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

*Agenda:* To review and evaluate grant applications.

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

*Meeting Format:* Virtual Meeting.

*Contact Person:* Wing-Hang Tong, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (302) 402–0360, [tongw@mail.nih.gov](mailto:tongw@mail.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Fellowships: Cancer Immunology and Immunotherapy II.

*Date:* July 9, 2025.

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

*Agenda:* To review and evaluate grant applications.

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

*Meeting Format:* Virtual Meeting.

*Contact Person:* Hasan Siddiqui, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W240, Rockville, MD 20850, 240–276–5122, [hasan.siddiqui@nih.gov](mailto:hasan.siddiqui@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: June 3, 2025.

**Sterlyn H. Gibson,**

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

[FR Doc. 2025–10338 Filed 6–5–25; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Cancer Institute Clinical Trials and Translational Research Advisory Committee.

The meeting will be held as a virtual meeting and is open public. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The meeting can be accessed from the NIH Videocast at the following link: <https://videocast.nih.gov/>.

*Name of Committee:* National Cancer Institute Clinical Trials and Translational Research Advisory Committee.

*Date:* July 16, 2025.

*Time:* 11:00 a.m. to 3:00 p.m., ET.

*Agenda:* Discussion of NCI's Clinical and Translational Research Programs.