

assessment category: “Incomplete: Need additional imaging evaluation and/or prior mammograms for comparison.” As such, it is not clear how a facility would comply with both the Alternative Standard and the other applicable requirements in the amended regulations.

Moreover, as discussed in the MQSA small entity compliance guide, FDA has generally exercised enforcement discretion regarding the final assessment category wording where the variation in wording does not change the meaning of the assessment category (e.g., “benign finding” instead of “benign” or “suspicious abnormality” instead of “suspicious”), and FDA intends to continue such a practice. Thus, FDA has determined that Alternative Standard #11 is no longer needed, no longer appropriate, and may cause confusion, and so withdrawal of Alternative Standard #11 is justified by § 900.12.

FDA also has determined that withdrawal of Alternative Standard #12 is justified by § 900.12. Alternative Standard #12 allowed use of an additional assessment category “Post Procedure Mammograms for Marker Placement.” As of the effective date of the MQSA final rule (September 10, 2024), the nearly identical assessment statement “Post-Procedure Mammogram for Marker Placement” is included in the amended § 900.12(c)(1)(iv)(G). Because amended § 900.12(c)(1)(iv)(G) incorporates Alternative Standard #12, FDA has determined that the alternative is no longer needed, no longer appropriate, and may cause confusion, and so withdrawal of Alternative Standard #12 is justified by § 900.12.

Finally, FDA is amending Alternative Standard #8, which permitted interpreting physicians to provide a separate assessment of findings for each breast in the medical report instead of a single overall assessment of findings as set forth in § 900.12(c)(1)(iv). Specifically, the alternative permitted: “A separate assessment of findings for each breast, classified in one of the following categories,” instead of “A separate final assessment of findings for each breast, classified in one of the following categories.” This language is being amended to use the term “final assessment” to match the updated language in amended § 900.12(c)(1)(v). As a result of the amended § 900.12, amending Alternative Standard #8 is justified by § 900.12.

Dated: August 20, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–19058 Filed 8–23–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Vaccine Advisory Committee

AGENCY: Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) hereby gives notice that the National Vaccine Advisory Committee (NVAC) will hold an in-person meeting. The meeting will be open to the public and public comment will be heard during the meeting.

DATES: The meeting will be held September 12–13, 2024. The confirmed meeting times and agenda will be posted on the NVAC website at <http://www.hhs.gov/nvpo/nvac/meetings/index.html> as soon as they become available.

ADDRESSES: Instructions regarding attending this meeting will be posted online at <http://www.hhs.gov/nvpo/nvac/meetings/index.html> at least one week prior to the meeting. Pre-registration is required for those who wish to attend the meeting in person or participate in public comment. Please register at <http://www.hhs.gov/nvpo/nvac/meetings/index.html>.

FOR FURTHER INFORMATION CONTACT: Ann Aikin, Acting Designated Federal Officer, Office of Infectious Disease and HIV/AIDS Policy, U.S. Department of Health and Human Services, Tower Building, Room, 1101 Wootton Parkway, Rockville, MD 20852. Email: nvac@hhs.gov. Phone: 202–795–7697.

SUPPLEMENTARY INFORMATION: Pursuant to section 2101 of the Public Health Service Act (42 U.S.C. 300aa–1), the Secretary of HHS was mandated to establish the National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The NVAC was established to provide advice and make recommendations to the Director of the National Vaccine Program on matters related to the Program’s responsibilities.

The Assistant Secretary for Health serves as Director of the National Vaccine Program.

During this meeting, the NVAC will hear presentations about implementation of the universal hepatitis B vaccine recommendations of adults aged 19–59 years and adults aged 60 years and older with risk factors for hepatitis B infection, new approaches for tuberculosis vaccine innovation, and research to inform future HIV vaccine development. The NVAC will also host panels on vaccine equity, provider payment, and planning for the development of the next national vaccine strategy.

Please note that agenda items are subject to change, as priorities dictate. Information on the final meeting agenda will be posted prior to the meeting on the NVAC website: <http://www.hhs.gov/nvpo/nvac/index.html>.

Members of the public will have the opportunity to provide comment at the NVAC meeting during the public comment period designated on the agenda. Public comments made during the meeting will be limited to three minutes per person to ensure time is allotted for all those wishing to speak. Members of the public may also submit written comments. Written comments should not exceed three pages in length. Individuals planning to submit comments should email their written comments or their request to provide a comment during the meeting to nvac@hhs.gov at least five business days prior to the meeting.

Dated: August 19, 2024.

Ann Aikin,

Acting Designated Federal Official, Office of the Assistant Secretary for Health.

[FR Doc. 2024–19053 Filed 8–23–24; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 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: September 25, 2024.

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 Drive, Bethesda, MD 20892 (Virtual meeting).

Contact Person: Byung Min Chung, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 496-4056, justin.chung@nih.gov.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Pathophysiological Basis of Mental Disorders and Addictions Study Section.

Date: September 25–26, 2024.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814 (In-Person meeting).

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.

(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 21, 2024.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-19061 Filed 8-23-24; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, NIDCD.

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 as indicated below in accordance with the provisions set forth in section 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 Deafness And Other Communication Disorders, 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, NIDCD.

Date: October 21–22, 2024.

Open: October 21, 2024, 9 a.m. to 9:30 a.m.

Agenda: Reports from the Institute staff.

Place: Porter Neuroscience Research Center, Building 35A, Room 610, 35 Convent Drive, Bethesda, MD 20892, In Person.

Closed: October 21, 2024, 9:30 a.m. to 5 p.m.

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

Place: Porter Neuroscience Research Center, Building 35A, Room 610, 35 Convent Drive, Bethesda, MD 20892, In Person.

Closed: October 22, 2024, 9 a.m. to 5 p.m.

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

Place: Porter Neuroscience Research Center, Building 35A, Room 610, 35 Convent Drive, Bethesda, MD 20892, In Person.

Contact Person: Lisa L. Cunningham, Ph.D., Senior Investigator, National Institute of Deafness and other Communication Diseases, National Institutes of Health, 35A Convent Drive, Rockville, MD 20850, 301-443-2766, lisa.cunningham@nih.gov.

Information is also available on the Institute's/Center's home page: <https://www.nidcd.nih.gov/about/advisory-committees>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: August 21, 2024.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-19062 Filed 8-23-24; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meetings

Pursuant to section 1009 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 General Medical Sciences Special Emphasis Panel; Review of K99/R00 applications.

Date: October 15–16, 2024.

Time: 10 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute of General Medical Sciences, Natcher Building, 45 Center Drive, Bethesda, Maryland 20892 (Virtual Meeting).

Contact Person: Lee Warren Slice, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN12, Bethesda, Maryland 20892, 301-435-0807, slicelw@mail.nih.gov.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; Review of NIH IDEa Networks of Biomedical Research Excellence (INBRE) applications.

Date: October 29, 2024.

Time: 10 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute of General Medical Sciences, Natcher Building, 45 Center Drive, Bethesda, Maryland 20892 (Virtual Meeting).

Contact Person: Jason M. Chan, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, MSC 6200, Bethesda, Maryland 20892, 301-594-3663, jason.chan2@nih.gov.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; Review of NIH IDEa Networks of Biomedical Research Excellence (INBRE) applications.

Date: November 4, 2024.

Time: 10 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute of General Medical