

received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled "Nonbinding Feedback After Certain FDA Inspections of Device Establishments" to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

**FOR FURTHER INFORMATION CONTACT:** Patrick Weixel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1535, Silver Spring, MD 20993-0002, 301-796-5537 or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240-402-7911.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is issuing this guidance to comply with section 702 of FDARA (Pub. L. 115-52), which amended section 704 of the FD&C Act (21 U.S.C. 374). The purpose of this guidance is to explain how the owner, operator, or agent in charge of a device establishment may submit a request for nonbinding feedback to FDA regarding actions the firm has proposed to take to address certain kinds of inspectional observations that have been documented on an FDA Inspectional Observations Form (Form FDA 483) and issued to the firm upon completion of an inspection of the firm's establishment. This guidance identifies a standardized method for communicating and submitting requests for nonbinding feedback and describes how FDA evaluates and responds to such requests.

FDA considered comments received on the draft guidance that appeared in the **Federal Register** of February 19, 2019 (84 FR 4823). FDA revised the guidance as appropriate in response to the comments, including clarifying that if a request for nonbinding feedback does not meet the statutory criteria, FDA may choose to respond to these requests through an alternate mechanism (e.g., written correspondence, teleconference, face-to-face meeting) at its discretion.

**II. Significance of Guidance**

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Nonbinding Feedback After Certain FDA Inspections

of Device Establishments." 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.

**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/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>. Persons unable to download an electronic copy of "Nonbinding Feedback After Certain FDA Inspections of Device Establishments" may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number 17047 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. 3501-3521). The collections of information in the following FDA guidance have been approved by OMB as listed in the following table:

21 CFR guidance	Topic	OMB control No.
"Nonbinding Feedback After Certain FDA Inspections of Device Establishments" .....	Nonbinding Feedback .....	0910-0886

Dated: April 16, 2020.  
**Lowell J. Schiller,**  
*Principal Associate Commissioner for Policy.*  
[FR Doc. 2020-08461 Filed 4-21-20; 8:45 am]  
**BILLING CODE 4164-01-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:* Center for Scientific Review Special Emphasis Panel; NIH Research Enhancement Award (R15) in Oncological Sciences.  
*Date:* May 27, 2020.

*Time:* 11:00 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:* Svetlana Kotliarova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, Bethesda, MD 20892, 301-594-7945, [kotliars@mail.nih.gov](mailto:kotliars@mail.nih.gov).  
*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Bioengineering Sciences and Technologies: AREA/REAP Review.  
*Date:* May 28, 2020.  
*Time:* 9:00 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:* David Filpula, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6181, MSC 7892, Bethesda, MD 20892, 301-435-2902, [filpuladr@mail.nih.gov](mailto:filpuladr@mail.nih.gov).

*Name of Committee:* Cell Biology Integrated Review Group; Cellular Signaling and Regulatory Systems Study Section.

*Date:* May 28–29, 2020.

*Time:* 10:00 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:* 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](mailto:balasundaramd@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Early Phase Clinical Trials in Imaging and Image-Guided Interventions (R01 Clinical Trial Required).

*Date:* May 28, 2020.

*Time:* 12:30 p.m. to 3:30 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:* Ileana Hancu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5116, Bethesda, MD 20817, 3014023911, [ileana.hancu@nih.gov](mailto:ileana.hancu@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: April 16, 2020.

**Ronald J. Livingston, Jr.,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2020-08468 Filed 4-21-20; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Diabetes and Digestive and Kidney Diseases; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council, May 12, 2020, 11:30 a.m. to May 12, 2020, 3:45 p.m., National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard,

Bethesda, MD 20892 which was published in the **Federal Register** on January 29, 2020, 85 FR 5218.

This notice is being amended to change the meeting date, time and location from May 12–13, 2020, 8:30 a.m. to 3:45 p.m., Porter Neuroscience Research Center, Building 35A, Convent Drive, Bethesda, MD 20892 to May 12, 2020, 11:30 a.m. to 3:45 p.m., as a virtual meeting. Any member of the public may submit written comments no later than 15 days after the meeting.

Dated: April 16, 2020.

**Miguelina Perez,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2020-08471 Filed 4-21-20; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Neurological Disorders and Stroke; 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 of Neurological Disorders and Stroke Special Emphasis Panel R13 review.

*Date:* April 23, 2020.

*Time:* 1:00 p.m. to 2:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6101 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* Li Jia, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH, 6001 Executive Boulevard, Room 3208D, Rockville, MD 20852, 301 451-2854, [li.jia@nih.gov](mailto:li.jia@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. 93.853, Clinical Research

Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: April 16, 2020.

**Tyeshia M. Roberson,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2020-08549 Filed 4-21-20; 8:45 am]

**BILLING CODE 4140-01-P**

## 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; Advancing and Examining Diversity Training in Aging Research (R24/R25).

*Date:* May 14, 2020.

*Time:* 1:00 p.m. to 4:30 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:* Carmen Moten, Ph.D., MPH, Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, Gateway Bldg., 2C212, 7201 Wisconsin Avenue Bethesda, MD 20814, (301) 402-7703, [cmoten@mail.nih.gov](mailto:cmoten@mail.nih.gov).

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

Dated: April 16, 2020.

**Miguelina Perez,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2020-08469 Filed 4-21-20; 8:45 am]

**BILLING CODE 4140-01-P**