

ESTIMATE ANNUALIZED BURDEN IN HOURS TABLE—Continued

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
IRB Registration Initial and Update	350	2	45/60	525
Total				6,175

Terry Clark,

Asst Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2018–23282 Filed 10–24–18; 8:45 am]

BILLING CODE 4150–36–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; Fellowships: Cell Biology, Developmental Biology, and Bioengineering.

Date: November 13–14, 2018.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Alexander Gubin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4196, MSC 7812, Bethesda, MD 20892, 301–435–2902, gubina@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA–HD–19–001 Safe and Effective Devices for Use in Neonatal, Perinatal and Pediatric Care Settings.

Date: November 15, 2018.

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

Agenda: To review and evaluate grant applications.

Place: JW Marriott New Orleans, 614 Canal Street, New Orleans, LA 70130.

Contact Person: Clara M. Cheng, Ph.D., Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6170, MSC 7892, Bethesda, MD 20892, 301–435–1041, cheng@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Endocrinology, Metabolism, Nutrition and Reproductive Sciences.

Date: November 15–16, 2018.

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

Agenda: To review and evaluate grant applications.

Place: JW Marriott New Orleans, 614 Canal Street, New Orleans, LA 70130.

Contact Person: Clara M. Cheng, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6170, MSC 7892, Bethesda, MD 20892, 301–435–1041, cheng@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Translational Research in Pediatric and Obstetric Pharmacology and Therapeutics.

Date: November 16, 2018.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Dianne Hardy, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6175, MSC 7892, Bethesda, MD 20892, 301–435–1154, dianne.hardy@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Discovery of Molecular Targets and Therapeutics for Pregnancy-Related Diseases; Drug Repurposing for Conditions Affecting Neonates and Pregnant Women.

Date: November 16, 2018.

Time: 3:30 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Dianne Hardy, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6175, MSC 7892, Bethesda, MD 20892, 301–435–1154, dianne.hardy@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Blood and Vascular Biology.

Date: November 19–20, 2018.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ai-Ping Zou, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7814, Bethesda, MD 20892, 301–408–9497, zouai@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Musculoskeletal, Oral, Skin, Rheumatology and Rehab Sciences AREA (R15) Review.

Date: November 20, 2018.

Time: 8:30 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: Aftab A Ansari, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4108, MSC 7814, Bethesda, MD 20892, 301–237–9931, ansaria@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: October 19, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–23267 Filed 10–24–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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 Neurological Disorders and Stroke Special Emphasis Panel; NINDS Diversity Training Grant Application Review.

Date: November 16, 2018.

Time: 12:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: William C. Benzing, Ph.D., Scientific Review Officer, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3204, MSC 9529, Bethesda, MD 20892-9529, (301) 496-0660, benzingw@mail.nih.gov.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Blueprint Neurotherapeutics Review Meeting.

Date: November 28, 2018.

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

Agenda: To review and evaluate grant applications.

Place: Georgetown Suites, 1111 30th Street NW, Washington, DC 20007.

Contact Person: Joel A. Saydoff, Ph.D., Scientific Review Officer, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3205, MSC 9529, Bethesda, MD 20892-9529, (301) 496-9223, joel.saydoff@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: October 18, 2018.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018-23264 Filed 10-24-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Investigational Agent Accountability Record Forms in the Conduct of Investigational Trials for the Treatment of Cancer (National Cancer Institute)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Charles Hall, Chief, Pharmaceutical Management Branch, Cancer Therapy Evaluation Program, Division of Cancer Diagnosis and Treatment, National Cancer Institute, 9609 Medical Center Drive, Bethesda, Maryland, 20892 or call non-toll-free number (240) 276-6575 or Email your request, including your address to: HallCh@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Investigational Agent Accountability Record Forms in the Conduct of Investigational Trials for the Treatment of Cancer, 0925-0613, Expiration Date 3/31/2019, Revision, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The U.S. Food and Drug Administration (FDA) holds the National Cancer Institute (NCI), Division of Cancer Treatment and Diagnosis/ Cancer Therapy Evaluation Program (NCI/DCTD/CTEP) and the Division of Cancer Prevention (DCP) responsible, as a sponsor of investigational drug trials, to assure the FDA that systems for accountability are being maintained by investigators in its clinical trials program. Data obtained from the Investigational Agent Accountability Record Forms (aka. Drug Accountability Record Forms—DARF) are used to track the dispensing of investigational anticancer agents from receipt from the NCI to dispensing or administration to patients. Requirements for the tracking of investigational agents under an Investigational New Drug Application are outlined in Title 21 Code of Federal Regulations (CRF) part 312. NCI and/or its auditors use this information to ensure compliance with federal regulations and NCI policies. Previously, the investigator registration forms and process were part of this submission. These forms were more appropriately submitted and approved under the CTEP Branch and Support Contracts Forms and Surveys in July 2018 (OMB No. 0925-0753; Expiration Date 7/31/2021). Thus, the investigator registration forms are no longer included in this request.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden are 3,033 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Category of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hours
Individuals (DARF)	2,133	16	4/60	2,275