

Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911; or Ei Thu Lwin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6236, Silver Spring, MD 20993-0002, 301-796-0728.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 20, 2019 (84 FR 70196), FDA published a notice with a 60-day comment period to request comments on the draft guidance for industry entitled "Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products." The Agency has received requests for extension of the comment period. The requests conveyed that additional time is needed to provide comments. FDA has considered the requests and is extending the comment period for 30 days, until March 19, 2020. The Agency believes that an additional 30 days will allow adequate time for interested persons to submit comments without compromising the timely publication of the final version of the guidance.

II. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <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.regulations.gov>.

Dated: January 22, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-01322 Filed 1-24-20; 8:45 am]

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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.

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 be holding the 66th full Council meeting in

Washington, DC. Agenda items will include: Discussion of *Ending the HIV Epidemic: A Plan for America* (EHE) Jurisdictional Plans, Focusing on the Four Pilot Sites: DeKalb County, Georgia; Baltimore, Maryland; East Baton Rouge, Louisiana; and the Cherokee Nation of Oklahoma; the Ready, Set, PrEP National Program; Stigma as a Barrier—Shared Experiences and Challenges from International and Domestic Perspectives; and Women and HIV. The meeting will be open to the public; a public comment session will be held during the meeting. Pre-registration is encouraged for members of the public who wish to attend the meeting and who wish to participate in the public comment session. Individuals who wish to attend the meeting and/or send in their public comment via email should send an email to PACHA@hhs.gov. Pre-Registration must be complete by Monday, February 3, 2020.

DATES: The Council meeting is scheduled to convene on Monday, February 10, 2020 from approximately 1:00 p.m. to 7:00 p.m. ET and Tuesday, February 11, 2020 from approximately 9:00 a.m. to 5:00 p.m. ET (times are tentative and subject to change). The meeting agenda will be posted on the PACHA web page at <https://www.hiv.gov/federal-response/pacha/about-pacha>. Public attendance is limited to available space.

ADDRESSES: Grand Hyatt Washington, 1000 H Street NW, Washington, DC 20001.

FOR FURTHER INFORMATION CONTACT: Ms. Caroline Talev, MPA, Public Health Analyst, Presidential Advisory Council on HIV/AIDS, 330 C Street SW, Room L609A, Washington, DC 20024; (202) 795-7622 or PACHA@hhs.gov. Additional information can be obtained by accessing the Council's page on the 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 13889, dated September 27, 2019. The Council was established to provide advice, information, and recommendations to the Secretary regarding programs and policies intended to promote effective prevention and care of HIV infection and AIDS. The functions of the Council are solely advisory in nature.

The Council consists of not more than 25 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, philanthropy, marketing or business, as well as other national leaders held in high esteem from other sectors of society. Council members are appointed by the Secretary or designee, in consultation with the White House.

Public attendance at the meeting is limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify Caroline Talev at PACHA@hhs.gov. Due to space constraints, pre-registration for public attendance is advisable and can be accomplished by contacting PACHA@hhs.gov by close of business Monday, February 3, 2020. Members of the public will have the opportunity to provide comments during the meeting. Comments will be limited to no more than three minutes per speaker. Any individual who wishes to participate in the public comment session must register with Caroline Talev at PACHA@hhs.gov by close of business Monday, February 3, 2020; registration for public comment will not be accepted by telephone. Individuals are encouraged to provide a written statement of any public comment(s) for accurate minute taking purposes. Any members of the public who wish to have printed material distributed to PACHA members at the meeting are asked to submit, at a minimum, 1 copy of the material(s) to Caroline Talev, no later than close of business Monday, February 3, 2020.

Dated: January 15, 2020.

B. Kaye Hayes,

Principal Deputy 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. 2020-01336 Filed 1-24-20; 8:45 am]

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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; CTSA Collaborative Innovation Awards Review Meeting.

Date: February 20, 2020.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: M. Lourdes Ponce, Ph.D., Scientific Review Officer, Office of Scientific Review, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health, 6701 Democracy Blvd., Democracy 1, Room 1073, Bethesda, MD 20892, 301-435-0810, lourdes.ponce@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 21, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020-01258 Filed 1-24-20; 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 10(d) 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: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group;

Integrative Nutrition and Metabolic Processes Study Section.

Date: February 20–21, 2020.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance, Washington, DC Hotel, 999 Ninth Street NW, Washington, DC 20001-4427.

Contact Person: Gregory S. Shelness, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6156, Bethesda, MD 20892-7892, 301-755-4335, greg.shelness@nih.gov.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Molecular Neuropharmacology and Signaling Study Section.

Date: February 20–21, 2020.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, DC, 2401 M Street NW, Washington, DC 20037.

Contact Person: Vanessa S. Boyce, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm. 4016F, MSC 7812, Bethesda, MD 20892, (301) 435-0908, boycevs@csr.nih.gov.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Chronic Dysfunction and Integrative Neurodegeneration Study Section.

Date: February 20–21, 2020.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Bayside, 4875 North Harbor Drive, San Diego, CA 92106.

Contact Person: Jenny R. Browning, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm. 5207, Bethesda, MD 20892, jenny.browning@nih.gov.

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group; Biodata Management and Analysis Study Section.

Date: February 20–21, 2020.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854.

Contact Person: Wenchi Liang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3150, MSC 7770, Bethesda, MD 20892, 301-435-0681, liangw3@csr.nih.gov.

Name of Committee: Emerging Technologies and Training Neurosciences Integrated Review Group; Molecular Neurogenetics Study Section.

Date: February 20–21, 2020.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westgate Hotel, 1055 Second Avenue, San Diego, CA 92101.

Contact Person: Mary G. Schueler, Ph.D., Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5214, MSC 7846, Bethesda, MD 20892, 301-915-6301, marygs@csr.nih.gov.

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group; Electrical Signaling, Ion Transport, and Arrhythmias Study Section.

Date: February 20, 2020.

Time: 8:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bahia Resort Hotel, 998 West Mission, Bay Drive, San Diego, CA 92109.

Contact Person: Sara Ahlgren, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, RM 4136, Bethesda, MD 20892, 301-435-0904, sara.ahlgren@nih.gov.

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group; Social Psychology, Personality and Interpersonal Processes Study Section.

Date: February 20–21, 2020.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Le Meridien Delfina Santa Monica, 530 Pico Blvd., Santa Monica, CA 90405.

Contact Person: Marc Boulay, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3110, MSC 7808, Bethesda, MD 20892, (301) 300-6541, boulaymg@csr.nih.gov.

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group; Developmental Therapeutics Study Section.

Date: February 20–21, 2020.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westgate Hotel, 1055 Second Avenue, San Diego, CA 92101.

Contact Person: Nicholas J. Donato, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4040, Bethesda, MD 20892, 301-827-4810, nick.donato@nih.gov.

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group; Myocardial Ischemia and Metabolism Study Section.

Date: February 20–21, 2020.

Time: 8:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard Silver Spring Downtown, 8506 Fenton Street, Silver Spring, MD 20910.

Contact Person: Richard D. Schneiderman, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4138, Bethesda, MD 20817, 301-402-3995, richard.schneiderman@nih.gov.

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group; Clinical and Integrative Cardiovascular Sciences Study Section.

Date: February 20–21, 2020.

Time: 8:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.