

The Agency received requests for extension of the comment period for the revised draft guidance. After considering the requests, and in light of the fact that the original comment period is scheduled to close on December 26, 2023, FDA has decided to extend the comment period for the revised draft guidance until January 5, 2024. The Agency believes that this extension allows adequate time for interested persons to submit comments to ensure that FDA can consider the comments before it begins work on the final version of the guidance.

Dated: November 20, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-25969 Filed 11-22-23; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Presidential Advisory Council on HIV/AIDS

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of a virtual meeting.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Service is hereby giving notice that the Presidential Advisory Council on HIV/AIDS (PACHA or the Council) will convene the 79th full council meeting utilizing virtual technologies on Wednesday, December 6, 2023. The meeting will be open to the public and there will be a public comment session during the meeting; pre-registration is required to provide public comment. To pre-register to provide public comment, please send an email to PACHA@hhs.gov and include your name, organization, and title by close of business Monday, November 27, 2023. If you decide you would like to provide public comment but do not pre-register, you may submit your written statement by emailing PACHA@hhs.gov by close of business Wednesday, December 13, 2023. The meeting agenda will be posted on the PACHA page on [HIV.gov](http://www.hiv.gov) at <https://www.hiv.gov/federal-response/pacha/about-pacha> prior to the meeting.

DATES: The meeting will be held on Wednesday, December 6 from approximately 11:00 a.m.–06:00 p.m. (ET).

ADDRESSES: To attend the meeting virtually, please visit www.hhs.gov/live.

FOR FURTHER INFORMATION CONTACT: Ms. Caroline Talev, MPA, Senior Management Analyst, at PACHA@hhs.gov or Caroline.Talev@hhs.gov or (202) 795-7622. Additional information can be obtained by accessing the Council's page on the [HIV.gov](http://www.hiv.gov) site at www.hiv.gov/pacha.

SUPPLEMENTARY INFORMATION: PACHA was established by Executive Order 12963, dated June 14, 1995, as amended by Executive Order 13009, dated June 14, 1996 and is currently operating under the authority given in Executive Order 14048, dated September 30, 2021. The Council was established to provide advice, information, and recommendations to the Secretary regarding programs and policies intended to promote effective HIV diagnosis, treatment, prevention, and quality care services. The functions of the Council are solely advisory in nature. The Council consists of not more than 35 members. Council members are selected from prominent community leaders with particular expertise in, or knowledge of, matters concerning HIV and AIDS, public health, global health, population health, philanthropy, marketing or business, as well as other national leaders held in high esteem from other sectors of society. PACHA selections also include persons with lived HIV experience and racial/ethnic and sexual and gender minority persons disproportionately affected by HIV. Council members are appointed by the Secretary.

Dated: October 31, 2023.

B. Kaye Hayes,

Deputy Assistant Secretary for Infectious Disease, Director, Office of Infectious Disease and HIV/AIDS Policy, Executive Director, Presidential Advisory Council on HIV/AIDS, Office of the Assistant Secretary for Health, Department of Health and Human Services.

[FR Doc. 2023-25877 Filed 11-22-23; 8:45 am]

BILLING CODE 4150-43-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Center for Advancing Translational Sciences Special Emphasis Panel, Preclinical Proof of Concept Studies for Rare Diseases (R21) January 24, 2024, 9:00 a.m. to January 25, 2024, 5:00 p.m., National Institutes of Health, National Center for Advancing Translational

Sciences, 6701 Democracy Boulevard, Bethesda, MD, 20892 which was published in the **Federal Register** on November 14, 2023, FR DOC 2023-25070, 88 FR 78052.

The meeting is being rescheduled due to panel member availability. The meeting will be held on February 1, 2024, 9:00 a.m. to February 2, 2024, 5:00 p.m. This meeting will be held virtually. The meeting is closed to the public.

Dated: November 17, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023-25885 Filed 11-22-23; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 1009 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 Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Investigator Initiated Program Project Applications (P01 Clinical Trial Not Allowed).

Date: December 20, 2023.

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

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 903 South 4th Street, RML 31/3118, Hamilton, MT 59840 (Virtual Meeting).

Contact Person: Kristin L. McNally, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 903 South 4th Street, RML 31/3118, Hamilton, MT 59840 mcnallyk@niaid.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 17, 2023.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023-25940 Filed 11-22-23; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 1009 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 Institute on Drug Abuse Special Emphasis Panel; Avenir Award Program for Genetics or Epigenetics of Substance Use Disorders.

Date: February 13-14, 2024.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ipolia R. Ramadan, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, Bethesda, MD 20892, (301) 827-4471, ramadanir@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: November 17, 2023.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023-25938 Filed 11-22-23; 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 Meeting

Pursuant to section 1009 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: Center for Scientific Review Special Emphasis Panel; Topics in Drug Development and Molecular Pharmacology—A.

Date: December 5, 2023.

Time: 3:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Bidyottam Mitra, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, Bethesda, MD 20894, (301) 435-4057, bidyottam.mitra@nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(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: November 17, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023-25884 Filed 11-22-23; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 1009 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: Microbiology, Infectious Diseases and AIDS Initial Review Group; Acquired Immunodeficiency Syndrome Research Study Section Acquired Immunodeficiency Syndrome Research Study Section (AIDS).

Date: December 13, 2023.

Time: 10:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G21B, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Robert C. Unfer, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G21B, Bethesda, MD 20852, (240) 669-5035, robert.unfer@nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 17, 2023.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023-25939 Filed 11-22-23; 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 Closed Meeting

Pursuant to section 1009 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 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 contract proposals, the disclosure of which