

the requirements of the applicable statutes and regulations. This draft guidance, when finalized, will contain both binding and nonbinding provisions.

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. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological

Health guidance documents is available at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>. This guidance document is also available at <https://www.regulations.gov>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics>. Persons unable to download an electronic copy of “Electronic Submission Template for Medical Device Q-Submissions” may send an email request to [CDRH-Guidance@](mailto:CDRH-Guidance@fda.hhs.gov)

fda.hhs.gov to receive an electronic copy of the document. Please use the document number GUI00007041 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new 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 the following table have been approved by OMB:

21 CFR part; guidance; or FDA Form	Topic	OMB control No.
“Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program”.	Q-submissions and Early Payor Feedback Request Programs for Medical Devices.	0910–0756

Dated: May 22, 2025.

Grace R. Graham,
Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–09615 Filed 5–28–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program: Revised Amount of the Average Cost of a Health Insurance Policy

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HRSA is publishing an updated monetary amount of the average cost of a health insurance policy as it relates to the National Vaccine Injury Compensation Program (VICP).

FOR FURTHER INFORMATION CONTACT: CAPT George Reed Grimes, Director, Division of Injury Compensation Programs, Health Systems Bureau, HRSA, HHS by mail at 5600 Fishers Lane, 08–W25A, Rockville, Maryland 20857; or call (301) 443–9350.

SUPPLEMENTARY INFORMATION: Section 100.2 of the VICP’s implementing regulation (42 CFR part 100) states that the revised amount of an average cost of a health insurance policy, as determined by the Secretary of HHS (the Secretary), is effective upon its delivery by the

Secretary to the United States Court of Federal Claims (the Court) and will be published periodically in a notice in the **Federal Register**. The Secretary delegated this responsibility to the Director of the Division of Injury Compensation Programs. This figure is calculated using the most recent Medical Expenditure Panel Survey–Insurance Component data available as the baseline for the average monthly cost of a health insurance policy. This baseline is adjusted by the annual percentage increase/decrease obtained from the most recent annual Kaiser Family Foundation Employer Health Benefits Survey.

In 2024, the Medical Expenditure Panel Survey–Insurance Component, available at www.meps.ahrq.gov, published the annual 2023 average total single premium per enrolled employee at private-sector establishments that provide health insurance. The figure published was \$8,182. This figure is divided by 12 to determine the cost per month of \$681.83. The \$681.83 figure is increased or decreased by the percentage change reported by the most recent Kaiser Family Foundation Employer Health Benefits Survey, available at www.kff.org. The increase from 2023 to 2024 was six percent. By adding this percentage increase, the calculated average monthly cost of a health insurance policy for a 12-month period is \$722.74.

Therefore, the Secretary announces that the revised average cost of a health insurance policy under the VICP is \$722.74 per month. In accordance with § 100.2, the revised amount was effective upon its delivery by the

Secretary to the Court. Such notice was delivered to the Court on January 7, 2025.

George Reed Grimes,
Director, Division of Injury Compensation Programs.

[FR Doc. 2025–09694 Filed 5–28–25; 8:45 am]

BILLING CODE 4165–15–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; Small Business: Bioengineering, Device Development and Neurosurgery.

Date: June 25–26, 2025.

Time: 9:00 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: Cristina Backman, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5211, MSC 7846, Bethesda, MD 20892, (301) 480-9069, cbackman@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PA/PAR Career Development Awards: Health Interventions and Clinical Care.

Date: June 26–27, 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: Karen Nieves Lugo, Ph.D., MPH, Scientific Review Officer, National Institute on Minority Health and Health Disparities, National Institutes of Health, 7201 Wisconsin Ave., Ste. 533, Bethesda, MD 20892, 301-402-1366, karen.nieveslugo@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA Panel: Complement-ARIE New Approach Methodologies (NAMs) Technology Development Centers (UM1).

Date: June 26–27, 2025.

Time: 9:30 a.m. to 5:30 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: Raj K. Krishnaraju, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6190, MSC 7804, Bethesda, MD 20892, (301) 435-1047, krishna@csr.nih.gov.

Name of Committee: Infectious Diseases and Immunology B Integrated Review Group; Bacterial-Host Interactions Study Section.

Date: June 26–27, 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: Uma Basavanna, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 827-1398, uma.basavanna@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Infectious Disease Drug Development and Molecular Pharmacology.

Date: June 26–27, 2025.

Time: 10:00 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: Ekaterina Mikhailovna Nestorovich, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 827-1367, ekaterina.nestorovich@nih.gov.

Name of Committee: Applied Immunology and Disease Control Integrated Review Group; Drug Discovery and Molecular Pharmacology A Study Section.

Date: June 26–27, 2025.

Time: 10:00 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: Bidyottam Mitra, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, Bethesda, MD 20892, (301) 435-0000, bidyottam.mitra@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Musculoskeletal, Oral, Osteoarthritis and Dermatology.

Date: June 26–27, 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: Aftab A. Ansari, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4108, MSC 7814, Bethesda, MD 20892, (301) 237-9931, ansaria@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA Panel- NS-24-038: Human Brain Single-cell Genomics Explorer (U24) Review.

Date: June 27, 2025.

Time: 11:00 a.m. to 1:00 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: Mir Ahamed Hossain, Ph.D., Scientific Review Officer, Scientific Review Branch, NINDS/NIH/DHHS Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-496-9223, mirahamed.hossain@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)

Date: May 22, 2025.

Bruce A. George,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-09610 Filed 5-28-25; 8:45 am]

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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; Program Project: Cancer Research.

Date: June 25–26, 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: Michael Edward Lindquist, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, 9609 Medical Center Drive, 7W634, National Cancer Institute, NIH, Rockville, MD 20850, (240) 276-5735, mike.lindquist@nih.gov.

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group; Cellular Immunotherapy of Cancer Study Section.

Date: June 26–27, 2025.

Time: 8:30 a.m. to 6:30 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: Shahana Majid, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 867-5309, shahana.majid@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Project: Cancer Research.

Date: June 26–27, 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: Majed M. Hamawy, Ph.D., MBA Scientific Review Officer, Research