

## 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, [yoonyoung.jang@nih.gov](mailto:yoonyoung.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).

**ACTION:** Notice of new taskings for the Homeland Security Academic Partnership Council (HSAPC).

**SUMMARY:** On November 14, 2023, the Secretary of DHS, Alejandro N. Mayorkas, issued three memoranda tasking the Homeland Security Academic Partnership Council (HSAPC) to establish three subcommittees further outlined below. This notice is not a solicitation for membership.

**FOR FURTHER INFORMATION CONTACT:** Zarinah “Traci” Silas, Executive Director of the Office of Academic Engagement and Designated Federal Officer, Homeland Security Academic Partnership Council, Department of Homeland Security at *HSAPC@hq.dhs.gov* or 202–891–2876.

**SUPPLEMENTARY INFORMATION:** The HSAPC provides organizationally independent, strategic, timely, specific, and actionable recommendations to the Secretary on key issues at the intersection of education, academia, and the DHS mission.

The Secretary has requested that the HSAPC form new subcommittees to study and provide recommendations in three critical areas for the Department:

1. Supporting K–12 school and higher education communities in fostering safety and inclusivity in schools and on campuses and supporting campus law enforcement professionals and others charged with keeping academic communities safe.

2. Combatting online child sexual exploitation and abuse (CSEA), including development of guidelines and best practices for educators and academic institutions to understand and reduce the risk of CSEA; establish processes and protocols to detect and report online CSEA and; partner with law enforcement and support communities to support investigations and victims. Additionally, the review and recommendation should include an assessment of DHS educational, awareness, and school safety resources to prevent, detect, and report CSEA. This should include best practices for content delivery, how it is delivered, who is delivering, and audience prioritization.

3. Foreign malign influence in higher education, including guidelines and best practices for higher education institutions to reduce the risk of and counter foreign malign influence; consideration of a public-private partnership to enhance collaboration and information sharing on foreign malign influence; and an assessment of how the U.S. Government can enhance its internal operations and posture to effectively coordinate and address

foreign malign influence-related national security risks posed to higher education institutions.

*Schedule:* The subcommittees’ findings and recommendations will be submitted to the HSAPC for its deliberation and vote during a public meeting on December 13, 2023 and a public meeting in Spring 2024.

**Zarinah T. Silas,**

*Designated Federal Officer, Homeland Security Academic Partnership Council, U.S. Department of Homeland Security.*

[FR Doc. 2023–25781 Filed 11–21–23; 8:45 am]

**BILLING CODE 9112–FN–P**

## DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2023–0046]

### Establishment of Faith-Based Security Advisory Council Subcommittee

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

**ACTION:** Notice of a new tasking for the Faith-Based Security Advisory Council (FBSAC).

**SUMMARY:** On November 14, 2023, the Secretary of DHS, Alejandro N. Mayorkas, issued a memorandum tasking the Faith-Based Security Advisory Council (FBSAC) to establish a subcommittee further outlined below. This notice is not a solicitation for membership.

**FOR FURTHER INFORMATION CONTACT:** Sameer Hossain, Designated Federal Officer, Faith-Based Security Advisory Council of Department of Homeland Security, at *FBSAC@hq.dhs.gov* or 202–891–2876.

**SUPPLEMENTARY INFORMATION:** The FBSAC provides organizationally independent, strategic, timely, specific, and actionable advice to the Secretary through the OPE Assistant Secretary, who serves as the DHS Faith-Based Organizations Security Coordinator on security and preparedness matters related to places of worship, faith communities, and faith-based organizations. The Council consists of members who are: faith-based organization security officials; faith-based organization leaders; faith leaders; State and local public safety, law enforcement, and emergency management leaders; and a representative from the Department of Justice or Federal Bureau of Investigation.

The Secretary has requested that the FBSAC form a new subcommittee to study and provide recommendations in

the following critical area for the Department:

1. Combatting online child sexual exploitation and abuse (CSEA), providing recommendations on how DHS can partner with faith-based organizations to inform faith-based leaders and communities about how to recognize and respond appropriately to incidents of online CSEA; and an assessment to gauge the strengths, gaps, and opportunities in faith-based community awareness, engagement, and whole-of-community involvement. This assessment should include recommendations for faith-based organization collaboration to raise public awareness of online CSEA.

*Schedule:* The subcommittees findings and recommendations will be submitted to the FBSAC for its deliberation and vote during a public meeting within 150 days of November 14, 2023.

Dated: November 16, 2023.

**Sameer Hossain,**

*Designated Federal Officer, Faith-Based Security Advisory Council, U.S. Department of Homeland Security.*

[FR Doc. 2023–25774 Filed 11–21–23; 8:45 am]

**BILLING CODE 9112–FN–P**

## DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2023–0043]

### Establishment of Homeland Security Advisory Council Subcommittee

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

**ACTION:** Notice of new tasking for the Homeland Security Advisory Council (HSAC).

**SUMMARY:** On November 14, 2023, DHS Secretary Alejandro Mayorkas issued a memorandum tasking the HSAC with establishing a subcommittee to provide recommendations to the Department to combat online child sexual exploitation and abuse. Details of the tasking are included below. This notice is not a solicitation for membership.

**FOR FURTHER INFORMATION CONTACT:** Rebecca Sternhell, Principal Deputy Assistant Secretary & Acting Executive Director, Homeland Security Advisory Council, Office of Partnership and Engagement, U.S. Department of Homeland Security at *HSAC@hq.dhs.gov* or 202–891–2876.

**SUPPLEMENTARY INFORMATION:** The Homeland Security Advisory Council provides organizationally independent, strategic, timely, specific, and