

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹—Continued

Activity/section of FD&C Act (as amended) or FDASIA	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Exemption from Profit Prohibition Information—520(m)(6)(A)(i) and (ii) of the FD&C Act	3	1	3	50	150
Request for Determination of Eligibility Criteria—613(b) of FDASIA	2	1	2	10	20
ADN Notification—520(m)(6)(A)(iii) of the FD&C Act	1	1	1	100	100
ADN Modification—520(m)(6)(C) of the FD&C Act	5	1	5	100	500
Total					1,370

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

FDA’s Center for Devices and Radiological Health receives an estimated average of six HDE applications per year. FDA estimates that three of these applications will be indicated for pediatric use. We estimate that we will receive approximately two requests for determination of eligibility criteria per year. FDA estimates that very few or no HDE holders will notify the Agency that the number of devices distributed in the year has exceeded the ADN. FDA estimates that five HDE holders will petition to have the ADN modified due to additional information on the number of individuals affected by the disease or condition.

Dated: May 11, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–11532 Filed 5–13–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Tribal Management Grant Program; Correction

AGENCY: Indian Health Service, HHS.

ACTION: Notice; correction.

SUMMARY: The Indian Health Service published a document in the **Federal Register** on April 7, 2016, for the FY 2016 Tribal Management Grant Program. The notice contained the incorrect Fiscal Year regarding funding availability.

FOR FURTHER INFORMATION CONTACT: Michelle Eagle Hawk, Deputy Director, Office of Direct Service and Contracting Tribes, Indian Health Service, 5600 Fishers Lane, Mail Stop 08E17, Rockville, MD 20857, telephone (301) 443–1104. (This is not a toll-free number.)

Correction

In the **Federal Register** of April 7, 2016, in FR Doc. 2016–07950, on page 20396, in the second column, under the heading “II. Award Information, Estimated Funds Available,” the correct first sentence should read as follows:

The total amount of funding identified for the current fiscal year (FY) 2016 is approximately \$2,412,000.

Dated: May 4, 2016.

Mary Smith,

Principal Deputy Director, Indian Health Service.

[FR Doc. 2016–11545 Filed 5–13–16; 8:45 am]

BILLING CODE 4165–16–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 (5 U.S.C. App.), 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: Heart, Lung, and Blood Initial Review Group; NHLBI Mentored Transition to Independence Review Committee.

Date: June 9–10, 2016.

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: Giuseppe Pintucci, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7192, Bethesda, MD 20892, 301–435–0287, Pintuccig@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: May 10, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–11397 Filed 5–13–16; 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 (5 U.S.C. App.), 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: Infectious Diseases and Microbiology Integrated Review Group; Virology—B Study Section.

Date: June 6–7, 2016.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Mayflower Hotel, 1127 Connecticut Avenue NW., Washington, DC 20036.

Contact Person: John C. Pugh, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1206, MSC 7808, Bethesda, MD 20892, (301) 435-2398, pughjohn@csr.nih.gov.

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Behavioral Genetics and Epidemiology Study Section.

Date: June 7, 2016.

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

Agenda: To review and evaluate grant applications.

Place: St. Regis, Washington, DC, 923 16th and K Streets NW., Washington, DC 20006.

Contact Person: George Vogler, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3140, MSC 7770, Bethesda, MD 20892, (301) 237-2693, voglergp@csr.nih.gov.

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Dissemination and Implementation Research in Health Study Section.

Date: June 8-9, 2016.

Time: 9:00 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: Jessica Bellinger, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3158, Bethesda, MD 20892, bellingerjd@csr.nih.gov.

Name of Committee: Cell Biology Integrated Review Group; Membrane Biology and Protein Processing Study Section.

Date: June 9-10, 2016.

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

Agenda: To review and evaluate grant applications.

Place: Warick Allerton Hotel, 701 N. Michigan Avenue, Chicago, IL 60611.

Contact Person: Janet M. Larkin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5142, MSC 7840, Bethesda, MD 20892, 301-806-2765, larkinja@csr.nih.gov.

Name of Committee: Immunology Integrated Review Group; Cellular and Molecular Immunology—A Study Section.

Date: June 9-10, 2016.

Time: 8:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Silver Spring, 8727 Colesville Road, Silver Spring, MD 20910.

Contact Person: David B Winter, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4204, MSC 7812, Bethesda, MD 20892, 301-435-1152, dwinter@mail.nih.gov.

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group; Genetic Variation and Evolution Study Section.

Date: June 9-10, 2016.

Time: 8:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Ronald Adkins, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2206, MSC 7890, Bethesda, MD 20892, 301-435-4511, ronald.adkins@nih.gov.

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

Date: June 9-10, 2016.

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

Agenda: To review and evaluate grant applications.

Place: Melrose Hotel, 2430 Pennsylvania Ave., NW, Washington, DC 20037.

Contact Person: Lynn E Luethke, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5166, MSC 7844, Bethesda, MD 20892, (301) 806-3323, luethkel@csr.nih.gov.

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

Date: June 9-10, 2016.

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

Agenda: To review and evaluate grant applications.

Place: Pier 5 Hotel, 711 Eastern Avenue, Baltimore, MD 21202.

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: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Biomedical Imaging Technology B Study Section.

Date: June 9-10, 2016.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Eileen W Bradley, DSC, IRG Chief, Surgical Sciences Biomedical Imaging and Bioengineering, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5100, MSC 7854, Bethesda, MD 20892, (301) 435-1179, bradleye@csr.nih.gov.

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

Date: June 9-10, 2016.

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

Agenda: To review and evaluate grant applications.

Place: Admiral Fell Inn, 888 South Broadway, Baltimore, MD 21231.

Contact Person: Richard A Currie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5128, MSC 7840, Bethesda, MD 20892, (301) 435-1219, currieri@csr.nih.gov.

Name of Committee: Oncology 1—Basic Translational Integrated Review Group; Tumor Cell Biology Study Section.

Date: June 9-10, 2016.

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

Agenda: To review and evaluate grant applications.

Place: Hilton Alexandria Old Town, 1767 King Street, Alexandria, VA 22314.

Contact Person: Charles Morrow, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6202, MSC 7804, Bethesda, MD 20892, 301-408-9850, morrowcs@csr.nih.gov.

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group; Modeling and Analysis of Biological Systems Study Section.

Date: June 9-10, 2016.

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

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Craig Giroux, Ph.D., Scientific Review Officer, BST IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5150, Bethesda, MD 20892, 301-435-2204, girouxcn@csr.nih.gov.

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group; Cardiovascular Differentiation and Development Study Section.

Date: June 9, 2016.

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

Agenda: To review and evaluate grant applications.

Place: Virginian Suites, 1500 Arlington Boulevard, Arlington, VA 22209.

Contact Person: Sara Ahlgren, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm. 4136, Bethesda, MD 20817-7814, 301-435-0904, sara.ahlgren@nih.gov.

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Language and Communication Study Section.

Date: June 9-10, 2016.

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

Agenda: To review and evaluate grant applications.

Place: Palomar Hotel, 2121 P Street NW., Washington, DC 20037.

Contact Person: Wind Cowles, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3172, Bethesda, MD 20892, cowleshw@csr.nih.gov.

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Macromolecular Structure and Function C Study Section.

Date: June 9-10, 2016.

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

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Washington, 1515 Rhode Island Ave. NW., Washington, DC 20005.

Contact Person: William A. Greenberg, Ph.D., Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4168, MSC 7806, Bethesda, MD 20892, (301) 435-1726, greenbergwa@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Development and Application of PET and SPECT Imaging Ligands as Biomarkers for Drug Discovery and for Pathophysiological Studies of CNS Disorders (R21).

Date: June 9, 2016.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Donald Scott Wright, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5108, MSC 7854, Bethesda, MD 20892, (301) 435-8363, wrightds@csr.nih.gov.

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Musculoskeletal Rehabilitation Sciences Study Section.

Date: June 10, 2016.

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

Agenda: To review and evaluate grant applications.

Place: Sheraton BWI (Baltimore), 1100 Old Elkridge Landing Road, Baltimore, MD 21090.

Contact Person: Maria Nurminskaya, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, Bethesda, MD 20892, (301) 435-1222, nurminskayam@csr.nih.gov.

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Macromolecular Structure and Function D Study Section.

Date: June 10, 2016.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: James W. Mack, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4154, MSC 7806, Bethesda, MD 20892, (301) 435-2037, mackj2@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Enabling Imaging Technologies.

Date: June 10, 2016.

Time: 8:00 a.m. to 6:00 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: Maria DeBernardi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6158, MSC 7892, Bethesda, MD 20892, 301-435-1355, debernardima@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR 13-345: Development of Pediatric Formulations and Drug Delivery Systems.

Date: June 10, 2016.

Time: 10:00 a.m. to 12:00 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: Sharon S. Low, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5104, MSC 5104, Bethesda, MD 20892-5104, 301-237-1487, lowss@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: May 11, 2016.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016-11472 Filed 5-13-16; 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 Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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: Center for Scientific Review Special Emphasis Panel; Biobehavior, Inflammation, and Stress.

Date: May 19, 2016.

Time: 3:30 p.m. to 4:30 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: Andrea B. Kelly, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3182, MSC 7770, Bethesda, MD 20892, (301) 455-1761, kellya2@csr.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.

(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: May 11, 2016.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016-11473 Filed 5-13-16; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App. 2), notice is hereby given of the joint meeting of the National Cancer Advisory Board (NCAB) and NCI Board of Scientific Advisors (BSA).

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting Web site (<http://videocast.nih.gov>).

A portion of the National Cancer Advisory Board 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 Cancer Advisory Board; *Ad Hoc* Subcommittee on Global Cancer Research.

Open: June 20, 2016, 4:30 p.m. to 6:00 p.m.

Agenda: Discussion on Global Cancer Research.

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

Contact Person: Dr. Edward Trimble, Executive Secretary, NCAB *Ad Hoc* Subcommittee on Global Cancer Research, National Cancer Institute—Shady Grove, National Institutes of Health, 9609 Medical