

SUPPLEMENTARY INFORMATION:**I. Background**

In the **Federal Register** of August 2, 2019, FDA published a notice of availability with a 60-day comment period to request comments on the draft guidance for industry and FDA staff entitled “Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment.”

The Agency has received a request for a 30-day extension of the comment period. The request conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response.

FDA has considered the request and is extending the comment period for the notice of availability for 30 days, until October 31, 2019. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying guidance on these important issues.

II. Significance of Guidance

FDA is issuing this draft guidance consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on this topic. 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Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet.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/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>. This guidance document is also available at <https://www.regulations.gov>. Persons unable to download an electronic copy of “Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1500059 to identify the guidance you are requesting.

Dated: August 28, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–18929 Filed 8–30–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****National Institute of Mental Health; Amended Notice of Meeting**

Notice is hereby given of a change in the meeting of the Mental Health Services Research Committee, November 7, 2019, 8:00 a.m. to November 7, 2019 p.m., 05:00 p.m., The Dupont Hotel, 1500 New Hampshire Avenue NW, Washington, DC 20036 which was published in the **Federal Register** on August 201, 2019, 84 FR 43150.

This notice is to amend the date of the Mental Health Service Research Committee (SERV) meeting from November 7, 2019 to November 8, 2019. The meeting times and location remain the same. The meeting is closed to the public.

Dated: August 27, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–18901 Filed 8–30–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****Office of the Director, National Institutes of Health; Amended Notice of Meeting**

Notice is hereby given of a change in the meeting of the Council of Councils, September 6, 2019, 08:15 a.m. to 04:00 p.m., National Institutes of Health, The Natcher Building, Building 45, Room E, 45 Center Drive, Bethesda, MD 20892 which was published in the **Federal Register** on February 08, 2019, 84 FR 2890.

The meeting notice is amended to change the open and closed session meeting times as follows: The morning open session will change from 8:15 a.m.–12:00 p.m. to 8:00 a.m.–12:00 p.m.; the closed session will change from 12:00 p.m.–1:30 p.m. to 12:00 p.m.–12:45 p.m.; and the afternoon open session will change from 1:30 p.m.–4:00 p.m. to 12:45 p.m.–4:15 p.m. The meeting is partially closed to the public.

Dated: August 27, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–18902 Filed 8–30–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****National Center for Advancing Translational Sciences; Amended Notice of Meeting**

Notice is hereby given of a change in the meeting of the Cures Acceleration Network Review Board, September 19, 2019, 11:00 a.m. to 4:30 p.m., PORTER NEUROSCIENCE RESEARCH CENTER, Building 35A, 35 Convent Drive, Bethesda, MD 20892 which was published in the **Federal Register** on June 27, 2019, 84 FR 30744 Pg. 30744.

This meeting notice is amended to change the start time from 11:00 a.m. to 10:00 a.m. The meeting is open to the public.

Dated: August 27, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–18895 Filed 8–30–19; 8:45 am]

BILLING CODE 4140–01–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: Biological Chemistry and Macromolecular Biophysics Integrated

Review Group; Biochemistry and Biophysics of Membranes Study Section.

Date: September 25, 2019.

Time: 8:00 a.m. to 8:00 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: 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: Cell Biology Integrated Review Group; Cellular Signaling and Regulatory Systems Study Section.

Date: September 26-27, 2019.

Time: 8:00 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: David Balasundaram, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5189, MSC 7840, Bethesda, MD 20892, 301-435-1022, balasundaramd@csr.nih.gov.

Name of Committee: Digestive, Kidney and Urological Systems Integrated Review Group; Hepatobiliary Pathophysiology Study Section.

Date: September 30-October 1, 2019.

Time: 8:00 a.m. to 6:00 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: Jianxin Hu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2156, Bethesda, MD 20892, 301-827-4417, jianxinh@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: August 27, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019-18894 Filed 8-30-19; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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/or contract proposals 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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Biorepository of Human Induced Pluripotent Stem Cells.

Date: September 23, 2019.

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

Agenda: To review and evaluate contract proposals.

Place: Office of Scientific Review/DERA, National Heart, Lung and Blood Institute, 6701 Rockledge Drive, Bethesda, MD 20879 (Telephone Conference Call).

Contact Person: Melissa E. Nagelin, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7202, Bethesda, MD 20892, 301-435-0297, nagelinmh2@nhlbi.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: August 27, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019-18898 Filed 8-30-19; 8:45 am]

BILLING CODE 4140-01-P

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; NIMH Clinical Trials to Test the Effectiveness of Treatment, Preventive, and Services Interventions (R01).

Date: September 20, 2019.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center Building (NSC), 6001 Executive Boulevard, Rockville, MD 20852, (Virtual Meeting).

Contact Person: Marcy Ellen Burstein, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6143, MSC 9606, Bethesda, MD 20892-9606, 301-443-9699, bursteinme@mail.nih.gov.

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

Date: September 27, 2019.

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

Agenda: To review and evaluate grant applications.

Place: The Dupont Hotel, 1500 New Hampshire Avenue NW, Washington, DC 20036.

Contact Person: Nicholas Gaiano, Ph.D., Review Branch Chief, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center/Room 6150/MS 9606, 6001 Executive Boulevard, Bethesda, MD 20892-9606, 301-443-2742, nick.gaiano@nih.gov.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Psychosocial Treatment Development.

Date: September 27, 2019.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center Building (NSC), 6001 Executive Boulevard, Rockville, MD 20852, (Virtual Meeting).

Contact Person: David I. Sommers, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Blvd., Room 6154, MSC 9606, Bethesda, MD 20892, 301-443-7861, dsommers@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: August 27, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019-18900 Filed 8-30-19; 8:45 am]

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