

practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from

the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. This guidance document is also available at <https://www.regulations.gov> or <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>. Persons unable to download an electronic copy of “Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic

copy of the document. Please use the document number 1677 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

| 21 CFR Part or guidance | Topic | OMB control No. |
|--|---|-----------------|
| “Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff”. | Q-submissions | 0910–0756 |
| “De Novo Classification Process (Evaluation of Automatic Class III Designation)”. | De Novo Requests | 0910–0844 |
| “Recommendations: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices”. | CLIA Waivers | 0910–0598 |
| “Medical Device Accessories—Describing Accessories and Classification Pathways”. | Accessories | 0910–0823 |
| 312 | Investigational New Drug Application | 0910–0014 |
| 601 | Biologics License Application | 0910–0338 |
| 807, subpart E | Premarket Notification | 0910–0120 |
| 812 | Investigational Device Exemption | 0910–0078 |
| 814, subparts A through E | Premarket Approval | 0910–0231 |
| 814, subpart H | Humanitarian Use Device; Humanitarian Device Exemption. | 0910–0332 |

Dated: May 1, 2019.
Lowell J. Schiller,
Principal Associate Commissioner for Policy.
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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: Biobehavioral and Behavioral Processes Integrated Review Group; Language and Communication Study Section.
Date: June 3, 2019.
Time: 8:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Canopy by Hilton, 940 Rose Avenue, Rockville, MD 20852.
Contact Person: Andrea B. Kelly, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, MSC 7770, Bethesda, MD 20892, (301) 455–1761, kellya2@csr.nih.gov.

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Adult Psychopathology and Disorders of Aging Study Section.
Date: June 3–4, 2019.
Time: 8:30 a.m. to 1:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Marines’ Memorial Club & Hotel, 609 Sutter Street, San Francisco, CA 94102.
Contact Person: Serena Chu, Ph.D., Scientific Review Officer, BBBP IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3178, MSC 7848, Bethesda, MD 20892, (301) 500–5829, sechu@csr.nih.gov.

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group; Bacterial Pathogenesis Study Section.
Date: June 3–4, 2019.
Time: 8:30 a.m. to 5:00 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: 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.
Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Integrative Physiology of Obesity and Diabetes Study Section.
Date: June 4–5, 2019.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Warwick Denver, 1776 Grant Street, Denver, CO 80203.
Contact Person: Raul Rojas, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6185, Bethesda, MD 20892, (301) 451–6319, rojasr@mail.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 2, 2019.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–09345 Filed 5–6–19; 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: Brain Disorders and Clinical Neuroscience Integrated Review Group; Pathophysiological Basis of Mental Disorders and Addictions Study Section.

Date: May 29, 2019.

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

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

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: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Biochemistry and Biophysics of Membranes Study Section.

Date: May 29–30, 2019.

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

Agenda: To review and evaluate grant applications.

Place: Hotel Spero, 405 Taylor Street, San Francisco, CA 94102.

Contact Person: Nuria E. Assa-Munt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4164, MSC 7806, Bethesda, MD 20892, (301) 451–1323, assamunu@csr.nih.gov.

Name of Committee: Oncology 1-Basic Translational Integrated Review Group; Cancer Etiology Study Section.

Date: May 31, 2019.

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

Agenda: To review and evaluate grant applications.

Place: Crowne Plaza Hotel-Seattle, 1113 6th Avenue, Seattle, WA 98101.

Contact Person: Ola Mae Zack Howard, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr., Room 4192, MSC 7806, Bethesda, MD 20892, 301–451–4467, howardz@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Training in Veterinary and Comparative Medicine.

Date: June 4, 2019.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Lystranne Alysia Maynard Smith, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–402–4809, lystranne.maynard-smith@nih.gov.

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Clinical and Integrative Diabetes and Obesity Study Section.

Date: June 5–6, 2019.

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

Agenda: To review and evaluate grant applications.

Place: Handlery Union Square Hotel, 351 Geary Street, San Francisco, CA 94102.

Contact Person: Hui Chen, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–435–1044, chenhui@csr.nih.gov.

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Neurobiology of Motivated Behavior Study Section.

Date: June 6–7, 2019.

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

Agenda: To review and evaluate grant applications.

Place: Marines' Memorial Club & Hotel, 609 Sutter Street, San Francisco, CA 94102.

Contact Person: Jasenka Borzan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892–7814, 301–435–1260, borzanj@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 2, 2019.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; 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 Alcohol Abuse and Alcoholism Special Emphasis Panel; RFA AA19–005 Medications Development for the Treatment of Alcohol Use Disorder.

Date: May 22, 2019.

Time: 2:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Room 2114, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Ranga Srinivas, Ph.D., Chief, Extramural Project Review Branch, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 6700 B Rockledge Drive, Room 2114, Bethesda, MD 20892, (301) 451–2067, srinivar@mail.nih.gov.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel; Member Conflict Review.

Date: June 7, 2019.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 6700 B Rockledge Drive, Room 2116, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Beata Buzas, Ph.D., Scientific Review Officer, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 6700 B Rockledge Drive, Room 2116, Bethesda, MD 20892, 301–443–0800, bbuzas@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research