

or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Victoria Wagman, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft document entitled “Recommendations To Reduce the Risk of Transfusion-Transmitted Malaria.” This guidance document provides blood establishments that collect blood and blood components with FDA’s revised recommendations to reduce the risk of TTM. Specifically, the guidance recommends selectively testing blood donations from donors at risk for malaria using an FDA-licensed donor screening NAT for *Plasmodium species (spp.)*, the causative agents of malaria.

The recommendations contained in this draft guidance apply to the collection of Whole Blood and blood components, except Source Plasma. We do not require blood establishments to screen Source Plasma donors for malaria risk factors because Source Plasma undergoes further manufacturing steps to effectively remove or inactivate pathogens such as *Plasmodia spp.* (see 21 CFR 630.15(b)(8)). Licensed plasma derivatives manufactured from Source Plasma have not transmitted malaria.

The draft guidance, when finalized, is intended to supersede the document entitled “Recommendations To Reduce the Risk of Transfusion-Transmitted Malaria,” dated December 2022.

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 “Recommendations To Reduce the Risk of Transfusion-Transmitted Malaria.” 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 part 601 and Form FDA 356h have been approved under OMB control number 0910–0338;

and the collections of information in 21 CFR parts 606 and 630 have been approved under OMB control number 0910–0116.

**III. Electronic Access**

Persons with access to the internet may obtain the draft guidance at <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: January 10, 2025.

**P. Ritu Nalubola,**

Associate Commissioner for Policy.

[FR Doc. 2025–01028 Filed 1–15–25; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Center for Advancing Translational 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 Center for Advancing Translational Sciences Special Emphasis Panel; NCATS RDCRC Grant Application Review.

**Date:** February 3–5, 2025.

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

**Agenda:** To review and evaluate cooperative agreement applications.

**Address:** National Center for Advancing Translational Sciences, National Institutes of Health, 9609 Medical Center Drive, Rockville, MD 20892.

**Meeting Format:** In Person and Virtual Meeting.

**Contact Person:** M. Lourdes Ponce, Ph.D., Scientific Review Officer, Office of Scientific Review, National Center for Advancing Translational Sciences, National Institutes of Health, 9609 Medical Center Drive, Suite 1E504, Bethesda, MD 20892, (301) 435–0810, [lourdes.ponce@nih.gov](mailto:lourdes.ponce@nih.gov).

**Name of Committee:** National Center for Advancing Translational Sciences Special

Emphasis Panel; RDCRN Research Consortia B.

*Date:* February 5–7, 2025.

*Time:* 10:00 a.m. to 6:30 p.m.

*Agenda:* To review and evaluate cooperative agreement applications.

*Address:* National Center for Advancing Translational Sciences, National Institutes of Health, 9609 Medical Center Drive, Rockville, MD 20892.

*Meeting Format:* In Person and Virtual Meeting.

*Contact Person:* Victor Henriquez, Ph.D., Scientific Review Officer, Office of Scientific Director, National Center for Advancing Translational Sciences, National Institutes of Health, 9609 Medical Center Drive, Suite 1E504, Bethesda, MD 20892, (301) 451-2405, [henriquv@mail.nih.gov](mailto:henriquv@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: January 10, 2025.

**David W. Freeman,**

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

[FR Doc. 2025-00980 Filed 1-15-25; 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 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 Mental Health Special Emphasis Panel; Suicide Prevention in Crisis Response and LMIC Across the Lifespan.

*Date:* February 14, 2025.

*Time:* 11:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Serena Chu, 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, 301-500-5829, email: [serena.chu@nih.gov](mailto:serena.chu@nih.gov).

*Name of Committee:* National Institute of Mental Health Special Emphasis Panel; Precision Mental Health: Develop Tools to Inform Treatment Selection in Depression.

*Date:* February 18, 2025.

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

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Regina Dolan-Sewell, 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, (240) 796-6785, email: [regina.dolan-sewell@nih.gov](mailto:regina.dolan-sewell@nih.gov).

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

Dated: January 10, 2025.

**Bruce A. George,**

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

[FR Doc. 2025-00857 Filed 1-15-25; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; 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 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 grant applications and contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Cancer Institute Special Emphasis Panel; PLCO U01 SEP Review Meeting.

*Date:* February 12, 2025.

*Time:* 10:00 a.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W102, Rockville, Maryland 20850.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Shakeel Ahmad, Ph.D., Branch Chief, Research Technology and Contract Review, Branch Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W102, Rockville, Maryland 20850, 240-276-6442, [ahmads@mail.nih.gov](mailto:ahmads@mail.nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel; TEP-7: SBIR Contract Review Meeting (Review of SBIR Topics 431 and 439).

*Date:* February 20, 2025.

*Time:* 12:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate contract proposals.

*Address:* National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W254, Rockville, Maryland 20850.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Susan Lynn Spence, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W254, Rockville, Maryland 20850, 240-620-0819, [susan.spence@nih.gov](mailto:susan.spence@nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel; SEP-9: NCI Clinical and Translational Cancer Research.

*Date:* February 27, 2025.

*Time:* 10:00 a.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W542, Rockville, Maryland 20850.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Biman Chandra Paria, Ph.D., Scientific Review Officer, Program Coordination and Referral Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W542, Rockville, Maryland 20850, 240-858-3814, [pariab@mail.nih.gov](mailto:pariab@mail.nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel; NCI Research Specialist Award (R50) Clinician Scientist.

*Date:* March 11–12, 2025.

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

*Agenda:* To review and evaluate grant applications.

*Address:* National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W526, Rockville, Maryland 20850.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Viktoriya Sidorenko, Ph.D., Scientific Review Officer, Program and Review Extramural Staff Training Office, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W526, Rockville, Maryland 20850, 240-276-5073, [viktoriya.sidorenko@nih.gov](mailto:viktoriya.sidorenko@nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel; NCI SEP: The Confluence of Cancer Stigma and HIV Stigma in HIV-positive Individuals (R01 and R21).

*Date:* March 20, 2025.

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

*Agenda:* To review and evaluate grant applications.