

the technical requirements for the approval of pharmaceuticals for human use in the ICH regions since 1990. More information on the current ICH process and structure can be found at the following website: <http://www.ich.org>.

## II. Participating in the Public Meeting

**Registration:** Persons interested in attending this public meeting must register online by October 12, 2018. To register to attend the public meeting either in person or via webcast, please visit the following website: <https://www.eventbrite.ca/e/health-canada-us-fda-ich-consultation-tickets-47713713000>. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting must register by October 12, 2018, 11:59 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, the number of participants from each organization may be limited. The agenda for the public meeting will be made available on the internet at <https://www.fda.gov/Drugs/NewsEvents/ucm612657.htm> approximately 2 weeks in advance of the meeting.

If you need special accommodations due to a disability, please contact William Lewallen (see **FOR FURTHER INFORMATION CONTACT**) no later than October 12, 2018.

**Requests for Oral Presentations:** If you wish to make a presentation during the public comment session, please contact William Lewallen (see **FOR FURTHER INFORMATION CONTACT**) no later than October 12, 2018. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation. All requests to make presentations must be received by the close of registration on October 12, 2018. If selected for presentation, any presentation materials must be emailed to William Lewallen (see **FOR FURTHER INFORMATION CONTACT**) no later than October 12, 2018. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

**Streaming Webcast of the Public Meeting:** This public meeting will also be webcast. To register to attend via webcast, please visit the following website: <https://www.eventbrite.ca/e/health-canada-us-fda-ich-consultation-tickets-47713713000>. FDA has verified the website addresses in this document, as of the date this document publishes

in the **Federal Register**, but websites are subject to change over time.

Dated: September 28, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–21594 Filed 10–3–18; 8:45 am]

**BILLING CODE 4164–01–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; CTSA Collaborative Innovation Awards Review Meeting (U01).

**Date:** October 24, 2018.

**Time:** 2:00 p.m. to 5:00 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** National Institutes of Health, One Democracy Plaza, Room 1068, 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](mailto: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: September 28, 2018.

**David D. Clary,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2018–21567 Filed 10–3–18; 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 a meeting Allergy, Immunology, and Transplantation Research Committee.

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:** Allergy, Immunology, and Transplantation Research Committee AITC January 2019 Council.

**Date:** October 23–24, 2018.

**Time:** 9:30 a.m. to 4:00 p.m.

**Agenda:** To review and evaluate grant applications.

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

**Contact Person:** James T. Snyder, Ph.D., Scientific Review Officer Scientific Review Program, Division of Extramural Activities/Room 3G31B, National Institutes of Health, NIAID, 5601 Fishers Lane MSC 9834, Bethesda, MD 20892–9834, (240) 669–5060, [james.snyder@nih.gov](mailto:james.snyder@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 28, 2018.

**Natasha M. Copeland,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2018–21572 Filed 10–3–18; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Diabetes and Digestive and Kidney Diseases; 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; RFA-DK-18-003: Elucidating the Effect of Glycemic Excursions on Patient Well-being and Cognitive Status in People with Type 1 Diabetes.

*Date:* October 18, 2018.

*Time:* 11:30 a.m. to 3:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Charlene J. Repique, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7347, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 451-3638, [charlene.repique@nih.gov](mailto:charlene.repique@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.

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Patient-Reported Outcomes in Diabetes.

*Date:* October 25, 2018.

*Time:* 1:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Michele L. Barnard, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7353, 6707 Democracy Boulevard, Bethesda, MD 20892-2542, (301) 594-8898, [barnardm@extra.niddk.nih.gov](mailto:barnardm@extra.niddk.nih.gov).

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK-RC2-Telephone Review.

*Date:* November 7, 2018.

*Time:* 2:30 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Xiaodu Guo, MD, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7023, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-4719, [guox@extra.niddk.nih.gov](mailto:guox@extra.niddk.nih.gov).

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Clinical Trial Review.

*Date:* November 13, 2018.

*Time:* 10:30 a.m. to 12:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Michele L. Barnard, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7353, 6707 Democracy Boulevard, Bethesda, MD 20892-2542, (301) 594-8898, [barnardm@extra.niddk.nih.gov](mailto:barnardm@extra.niddk.nih.gov).

[Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS]

Dated: September 28, 2018.

**David D. Clary,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2018-21568 Filed 10-3-18; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel.

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 Biomedical Imaging and Bioengineering Special Emphasis Panel; Mentored Career Development (K) Award Application Review (2019/01).

*Date:* October 25, 2018.

*Time:* 9:30 a.m. to 2:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, National Institute of Biomedical Imaging and

Bioengineering, Two Democracy Plaza, Suite 920, 6707 Democracy Boulevard, Bethesda, MD 20892, (Virtual Meeting).

*Contact Person:* John P. Holden, Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Blvd., Suite 920, Bethesda, MD 20892, 301-496-8775, [john.holden@nih.gov](mailto:john.holden@nih.gov).

*Name of Committee:* National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; Conference Award (R13) Application Review (2019/01).

*Date:* October 25, 2018.

*Time:* 2:00 p.m. to 5:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, National Institute of Biomedical Imaging and Bioengineering, Two Democracy Plaza, Suite 920, 6707 Democracy Boulevard, Bethesda, MD 20892, (Virtual Meeting).

*Contact Person:* John P. Holden, Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, 6707 Democracy Blvd., Suite 920, Bethesda, MD 20892, (301) 496-8775, [john.holden@nih.gov](mailto:john.holden@nih.gov).

Dated: September 28, 2018.

**David D. Clary,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2018-21569 Filed 10-3-18; 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:* Center for Scientific Review Special Emphasis Panel; RFA Panel: Cellular and Molecular Biology of Complex Brain Disorders.

*Date:* October 29-30, 2018.

*Time:* 8:00 a.m. to 2:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Villa Florence Hotel, 225 Powell Street, San Francisco, CA 94102.

*Contact Person:* Brian H Scott, Ph.D., Scientific Review Officer, National Institutes