

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 is also available at <https://www.regulations.gov>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. Persons unable to download an electronic copy of “Feasibility and Early Feasibility Clinical Studies for Certain

Medical Devices Intended to Therapeutically Improve Glycemic Control in Patients with Type 2 Diabetes Mellitus” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 19045 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. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations and guidances have been approved by OMB as listed in the following table:

21 CFR part or guidance	Topic	OMB control No.
807, subpart E	Premarket Notification	0910–0120
814, subparts A through E	Premarket Approval	0910–0231
812	Investigational Device Exemption	0910–0078
“Requests for Feedback on Medical Device Submissions: The Q-Submission Program”.	Q-submissions; Pre-submissions	0910–0756
50, 56	Protection of Human Subjects and Institutional Review Boards.	0910–0130

Dated: April 28, 2022.
Lauren K. Roth,
Associate Commissioner for Policy.
 [FR Doc. 2022–09738 Filed 5–5–22; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Global Affairs: Virtual Stakeholder Listening Session in Preparation for the 75th World Health Assembly

Time and date: The session will be held on Friday, May 13, 2022, from 10:00 a.m.–12:00 p.m. Eastern Time (ET).

Place: The session will be held virtually, and registration is required. Please RSVP by May 6, 2022 by sending your full name, email address, and organization to OGA.RSVP@hhs.gov. OGA encourages early registration.

Status: Open, but requiring RSVP to OGA.RSVP@hhs.gov to register.

Purpose: The U.S. Department of Health and Human Services (HHS)—charged with leading the U.S. delegation to the 75th World Health Assembly—will hold an informal Stakeholder Listening Session on Friday, May 13, 10:00 a.m.–12:00 p.m. ET. The listening session will be held virtually, and the meeting link will be shared with registered participants prior to the session.

The Stakeholder Listening Session will help the HHS Office of Global Affairs prepare the U.S. delegation to the World Health Assembly by taking full advantage of the knowledge, ideas, feedback, and suggestions from all

communities interested in and affected by agenda items to be discussed at the 75th World Health Assembly. The U.S. Government will consider contributions received from the stakeholders as it develops the U.S. positions.

The listening session will be organized by agenda item, and participation is welcome from stakeholder communities, including:

- Public health and advocacy groups;
- State, local, and Tribal groups;
- Private industry;
- Minority health organizations; and
- Academic and scientific organizations.

All agenda items to be discussed at the 75th World Health Assembly can be found at this website: https://apps.who.int/gb/e/e_wha75.html.

RSVP: Registration is required for the event. Please send your full name, email address, and organization to OGA.RSVP@hhs.gov to register. Please RSVP no later than Friday, May 6, 2022.

Written comments are welcome and encouraged, even if you are planning on attending the virtual session. Please send written comments to the email address: OGA.RSVP@hhs.gov.

We look forward to hearing your comments related to the 75th World Health Assembly agenda items.

Dated: May 2, 2022.

Susan C. Kim,
Chief of Staff, Office of Global Affairs.
 [FR Doc. 2022–09710 Filed 5–5–22; 8:45 am]

BILLING CODE 4150–38–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

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: Heart, Lung, and Blood Initial Review Group; NHLBI Mentored Transition to Independence Study Section.

Date: June 9–10, 2022.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge I, 6705 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Giuseppe Pintucci, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 205-H, Bethesda, MD 20892, (301) 827–7969, Pintuccig@nhlbi.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and

Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: May 2, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022-09716 Filed 5-5-22; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Heart, Lung, and Blood 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 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 Heart, Lung and Blood Advisory Council.

Date: June 14, 2022.

Closed: 10:00 a.m. to 12:00 p.m.

Agenda: To Review and Evaluate Grant Applications.

Place: National Institutes of Health, Rockledge I, 6705 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Open: 12:00 p.m. to 5:00 p.m.

Agenda: To Discuss Program Policies and Issues.

Place: National Institutes of Health, Rockledge I, 6705 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Virtual Access: The meeting will be videocast and can be accessed from the NIH Videocast. <https://www.nhlbi.nih.gov/about/advisory-and-peer-review-committees/advisory-council>. Please note, the link to the videocast meeting will be posted within a week of the meeting date.

Contact Person: Laura K. Moen, Ph.D., Director, Division of Extramural Research

Activities, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 206-Q, Bethesda, MD 20892, 301-827-5517, moen@mail.nih.gov.

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their 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: www.nhlbi.nih.gov/meetings/nhlbac/index.htm, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: May 2, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022-09714 Filed 5-5-22; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

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 Center for Advancing Translational Sciences, Special Emphasis Panel.

Date: June 14, 2022.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Boulevard, Room 1037, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rahat (Rani) Khan, Ph.D., Scientific Review Officer, Office of Scientific Review, National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Boulevard, Room 1037, Bethesda, MD 20892, (301) 594-7319, khanr2@csr.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: May 2, 2022.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022-09693 Filed 5-5-22; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Statement of Delegation of Authority

Notice is hereby given that I have delegated to the Director, National Institutes of Health (NIH), the authorities vested in the Secretary of Health and Human Services under Section 2 of the Accelerating Access to Critical Therapies for ALS Act (Pub. L. 117-79), as amended, to award grants to participating entities for purposes of scientific research utilizing data from expanded access to investigational drugs for individuals who are not otherwise eligible for clinical trials for the prevention, diagnosis, mitigation, treatment, or cure of amyotrophic lateral sclerosis.

These authorities may be redelegated. Exercise of this authority shall be in accordance with established policies, procedures, guidelines, and regulations as prescribed by the Secretary. The Secretary retains the authority to submit reports to Congress and promulgate regulations.

This delegation is effective immediately. I hereby affirm and ratify any actions taken by you or your subordinates that involved the exercise