

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹—Continued

21 CFR section	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Subtotal	2,896,743
Cancellations: Through ABI/ACS						
1.282	3540	7,040	1	7,040	0.25 (15 minutes)	1,760
Through PNSI						
1.282 and 1.283(a)(5)	3540	35,208	1	35,208	0.25 (15 minutes)	8,802
Subtotal	10,562
Requests for Review and Post-hold Submissions						
1.283(d) and 1.285(j),	N/A	1	1	1	8	8
1.285(i)	N/A	263	1	263	1	263
Subtotal	271
Total	14,932,412	2,907,576

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

² To avoid double counting, an estimated 396,416 burden hours already accounted for in the importer's entry notice information collection approved under OMB control number 0910-0046 are not included in this total.

³ The term "Form FDA 3540" refers to the electronic submission system known as PNSI, which is available at <https://www.access.fda.gov>.

Based on our experience and the average number of prior notice submissions, cancellations, and requests for review received in the past 3 years, we have made no adjustments in our burden estimate for the information collection. We estimate that 1,700 users of ABI/ACS will submit an average of 7,647 prior notices annually, for a total of 12,999,900 prior notices received through ABI/ACS. We assume the reporting burden for a prior notice submitted through ABI/ACS to be 10 minutes, or 0.167 hour, per notice, for a total annual burden of 2,170,983 hours. This estimate takes into consideration the burden hours already counted in the information collection approval for FDA importer's entry notice (OMB control number 0910-0046), as previously discussed.

We estimate that 27,000 registered users of PNSI will submit an average of 70 prior notices annually, for a total of 1,890,000 prior notices received annually. We assume the reporting burden for a prior notice submitted through PNSI to be 23 minutes, or 0.384 hour, per notice, for a total burden of 725,760 hours.

We estimate that 7,040 users of ABI/ACS will submit an average of 1 cancellation annually, for a total of 7,040 cancellations received annually through ABI/ACS. We assume the reporting burden for a cancellation submitted through ABI/ACS to be 15 minutes, or 0.25 hour, per cancellation, for a total burden of 1,760 hours.

We estimate that 35,208 registered users of PNSI will submit an average of 1 cancellation annually, for a total of 35,208 cancellations received annually. We assume the reporting burden for a cancellation submitted through PNSI to be 15 minutes, or 0.25 hour, per cancellation, for a total burden of 8,802 hours.

We estimate that one or fewer requests for review under § 1.283(d) or § 1.285(j) will be submitted annually. We assume that it will take respondents 8 hours to prepare the factual and legal information necessary to prepare a request for review. Thus, we estimate a total reporting burden of 8 hours.

We estimate that 263 post-hold submissions under § 1.285(i) will be submitted annually. We assume that it will take about 1 hour to prepare the written notification described in § 1.285(i)(2), for a total reporting burden of 263 hours.

Dated: May 12, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-10825 Filed 5-19-20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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 Institute on Aging Special Emphasis Panel; Research Education on Alzheimer's Disease and Related Dementias.

Date: June 4, 2020.

Time: 2:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Kimberly Firth, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, Gateway Building, 7201 Wisconsin Avenue, Suite 2W200, Bethesda,

MD 20892, (301) 402-7702, firthkm@mail.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. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: May 14, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020-10792 Filed 5-19-20; 8:45 am]

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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: Center for Scientific Review Special Emphasis Panel; PAR Panel: Development of the INCLUDE Project Data Coordinating Center.

Date: June 15, 2020.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Janita N. Turchi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda 20892, (301) 402-4005, turchij@mail.nih.gov.

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

Date: June 17-18, 2020.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: C-L Albert Wang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of

Health, 6701 Rockledge Drive, Room 4146, MSC 7806, Bethesda, MD 20892, (301) 435-1016, wangca@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Understanding Alzheimer's Disease.

Date: June 17-18, 2020.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Boris P. Sokolov, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217A, MSC 7846, Bethesda, MD 20892, (301) 408-9115, bsokolov@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA Panel: Tobacco Regulatory Science A (or B).

Date: June 17, 2020.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Sepandarmaz Aschrafi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4040D, Bethesda, MD 20892, (301) 451-4251, Armaz.aschrafi@nih.gov.

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group; Biodata Management and Analysis Study Section.

Date: June 18-19, 2020.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Wenchi Liang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3150, MSC 7770, Bethesda, MD 20892, (301) 435-0681, liangw3@csr.nih.gov.

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

Date: June 18-19, 2020.

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

Agenda: To review and evaluate grant applications.

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

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: Cardiovascular and Respiratory Sciences Integrated Review Group; Myocardial Ischemia and Metabolism Study Section.

Date: June 18-19, 2020.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Richard D. Schneiderman, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4138, Bethesda, MD 20817, (301) 402-3995, richard.schneiderman@nih.gov.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Clinical Neuroplasticity and Neurotransmitters Study Section.

Date: June 18-19, 2020.

Time: 9:30 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Suzan Nadi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217B, MSC 7846, Bethesda, MD 20892, (301) 435-1259, nadis@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA-MH-20-330/331: Novel Imaging Approaches for Detection of Persistent HIV and Neuroimmune Dysfunction Associated with HIV in the Central Nervous System.

Date: June 19, 2020.

Time: 10:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Shinako Takada, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 402-9448, shinako.takada@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 14, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

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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.