considered by FDA and the Efficacy Expert Working Group.

The draft guidance outlines strategies and considerations for developing and implementing clinical studies that include pregnant or breastfeeding women. This draft guidance includes approaches to plan, collect data, evaluate outcomes, and monitor safety of pregnant and breastfeeding women participating in clinical trials safely and ethically. Additionally, the draft guidance includes recommendations for recruiting and retaining pregnant and breastfeeding women in clinical trials. The draft guidance also emphasizes reduction of burden on pregnant and breastfeeding women participating in these trials.

This draft guidance has been left in the original ICH format. The final guidance will be reformatted and edited to conform with FDA's good guidance practices regulation (21 CFR 10.115) and style before publication. The draft guidance, when finalized, will represent the current thinking of FDA on ''E21 Inclusion of Pregnant and Breastfeeding Women in Clinical Trials.'' 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.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

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 11 relating to electronic records and signatures have been approved under OMB control number 0910–0303. The collections of information in 21 CFR parts 50 and 56 relating to the protection of human subjects, informed consent, and institutional review boards have been approved under OMB control number 0910–0130. The collections of information in 21 CFR part 58 relating to good laboratory practice for nonclinical laboratory studies have been approved under OMB control number 0910–0119. The collections of information in 21 CFR 201.56 and 201.57 relating to the content and format requirements of labeling for prescription drug products have been approved under OMB control number 0910–0572. The collections of information in 21 CFR 310.305 and 314.80 relating to submission of adverse drug experience reports have been approved under OMB control number 0910–0230. The collections of information in 21 CFR part 312 relating to the investigational new drug application pathway, which includes clinical trials, clinical trial design, benefit-risk planning, and submission of IND safety reports and reports of serious and unexpected adverse events have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 relating to the content and format of investigational new drugs applications, regulatory requirements relating to postmarketing study commitments, and risk evaluation and mitigation strategies relating to benefit-risk assessments, have been approved under OMB control number 0910–0001.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance 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: July 15, 2025

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–13680 Filed 7–18–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; 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 Deafness and Other Communication Disorders Advisory Council.

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 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 Deafness and Other Communication Disorders Advisory Council.

Date: September 4–5, 2025.

Open: September 04, 2025, 1:00 p.m. to 5:00 p.m.

Agenda: staff reports on divisional, programmatical, and special activities.

Address: National Institutes of Health, Neuroscience Center, Rooms 1135/45/55, 6001 Executive Boulevard, Rockville, MD 20852, In Person and Virtual Meeting.

Closed: September 05, 2025, 9:00 a.m. to 9:40 a.m.

Agenda: To review and evaluate BSC Report.

Address: National Institutes of Health, Neuroscience Center, Rooms 1135/45/55, 6001 Executive Boulevard, Rockville, MD 20852, In Person and Virtual Meeting.

Closed: September 05, 2025, 10:00 a.m. to 1:05 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Neuroscience Center, Rooms 1135/45/55, 6001 Executive Boulevard, Rockville, MD 20852, In Person and Virtual Meeting.

Contact Person: Rebecca Wagenaar-Miller, Ph.D., Director, Division of Extramural Activities, NIDCD/NIH, 6001 Executive Boulevard, Bethesda, MD 20892, (301) 496–8693, *rebecca.wagenaar-miller@nih.gov*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *https://www.nidcd.nih.gov/about/advisory-council,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: July 17, 2025.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–13669 Filed 7–18–25; 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; Career Development Review in Alzheimer's Disease and Related Dementias.

Date: August 19, 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: Kristin L McNally, Ph.D., Scientific Review Officer, Scientific Review Program, Immunology Review Branch, National Institutes of Health, Hamilton, MT 59840, *mcnallyk@niaid.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Collaborative Applications: Review of Complex Integrated Multi-Component Projects in Aging Research.

Date: August 20–21, 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: Bo-Shiun Chen, Ph.D., Scientific Review Officer, Scientific Review Branch, NINDS/NIH NCS, 6001 Executive Blvd., Suite 3208, NCS 9529, Bethesda, MD 20892, (301) 496–9223, *bo-shiun.chen@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: July 16, 2025.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–13584 Filed 7–18–25; 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 Center for Scientific Review Special Emphasis Panel, Cellular and Molecular Aspects of the Blood-Brain Barrier and Neurovascular System and Therapeutic Strategies, August 07, 2025, 09:00 a.m. to August 07, 2025, 05:30 p.m., National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD, 20892 which was published in the **Federal Register** on July 02, 2025, 90 FR 29030, Doc.2025–12382

This meeting is being amended to change the contact person from Eric Tucker to Jacek Topczewski, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, Bethesda, MD 20892, *topczewskij2@csr.nih.gov.* The meeting is closed to the public.

Dated: July 16, 2025.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–13585 Filed 7–18–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2025–0097]

Notification of the Removal of Conditions of Entry on Vessels Arriving From the Republic of Djibouti

AGENCY: Coast Guard, DHS.

ACTION: Notice.

SUMMARY: The Coast Guard announces that it is removing the conditions of entry on vessels arriving from the Republic of Djibouti.

DATES: The policy announced in this notice is effective on July 21, 2025.

FOR FURTHER INFORMATION CONTACT: For information about this document call or email J.J. Hudson, Chief, Office of International and Domestic Port Security, United States Coast Guard, telephone 571–607–6445, *Juliet.J.Hudson@uscg.mil.*

SUPPLEMENTARY INFORMATION:

Background and Purpose

The authority for this notice is 5 U.S.C. 552(a) (''Administrative Procedure Act''), 46 U.S.C. 70110 (''Maritime Transportation Security Act''), and Department of Homeland Security Delegation No. 0170.1(II)(97.f). As delegated, section 70110(a) authorizes the Coast Guard to impose conditions of entry on vessels arriving in U.S. waters from ports that the Coast Guard has not found to maintain effective anti-terrorism measures.

In 2019, the Coast Guard determined that effective anti-terrorism measures were not in place in the ports of Djibouti. Accordingly, conditions of entry were imposed on vessels arriving from Djibouti. Based on recent assessments, the Coast Guard has determined that Djibouti is maintaining effective anti-terrorism measures, and is, accordingly, removing the conditions of entry announced in previously published Notices. With this notice, the current list of countries assessed and not maintaining effective anti-terrorism measures is as follows: *Cambodia, Cameroon, Comoros, Cuba, Equatorial Guinea, Federated States of Micronesia, The Gambia, Guinea-Bissau, Iran, Iraq, Libya, Madagascar, Nauru, Nigeria, Sao Tome and Principe, Seychelles, Sudan, Syria, Timor-Leste, Venezuela, Yemen.* The current Port Security Advisory is available at: *http://www.dco.uscg.mil/Our-Organization/Assistant-Commandant-for-Prevention-Policy-CG-5P/International-Domestic-Port-Assessment/.*

Thomas G. Allan Jr.,

Vice Admiral, USCG, Acting Deputy Commandant for Operations.

[FR Doc. 2025–13656 Filed 7–18–25; 8:45 am]

BILLING CODE P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. ICEB–2023–0014]

Privacy Act of 1974; System of Records

AGENCY: U.S. Immigration and Customs Enforcement, Department of Homeland Security.

ACTION: Notice of a Modified System of Records.