I. Background

This public workshop is intended to meet a performance goal FDA agreed to under the FDA User Fee Reauthorization Act of 2022, in accordance with the PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027 letter (PDUFA VII letter), which is available at *https://www.fda.gov/media/151712/download.* Specifically, section I.4.e of the PDUFA VII letter outlines goals to enhance FDA's capacity to review complex innovative designs and convene a public workshop to discuss aspects of complex adaptive, Bayesian, and other novel clinical trial designs.

II. Topics for Discussion at the Public Workshop

The purpose of this public workshop is to facilitate discussion on the use of external data sources, Bayesian statistical methods, and simulations in complex innovative trial designs as well as trial implementation (*e.g.,* examples of defining and mitigating bias when using select trial design methods). Discussion topics will include considerations for external data sources, Bayesian statistical methods, simulations, and clinical trial implementation and will be based on FDA accumulated experience both within and outside of the Complex Innovative Trial Design Meeting Program (*https://www.fda.gov/drugs/development-resources/complex-innovative-trial-design-meeting-program*).

The workshop will consist of two sessions. The first session will focus on case studies that will illustrate various aspects of complex innovative designs and implementation. The second session will consist of panel discussions motivated by the case studies. There will be an opportunity for public comment.

Workshop updates, agenda, and background materials (if any) will be made available at *https://www.fda.gov/news-events/advancing-use-complex-innovative-designs-clinical-trials-pilot-practice-03052024* prior to the workshop.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit *https://ComplexInnovativeDesignsWorkshop.eventbrite.com* by February 27, 2024, 11:59 p.m. Eastern Time. Registration will be available starting January 16, 2024. Please provide complete contact information for each attendee, including name, affiliation, and email. If you are unable to attend the workshop in person, you can register to view a live webcast of the workshop. You will be asked to indicate in your registration if you plan to attend in person or via the webcast.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by February 27, 2024, 11:59 p.m. Eastern Time. Early registration is recommended because onsite seating is limited; therefore, FDA may limit the number of in-person participants from each organization. Registrants will receive a confirmation email after they register.

If you need special accommodations due to a disability, please contact Tuan Pham (see **FOR FURTHER INFORMATION CONTACT**) at least 14 days before the workshop.

Streaming Webcast of the Public Workshop: This public workshop will also be available on webcast. To register for the webcast of this public workshop, visit *https://ComplexInnovativeDesignsWorkshop.eventbrite.com* by February 27, 2024, 11:59 p.m. Eastern Time. Please provide complete contact information for each attendee, including name, affiliation, and email. A link to the webcast will be provided following registration. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A link to the transcript will also be available on the internet at *https://www.fda.gov/news-events/advancing-use-complex-innovative-designs-clinical-trials-pilot-practice-03052024.*

Dated: November 17, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–25854 Filed 11–21–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting of the National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel.

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 Biomedical Imaging and Bioengineering Special Emphasis Panel; Brain Initiative RFA (EB–22–003) Review SEP.

Date: February 2, 2024.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Democracy II, Suite 920, 6707 Democracy Blvd., Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Yoon-Young Jang, M.D., Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Blvd., Bethesda, MD 20892, (301) 451–3397, *yoon-young.jang@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health.)

Dated: November 16, 2023.

Patricia B. Hansberger,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–25847 Filed 11–21–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2023–0041]

Establishment of Homeland Security Academic Partnership Council Subcommittees

AGENCY: The Office of Partnership and Engagement (OPE), The Department of Homeland Security (DHS).