

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN^{1 2}

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
310.305(c)(5)	3	1	3	1	3
314.80(c)(1)(iii)	5	1	5	1	5
314.80(c)(2)	810	17.19	13,923.90	60	835,434
Reports of serious adverse drug events (21 U.S.C. 379aa(b) and (c))	283	687.099	194,449	6	1,166,694
Total					2,002,136

¹ The reporting burden for § 310.305(c)(1), (2), and (3), and § 314.80(c)(1)(i) and (ii) is covered under OMB control number 0910–0645.

² The capital costs or operating and maintenance costs associated with this collection of information are approximately \$25,000 annually.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN^{1 2}

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
310.305(g)	25	1	25	16	400
314.80(j)	352	1,870	658,240	16	10,531,840
Recordkeeping (21 U.S.C. 379aa(e)(1))	300	885.6667	265,700	8	2,125,600
Total					12,657,840

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

² There are maintenance costs of approximately \$22,000 annually.

Based on submissions received we have increased our burden estimate for reporting under part 314.80(c)(2) and recordkeeping under part 314.80(j). Additionally, and as previously stated, we are consolidating burden associated with reporting and recordkeeping under section 760 of the FD&C Act. Based on our records, we received 194,449 total annual reports from approximately 283 respondents for nonprescription drugs marketed without an approved application. We estimate each submission takes approximately 6 hours to prepare and submit. We estimate that there are 265,700 records per year maintained by approximately 300 respondents, and that it takes 8 hours to maintain each record.

Dated: November 2, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–24442 Filed 11–7–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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 on Drug Abuse Special Emphasis Panel; R13 Conference Grant Review.

Date: November 14, 2018.

Time: 12:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Ipolia R. Ramadan, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, Division of Extramural Research, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Boulevard, Room 4228, MSC 9550, Bethesda, MD 20892, 301–827–5842, ramadanir@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.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Multi-site Clinical Trials.

Date: November 16, 2018.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Ipolia R. Ramadan, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, Division of Extramural Research, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Boulevard, Room 4228, MSC 9550, Bethesda, MD 20892, 301–827–5842, ramadanir@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.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: November 2, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–24470 Filed 11–7–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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 Mental Health Special Emphasis Panel; Silvio O. Conte Centers for Basic Neuroscience or Translational Mental Health Research (P50).

Date: November 14, 2018.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Rebecca Steiner Garcia, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH Neuroscience Center, 6001 Executive Blvd., Room 6149, MSC 9608, Bethesda, MD 20892-9608, 301-443-4525, steinerr@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.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; First in Human and Early Stage Clinical Trials of Novel Investigational Drugs or Devices for Psychiatric Disorders.

Date: November 14, 2018.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Vinod Charles, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH Neuroscience Center, 6001 Executive Blvd., Room 6151, MSC 9606, Bethesda, MD 20892-9606, 301-443-1606, charlesvi@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.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; NRSA Institutional Research Grant Training Review.

Date: November 16, 2018.

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

Agenda: To review and evaluate grant applications

Place: Washington Plaza Hotel, 10 Thomas Circle NW, Washington, DC 20005.

Contact Person: Nicholas Gaiano, Ph.D., Review Branch Chief, Division of Extramural Activities, National Institute of Mental Health, NIH Neuroscience Center/Room 6150/MSB 9606, 6001 Executive Boulevard,

Bethesda, MD 20892-9606, 301-443-2742, nick.gaiano@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 No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: November 5, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018-24480 Filed 11-7-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Toxicology Program Board of Scientific Counselors; Announcement of Meeting; Request for Comments

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This notice announces the next meeting of the National Toxicology Program (NTP) Board of Scientific Counselors (BSC). The BSC, a federally chartered, external advisory group composed of scientists from the public and private sectors, will review and provide advice on programmatic activities. The meeting is open to the public and registration is requested for both attendance and oral comment and required to access the webcast. Information about the meeting and registration are available at <http://ntp.niehs.nih.gov/go/165>.

DATES:

Meeting: Scheduled for December 11, 2018 at 8:30 a.m. to adjournment on December 12, 2018 at approximately 5:00 p.m. Eastern Standard Time (EST).

Written Public Comment Submissions: Deadline is December 3, 2018.

Registration for Oral Comments: Deadline is December 3, 2018.

Registration to Attend Meeting In-person or to View Webcast: Deadline is December 12, 2018.

Registration to view the meeting via the webcast is required.

ADDRESSES:

Meeting Location: Rodbell Auditorium, Rall Building, National Institute of Environmental Health Sciences (NIEHS), 111 T.W. Alexander Drive, Research Triangle Park, NC 27709.

Meeting web page: The preliminary agenda, registration, and other meeting

materials are at <http://ntp.niehs.nih.gov/go/165>.

Webcast: The URL for viewing the meeting webcast will be provided to registrants.

FOR FURTHER INFORMATION CONTACT: Dr. Mary Wolfe, Designated Federal Official for the BSC, Office of Liaison, Policy and Review, Division of NTP, NIEHS, P.O. Box 12233, K2-03, Research Triangle Park, NC 27709. Phone: 984-287-3209, Fax: 301-451-5759, email: wolfe@niehs.nih.gov. Hand Deliver/Courier address: 530 Davis Drive, Room K2130, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION: The BSC will provide input to the NTP on programmatic activities and issues. The agenda on December 11 will recognize NTP's 40th anniversary with the theme "Celebrate the Past, and Embrace the Future," and on December 12, several talks will focus on translation as a scientific framework. Please see the preliminary agenda for information about the specific presentations. The preliminary agenda, roster of BSC members, background materials, public comments, and any additional information, when available, will be posted on the BSC meeting website (<http://ntp.niehs.nih.gov/go/165>) or may be requested in hardcopy from the Designated Federal Official for the BSC. Following the meeting, summary minutes will be prepared and made available on the BSC meeting website.

Meeting Attendance Registration: The meeting is open to the public with time set aside for oral public comment; in-person attendance at the NIEHS is limited by the space available (~100 attendees). Registration for in-person attendance is on a first-come, first-served basis, and registrants will be assigned a number in their confirmation email. After the first 100 registrants, persons will be placed on a wait list and notified should an opening become available. Registration to attend the meeting in-person or view the webcast is by December 12, 2018 at <http://ntp.niehs.nih.gov/go/165>. Registration is required to view the webcast; the URL for the webcast will be provided in the email confirming registration. Visitor and security information for those attending in-person is available at niehs.nih.gov/about/visiting/index.cfm. Individuals with disabilities who need accommodation to participate in this event should contact Ms. Robbin Guy at phone: (984) 287-3136 or email: guyr2@niehs.nih.gov. TTY users should contact the Federal TTY Relay Service at 800-877-8339. Requests should be made at