docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Adam Kroetsch, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1168, Silver Spring, MD 20993–0002, 301–796–3842, *REMS_Standardization@fda.hhs.gov;* or Aaron Sherman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6366, Silver Spring, MD 20993–0002, 240–402–0493, *REMS_Standardization@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On October 5, 2015, FDA launched the REMS Platform Standards Initiative (previously referred to as the ''Common REMS Platform Initiative''), with the goal of developing and leveraging electronic health data standards, referred to as ''REMS platform standards,'' to further standardize certain activities associated with REMS with elements to assure safe use (ETASU), and integrate them into existing health care systems. (Information about the initiative can be found at: *http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM507451.pdf*). Since then, FDA has been working to determine the most effective methods for carrying out this initiative, including how best to engage the public on the project and advance the development of REMS platform standards. To achieve these ends, FDA is publishing the ''REMS Platform Standards Initiative: Needs Assessment,'' which seeks to provide REMS stakeholders, standards developers, and health information technology (IT) systems developers with specific, detailed information on the areas in which standards development is needed and the information that the data standards would need to communicate to effectively carry out REMS activities. FDA seeks comment on the document as a whole, as well as on the specific questions that follow.

(1) Does this needs assessment cover all of the REMS activities for which standards development would be beneficial?

(2) Which REMS activities should be given highest priority for standards development?

(3) What standards already exist that could be used to address the needs and facilitate the REMS activities described in the needs assessment?

(4) Where (if at all) do new standards need to be developed?

(5) What other opportunities exist to leverage health IT to facilitate the completion of REMS activities?

FDA hopes that the needs assessment will help identify areas where standards development projects to support REMS are already underway, as well as areas that are ripe for standards development, enabling interested stakeholders to engage further in this project.

What is the REMS Platform Standards Initiative?

The goal of the REMS Platform Standards Initiative is to leverage electronic health data standards to standardize certain activities in REMS with ETASU and integrate them into health IT systems. Under the initiative, FDA seeks to work with third-party standards development organizations to encourage the development of electronic data standards that may be used to facilitate communication between REMS and their participants. Once the standards are developed, FDA would maintain a list of REMS platform standards, encourage their use in REMS with ETASU, and encourage the development of tools that use these standards to integrate REMS into health care providers' existing systems.

Why is FDA launching the REMS Platform Standards Initiative?

This initiative was launched for a number of reasons. Stakeholders have requested a centralized method to enroll in and interact with REMS with ETASU and more fundamental standardization of REMS architecture. There is also a need for a comprehensive set of standards for REMS to help minimize REMS burden on the health care delivery system and integrate REMS into health IT systems.

The goal of the REMS Platform Standards Initiative is to give all stakeholders—including sponsors, data vendors, clinical decision support system developers (such as those for hospitals, private practices, etc.)—a ''fixed target'' for standardization and integration. If successful, this will clarify how sponsors can develop standardized REMS that are more easily integrated into the health care system and what health care providers must do to comply with those REMS. Ultimately, REMS that are more effectively standardized and integrated into the health care system should facilitate enhanced compliance and safer use of drugs that have REMS.

II. Electronic Access

Persons with access to the Internet may obtain the needs assessment at *https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM565594.pdf.*

Dated: September 19, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–21218 Filed 10–2–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; 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: National Institute of Child Health and Human Development Special Emphasis Panel NICHD Education Grants.

Date: November 6, 2017.

Time: 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6710 B Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Joanna Kubler-Kielb, Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892–7510, 301–435–6916, *kielbj@mail.nih.gov*.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel, SPROUTS: Development of eating behaviors in early childhood.

Date: November 13, 2017.

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

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6710 B Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Sathasiva B. Kandasamy, Ph.D., Scientific Review Administrator Division of Scientific Review National Institute of Child Health and Human D, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892–9304, (301) 435–6680, *skandasa@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: September 27, 2017.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–21139 Filed 10–2–17; 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 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following NHLBI Mentored Clinical and Basic Science Review Committee 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 Clinical and Basic Science Review Committee.

Date: October 26–27, 2017.

Time: 10:30 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Crowne Plaza National Airport, 1480 Crystal Drive, Arlington, VA 22202.

Contact Person: Keith A. Mintzer, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7186, Bethesda, MD 20892–7924, 301–827–7949, *mintzerk@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: September 27, 2017.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–21136 Filed 10–2–17; 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 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 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 would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel NIAID Peer Review Meeting.

Date: October 26–27, 2017.

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

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892, (Telephone Conference Call).

Contact Person: Susana Mendez, DVM, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G53B, National Institutes of Health, NIAID, 5601 Fishers Lane Dr., MSC 9823, Bethesda, MD 20892–9823, (240) 669–5077, *mendezs@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: September 27, 2017.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–21138 Filed 10–2–17; 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 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: Brain Disorders and Clinical Neuroscience Integrated Review Group; Diseases and Pathophysiology of the Visual System Study Section.

Date: October 26–27, 2017.

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

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Nataliya Gordiyenko, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5202, MSC 7846, Bethesda, MD 20892, 301–435–1265, *gordiyenkon@csr.nih.gov*.

Name of Committee: Oncology 1—Basic Translational Integrated Review Group; Cancer Etiology Study Section.

Date: October 26–27, 2017.

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

Agenda: To review and evaluate grant applications.

Place: Marines' Memorial Club & Hotel, 609 Sutter Street, San Francisco, CA 94102.

Contact Person: Ola Mae Zack Howard, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr., Room 4192, MSC 7806, Bethesda, MD 20892, 301–451–4467, *howardz@mail.nih.gov*.

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Neurotoxicology and Alcohol Study Section.

Date: October 26–27, 2017.

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

Agenda: To review and evaluate grant applications.

Place: Residence Inn Washington, DC Downtown, 1199 Vermont Avenue NW., Washington, DC 20005.

Contact Person: Jana Drgonova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5213, Bethesda, MD 20892, 301–827–2549, *jdrgonova@mail.nih.gov.*