II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or https://www.regulations.gov.


Leslie Kux,
Associate Commissioner for Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental and Craniofacial Research; 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 Dental and Craniofacial Research Special Emphasis Panel.

Date: October 18, 2018.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Democracy One, Room 651, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Nisan Bhattacharyya, Ph.D., Scientific Review Officer, Scientific Review Branch, NIDCR, NIH, 6701 Democracy Boulevard, Suite 668, Bethesda, MD 20892, 301–451–2405, nisan_bhattacharyya@nih.gov.
DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental and Craniofacial Research Special Emphasis Panel.

- **Name of Committee:** National Institute of Dental and Craniofacial Research Special Emphasis Panel.
- **Date:** October 30, 2018.
- **Time:** 9:00 a.m. to 5:00 p.m.
- **Agenda:** To review and evaluate grant applications.
- **Place:** National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

**Contact Person:** Natasha M. Copeland, Program Analyst, Office of Federal Advisory Committee Policy.

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) of 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: Microbiology and Infectious Diseases B Subcommittee MID–B September Review Meeting.
- **Date:** September 25–26, 2018.
- **Time:** 9:00 a.m. to 5:00 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:** Ellen S. Buczk, Ph.D., Scientific Review Officer, Scientific Review Program Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7616 Bethesda, MD 20892–7616, 301–451–2676, ebuczko1@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHHS)

**Dated:** August 30, 2018.

Natasha M. Copeland, Program Analyst, Office of Federal Advisory Committee Policy.

[F] [2018–19317 Filed 9–5–18; 8:45 am]

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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; R13 Conference Grant Applications.
- **Date:** September 273, 2018.
- **Time:** 11:00 a.m. to 12:30 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:** Jian Yang, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7111, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, 301-594–7799, yangj@extra.niddk.nih.gov.

**Name of Committee:** National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; PAR–17–123; Biomarkers for NIDDK Using Biosamples from the Repository (R01).
- **Date:** October 2, 2018.
- **Time:** 11:00 a.m. to 1:00 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:** Najma S. Begum, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7349, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, 301-594–8894, begumn@niddk.nih.gov.

**Name of Committee:** National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; PAR–17–270; NIDDK Central Repositories Non-renewable Sample Access (X01).
- **Date:** October 3, 2018.
- **Time:** 1:00 p.m. to 2:30 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:** Najma S. Begum, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7349, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, 301-594–8894, begumn@niddk.nih.gov.

**Name of Committee:** National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK–KUH Fellowship Review Meeting.
- **Date:** October 5, 2018.
- **Time:** 8:00 a.m. to 4:00 p.m.
- **Agenda:** To review and evaluate grant applications.

**Place:** Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015.

**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, 301-594–719, guox@extra.niddk.nih.gov.

**Name of Committee:** National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Time-Sensitive Obesity Policy.
- **Date:** October 5, 2018.
- **Time:** 1:30 p.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:** Michele L. Barnard, Ph.D., Scientific Review Officer, Review Branch,