

The purpose of the information package is to provide Agency staff the opportunity to adequately prepare for the meeting, including the review of relevant data concerning the product. In

the Agency's experience, reviewing such information is critical to achieving a productive meeting. If the information package was previously submitted in the meeting request, it should be

revised, as applicable, so that the information reflects the most current and accurate information available.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Meeting Requests					
Combining and Sending Meeting Request Letters for Manufacturers, Importers, and Researchers	83	1	83	10	830
Meeting Information Packages					
Combining and Submitting Meeting Information Packages for Manufacturers, Importers, and Researchers	83	1	83	18	1,494
Total					2,324

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's estimate of the number of respondents for meeting requests in table 1 is based on the number of meeting requests received and projected over the next 3 years. FDA estimates that 83 preapplication meetings will be requested.

The hours per response for combining and sending meeting request letters are estimated at 10 hours each, and the total burden hours for meeting requests are expected to be 830 hours. Based on FDA's experience, the Agency expects it will take respondents this amount of time to prepare, gather, copy, and submit brief statements about the product and a description of the purpose and details of the meeting.

FDA's estimates that 83 respondents will compile meeting information packages and submit to FDA at 18 hours per response. Based on FDA's experience, the Agency expects that it will take respondents 1,494 hours (83 respondents × 18 hours) to gather, copy, and submit brief statements about the product, a description of the details of the anticipated meeting, and data and information that generally would already have been generated for the planned research and/or product development.

The total number of burden hours for this collection of information is estimated to be 2,324 hours (830 hours to prepare and submit meeting requests and 1,494 hours to prepare and submit information packages).

Our estimated burden for the information collection reflects an overall increase of 16 respondents and 448 hours. We attribute this adjustment to an increase in the number of industry meetings as the premarket tobacco

application compliance deadlines will come due in the next 3 years.

Dated: September 4, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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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: Healthcare Delivery and Methodologies Integrated Review Group; Clinical Management of Patients in Community-based Settings Study Section.

Date: September 27–28, 2018.

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

Agenda: To review and evaluate grant applications.

Place: Warwick Denver, 1776 Grant Street, Denver, CO 80203.

Contact Person: Martha L Hare, Ph.D., RN, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3154, MSC 7770, Bethesda, MD 20892, (301) 451–8504, harem@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Hypertension and Microcirculation.

Date: October 2, 2018.

Time: 8:00 a.m. to 2:00 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: Katherine M. Malinda, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4140, MSC 7814, Bethesda, MD 20892, 301–435–0912, Katherine_Malinda@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Dental, Microbiology and Oral Biology.

Date: October 3, 2018.

Time: 12:00 p.m. to 3:00 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: Baljit S Moonga, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7806, Bethesda, MD 20892, 301–435–1777, moongabs@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–17–094: Maximizing Investigators' Research Award (R35).

Date: October 10–11, 2018.

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

Agenda: To review and evaluate grant applications.

Place: Residence Inn Capital View, 2850 South Potomac Avenue, Arlington, VA 22202.

Contact Person: Jonathan Arias, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5170, MSC 7840, Bethesda, MD 20892, 301-435-2406, ariasj@csr.nih.gov.
(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: September 6, 2018.

David D. Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

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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: Biobehavioral and Behavioral Processes Integrated Review Group; Biobehavioral Regulation, Learning and Ethology Study Section.

Date: October 4-5, 2018.

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

Agenda: To review and evaluate grant applications.

Place: Hotel Zoe, Fisherman's Wharf, 425 North Point Street, San Francisco, CA 94133.

Contact Person: Unja Hayes, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 301-827-6830, unja.hayes@nih.gov.

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group; Prokaryotic Cell and Molecular Biology Study Section.

Date: October 4-5, 2018.

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

Agenda: To review and evaluate grant applications.

Place: Kinzie Hotel, 20 West Kinzie Street, Chicago, IL 60654.

Contact Person: Luis Dettin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2208, Bethesda, MD 20892, 301-451-1327, dettinle@csr.nih.gov.

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Motor Function, Speech and Rehabilitation Study Section.

Date: October 4, 2018.

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

Agenda: To review and evaluate grant applications.

Place: Westin Georgetown, 2350 M Street NW, Washington, DC 20037.

Contact Person: Biao Tian, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3166, MSC 7848, Bethesda, MD 20892, 301-402-4411, tianbi@csr.nih.gov.

Name of Committee: Vascular and Hematology Integrated Review Group; Atherosclerosis and Inflammation of the Cardiovascular System Study Section.

Date: October 11-12, 2018.

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: Natalia Komissarova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5207, MSC 7846, Bethesda, MD 20892, 301-435-1206, komissar@mail.nih.gov.

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group; Psychosocial Development, Risk and Prevention Study Section.

Date: October 11-12, 2018.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Anna L. Riley, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3114, MSC 7759, Bethesda, MD 20892, 301-435-2889, rileyann@csr.nih.gov.

Name of Committee: Immunology Integrated Review Group; Hypersensitivity, Autoimmune, and Immune-mediated Diseases Study Section.

Date: October 11-12, 2018.

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

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Alexandria Old Town, 1900 Diagonal Road, Alexandria, VA 22314.

Contact Person: Deborah Hodge, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4207, MSC 7812, Bethesda, MD 20892, 301-435-1238, hodged@mail.nih.gov.

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group; Behavioral Medicine, Interventions and Outcomes Study Section.

Date: October 11-12, 2018.

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

Agenda: To review and evaluate grant applications.

Place: Baltimore Marriott Waterfront, 700 Aliceanna Street, Baltimore, MD 21202.

Contact Person: Lee S. Mann, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3224, MSC 7808, Bethesda, MD 20892, 301-435-0677, mannl@csr.nih.gov.

Name of Committee: Digestive, Kidney and Urological Systems Integrated Review Group; Hepatobiliary Pathophysiology Study Section.

Date: October 11-12, 2018.

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

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Jianxin Hu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2156, Bethesda, MD 20892, 301-827-4417, jianxinh@csr.nih.gov.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Neural Oxidative Metabolism and Death Study Section.

Date: October 11-12, 2018.

Time: 8:00 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Crystal Gateway Marriott, 1700 Jefferson Davis Highway, Arlington, VA 22202.

Contact Person: Carol Hamelink, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4192, MSC 7850, Bethesda, MD 20892, (301) 213-9887, hamelinc@csr.nih.gov.

Name of Committee: Immunology Integrated Review Group; Innate Immunity and Inflammation Study Section.

Date: October 11-12, 2018.

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

Agenda: To review and evaluate grant applications.

Place: Sheraton Grand at Wild Horse Pass, 5594 W Wild Horse Pass Boulevard, Phoenix, AZ 85226.

Contact Person: Tina McIntyre, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4202, MSC 7812, Bethesda, MD 20892, 301-594-6375, mcintyrt@csr.nih.gov.

Name of Committee: Digestive, Kidney and Urological Systems Integrated Review Group; Xenobiotic and Nutrient Disposition and Action Study Section.

Date: October 11, 2018.

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

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Martha Garcia, Ph.D., Scientific Review Officer, Center for