

Use” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1755 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations and guidance. 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. 3501–3520). The collections of information in 21 CFR part 807 subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR 801 and 21 CFR 809.10 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; the collections of information in the guidance document “Recommendations: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices” have been approved under OMB control number 0910–0598; and the collections of information in the guidance document “Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff” have been approved under OMB control number 0910–0756.

Dated: October 4, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–24430 Filed 10–7–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health (NIMH); Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of an Interagency Autism Coordinating Committee (IACC or Committee) meeting.

The purpose of the IACC meeting is to discuss business, agency updates, and issues related to autism spectrum disorder (ASD) research and services activities. The Committee will discuss the 2016–2017 update of the IACC Strategic Plan. The meeting will be open

to the public and will be accessible by webcast and conference call.

Name of Committee: Interagency Autism Coordinating Committee (IACC).

Type of meeting: Open Meeting.

Date: October 26, 2016.

Time: 9:00 a.m. to 5:00 p.m.* Eastern Time

* Approximate end time.

Agenda: To discuss business, updates, and issues related to ASD research and services activities. The Committee will discuss updates of the IACC Strategic Plan.

Place: National Institutes of Health, 31 Center Drive, Building 31, C Wing, 6th Floor, Conference Room 6, Bethesda, MD 20892.

Webcast Live: <https://videocast.nih.gov>.

Conference Call Access: Dial: 888–469–2037, Access code: 3353029.

Cost: The meeting is free and open to the public.

Registration: A registration web link will be posted on the IACC Web site (www.iacc.hhs.gov) prior to the meeting. Pre-registration is recommended to expedite check-in. Seating in the meeting room is limited to room capacity and on a first come, first served basis. Onsite registration will also be available.

Deadlines: Notification of intent to present oral comments: Wednesday, October 12, 2016 by 5:00 p.m. ET.

Submission of written/electronic statement for oral comments: Tuesday, October 18, 2016 by 5:00 p.m. ET.

Submission of written comments: Tuesday, October 18, 2016 by 5:00 p.m. ET.

For IACC Public Comment guidelines please see: <https://iacc.hhs.gov/meetings/public-comments/guidelines/>.

Access: Medical Center Metro Station (Red Line).

Contact Person: Ms. Angelice Mitras, Office of Autism Research Coordination, National Institute of Mental Health, NIH, 6001 Executive Boulevard, Room 6182A, Bethesda, MD 20892–9669, Phone: 301–435–9269, Email: IACCPublicInquiries@mail.nih.gov.

Public Comments: Any member of the public interested in presenting oral comments to the Committee must notify the Contact Person listed on this notice by 5:00 p.m. ET on Wednesday, October 12, 2016, with their request to present oral comments at the meeting, and a written/electronic copy of the oral presentation/statement must be submitted by 5:00 p.m. ET on Tuesday, October 18,

A limited number of slots for oral comment are available, and in order to ensure that as many different individuals are able to present throughout the year as possible, any given individual only will be permitted to present oral comments once per calendar year (2016). Only one representative of an organization will be allowed to present oral comments in any given meeting; other representatives of the same group may provide written comments. If the oral comment session

is full, individuals who could not be accommodated are welcome to provide written comments instead. Comments to be read or presented in the meeting must not exceed 250 words or 3 minutes, but a longer version may be submitted in writing for the record. Commenters going beyond the 250 word or 3 minute time limit in the meeting may be asked to conclude immediately in order to allow other comments and presentations to proceed on schedule.

Any interested person may submit written public comments to the IACC prior to the meeting by emailing the comments to IACCPublicInquiries@mail.nih.gov or by submitting comments at the web link: <https://iacc.hhs.gov/meetings/public-comments/submit/index.jsp> by 5:00 p.m. ET on Tuesday, October 18, 2016. The comments should include the name, address, telephone number, and when applicable, the business or professional affiliation of the interested person. NIMH anticipates written public comments received by 5:00 p.m. ET on Tuesday, October 18, 2016 will be presented to the Committee prior to the meeting for the Committee's consideration. Any written comments received after the 5:00 p.m. ET, October 18, 2016 deadline through October 25, 2016 will be provided to the Committee either before or after the meeting, depending on the volume of comments received and the time required to process them in accordance with privacy regulations and other applicable Federal policies. All written public comments and oral public comment statements received by the deadlines for both oral and written public comments will be provided to the IACC for their consideration and will become part of the public record. Attachments of copyrighted publications are not permitted, but web links or citations for any copyrighted works cited may be provided.

In the 2009 IACC Strategic Plan, the IACC listed the “Spirit of Collaboration” as one of its core values, stating that, “We will treat others with respect, listen to diverse views with open minds, discuss submitted public comments, and foster discussions where participants can comfortably offer opposing opinions.” In keeping with this core value, the IACC and the NIMH Office of Autism Research Coordination (OARC) ask that members of the public who provide public comments or participate in meetings of the IACC also seek to treat others with respect and consideration in their communications and actions, even when discussing issues of genuine concern or disagreement.

Remote Access: The meeting will be open to the public through a conference call phone number and webcast live on the Internet. Members of the public who participate using the conference call phone number will be able to listen to the meeting but will not be heard. If you experience any technical problems with the webcast or conference call, please send an email to IACCPublicInquiries@mail.nih.gov.

Individuals wishing to participate in person or by using these electronic services and who need special assistance, such as captioning of the conference call or other reasonable accommodations, should submit a request to the Contact Person listed on this notice at least five days prior to the meeting.

Security: In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs and hotel and airport shuttles, will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit. Also as a part of security procedures, attendees should be prepared to present a photo ID at the meeting registration desk during the check-in process. Pre-registration is recommended. Seating will be limited to the room capacity and seats will be on a first come, first served basis, with expedited check-in for those who are pre-registered.

Meeting schedule subject to change.

Information about the IACC is available on the Web site: <http://www.iacc.hhs.gov>.

Dated: October 4, 2016.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016-24409 Filed 10-7-16; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, Office of Science Policy, Office of Biotechnology Activities; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the meeting of the National Science Advisory Board for Biosecurity (NSABB).

Name of Committee: National Science Advisory Board for Biosecurity.

Date: November 4, 2016.

Time: 12:00 p.m.–3:00 p.m. Eastern.

Agenda: Presentations and discussions regarding: (1) Stakeholder engagement on implementation of the U.S. Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (DURC); (2) status of the Blue Ribbon Panel review of the 2014 variola virus incident on the NIH Bethesda campus; and (3) other business of the Board.

Place: National Institutes of Health, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892 (Telephone Conference call only; No in-person meeting).

Call-in Information: U.S. Toll-Free Dial-In: 1 (888) 939-3921. Confirmation Number: 43519965.

Contact Person: Christopher Viggiani, Ph.D., Executive Director, NSABB, NIH Office of Science Policy, 6705 Rockledge Drive, Suite 750, Bethesda, Maryland 20892, (301) 496-9838, viggianic@od.nih.gov.

Under authority 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, the Department of Health and Human Services established the National Science Advisory Board for Biosecurity (NSABB) to provide advice regarding federal oversight of dual use research—defined as legitimate biological research that generates information and technologies that could be misused to pose a biological threat to public health and/or national security.

The toll-free teleconference line will be open to the public at 11:30 a.m. to allow time for operator-assisted check-in. Persons planning to participate in the teleconference may also pre-register online via the link provided below or by calling Palladian Partners, Inc. (Contact: Ida Donner at 301-273-2838). Pre-registration will close at 12:00 p.m. Eastern on November 1, 2016. After that time, attendees may register their information with the teleconference operator upon dialing into the meeting. Individuals who plan to participate and need special assistance should submit a request to the contact person listed on this notice by October 28.

Meeting materials: The meeting agenda and links to the online pre-registration will be available at: <http://osp.od.nih.gov/office-biotechnology-activities/biosecurity/nsabb/nsabb-meetings-and-conferences>. Please check this Web site for updates.

Public Comments: Time will be allotted on the agenda for the delivery of oral public comments. Members of the public interested in delivering prepared comments relevant to the mission of the NSABB should indicate so upon registration. Sign-up for delivering prepared oral comments will be limited to one per person or organization representative per open comment period. Individual comments will be time-limited to facilitate broad participation from multiple speakers.

In addition, interested persons may file written comments at any time with the Board via an email sent to nsabb@od.nih.gov or by regular mail sent to the Contact Person listed on this notice. Written statements should include the name, contact information, and when applicable, the professional affiliation of the interested person. Written comments received by 12:00 p.m. Eastern on November

1, 2016 will be relayed to the NSABB prior to the teleconference meeting. Any written comments received after this deadline will be provided to the Board either before or after the meeting, depending on the volume of comments received and the time required to process them in accordance with privacy regulations and other applicable federal policies.

Dated: October 4, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016-24412 Filed 10-7-16; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Board of Scientific Counselors, NIEHS.

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 OF ENVIRONMENTAL HEALTH SCIENCES, 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, NIEHS.

Date: November 13–15, 2016.

Closed: November 13, 2016, 7:00 p.m. to 10:00 p.m.

Agenda: To review and evaluate programmatic and personnel issues.

Place: Doubletree Guest Suites, 2515 Meridian Parkway, Research Triangle Park, NC 27713.

Open: November 14, 2016, 8:30 a.m. to 11:50 a.m.

Agenda: Scientific Presentations.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium,