

meet the other statutory requirements, FDA is required to respond to each request within 45 days. If multiple requests for nonbinding feedback are not timely, then these requests will not be subject to a response from FDA within 45 days.

Finally, FDA acknowledges that when the inspectional observations involve a public health priority, implicate a systemic or major action, or relate to an emerging safety issue, continued communication between FDA and the firm may be needed after issuance of the nonbinding feedback to ensure adequate protection of public health. In such

cases, FDA may continue communication with the firm and/or take any action necessary to ensure adequate protection of public health.

FDA received one comment regarding ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

(Comment 8) One commenter requested that FDA develop templates for manufacturers to submit when requesting nonbinding feedback.

(Response) At this time, FDA does not believe that providing a template would

be appropriate since the content of the request for nonbinding feedback is expected to be situationally dependent and different firms may have different preferred formats for requesting nonbinding feedback. FDA believes that use of a template may be too restrictive and could result in pertinent information not being included in the request for nonbinding feedback. Nonetheless, FDA may choose to utilize a template at a later date if it determines it would be beneficial to firms to do so.

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
Requests for nonbinding feedback after certain FDA inspections of device establishments	220	1	220	500	110,000

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

Our estimate that 220 respondents per year will request nonbinding feedback is based on recent inspectional data. Based on the recommendations in the guidance and our experience with similar information collections, we believe it will take approximately 500 hours to complete a request for nonbinding feedback. Therefore, we estimate the burden of this information collection to be 110,000 hours.

Dated: March 9, 2020.

Lowell J. Schiller,
Principal Associate Commissioner for Policy.
[FR Doc. 2020-05131 Filed 3-12-20; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, NIDA.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the NATIONAL INSTITUTE ON DRUG ABUSE, including consideration of personnel qualifications and

performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIDA.

Date: May 7–8, 2020.

Time: 8:00 a.m. to 3:15 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: Intramural Research Program, Biomedical Research Center, Johns Hopkins Bayview Campus, 251 Bayview Boulevard, Room BRC 03C219, Baltimore, MD 21224.

Contact Person: Joshua Kysiak, Program Specialist, Biomedical Research Center, Intramural Research Program, National Institute on Drug Abuse, NIH, DHHS, 251 Bayview Boulevard, Baltimore, MD 21224, 443-740-2465, kysiakjo@nida.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: March 9, 2020.

Tyeshia M. Roberson,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020-05096 Filed 3-12-20; 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; Member Conflict SEP.

Date: April 14, 2020.

Time: 12:00 p.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Ramesh Vemuri, Ph.D., Chief, Scientific Review Branch, Scientific Review Branch, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Gateway Building, Suite 2W200, Bethesda, MD 20892, (301) 402-7700, rv23r@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: March 9, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020-05144 Filed 3-12-20; 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; Neurolinguistics and Language Learning.

Date: March 26, 2020.

Time: 3:00 p.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 (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.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: AIDS and Related Research.

Date: April 6, 2020.

Time: 2:00 p.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 (Telephone Conference Call).

Contact Person: Kenneth A Roebuck, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5106, MSC 7852, Bethesda, MD 20892, (301) 435-1166, roebuckk@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Neuropsychiatric and Neurodegenerative Disorders and Diseases.

Date: April 6, 2020.

Time: 12:00 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 (Telephone Conference Call).

Contact Person: Samuel C Edwards, Ph.D., Chief, BDCN IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5210, MSC 7846, Bethesda, MD 20892, (301) 435-1246, edwards@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RM18-009: NIH Transformative Research Awards (R01) Review.

Date: April 7, 2020.

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, Bethesda, MD 20814.

Contact Person: Raymond Jacobson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5858, MSC 7849, Bethesda, MD 20892, (301) 996-7702, jacobsonrh@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Biobehavioral Processes of Cognition and Stress.

Date: April 8, 2020.

Time: 2:00 p.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 (Telephone Conference Call).

Contact Person: Katherine Colona Morasch, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3170, Bethesda, MD 20892, moraschk@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Virology.

Date: April 15-16, 2020.

Time: 9:00 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: Susan Daum, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3202, Bethesda, MD 20892, (301) 827-7233, susan.boyle-vavra@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Topics in Virology.

Date: April 15, 2020.

Time: 1:00 p.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: Marci Scidmore, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of

Health, 6701 Rockledge Drive, Room 3192, MSC 7808, Bethesda, MD 20892, (301) 435-1149, marci.scidmore@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: March 9, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020-05113 Filed 3-12-20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Notice is hereby given of a meeting of the HEAL (Helping to End Addiction Long-term) Multi-Disciplinary Working Group

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 meeting will be closed to the public in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended. The program documents and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the program documents, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: HEAL Multi-Disciplinary Working Group Meeting.

Date: March 18, 2020.

Open: March 18, 2020, 8:30 a.m. to 10:30 a.m.

Closed: March 18, 2020, 10:30 a.m. to 3:20 p.m.

Open: March 18, 2020, 3:20 p.m. to 4:00 p.m.

Agenda: Provide an update on Helping to End Addiction Long-Term (HEAL) Initiatives and obtain expertise from the MDWG relevant to the NIH HEAL Initiative and to specific HEAL projects.

Videocast: For those not able to attend in person, this meeting will be live webcast at: <https://videocast.nih.gov/>.

Place: National Institutes of Health, Building 1, Wilson Hall, 1 Center Drive, Bethesda, MD 20892.