

manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2015-D-3638 for “Minutes of Institutional Review Board Meetings: Guidance for Institutions and Institutional Review Boards; Draft Guidance; Availability” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the

electronic and written/paper comments received, go to <http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Janet Donnelly, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5167, Silver Spring, MD 20993-0002, 301-796-4187; or Irene Stith-Coleman, Office for Human Research Protections, 1101 Wootton Pkwy., Suite 200, Rockville, MD 20852, 240-453-6900.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 5, 2015 (80 FR 68545), OHRP and FDA published a notice of availability with a 60-day comment period to request comments on a draft guidance document entitled “Minutes of Institutional Review Board Meetings: Guidance for Institutions and Institutional Review Boards; Draft Guidance; Availability.” The Agencies are taking the initiative to extend the comment period for an additional 30 days because the timing of the due date for comments intersects with comment periods on other **Federal Register** documents requiring review by the same group of stakeholders. We believe that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying finalizing the guidance on these important issues.

Dated: December 9, 2015.

Leslie Kux,

Associate Commissioner for Policy, U.S. Food and Drug Administration.

Dated: December 4, 2015.

Karen B. DeSalvo,

Acting Assistant Secretary for Health, U.S. Department of Health and Human Services.

[FR Doc. 2015-31593 Filed 12-15-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of meetings of the National

Center for Advancing Translational Sciences.

The meetings 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 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: Cures Acceleration Network Review Board.

Date: January 14, 2016.

Time: 8:30 a.m. to 4:30 p.m.

Agenda: Report from the Institute Director.

Place: National Institutes of Health, Building 31, Conference Room 10, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Anna L. Ramsey-Ewing, Ph.D., Executive Secretary, National Center for Advancing Translational Sciences, 1 Democracy Plaza, Room 1072, Bethesda, MD 20892, 301-435-0809, anna.ramseyewing@nih.gov.

Name of Committee: National Center for Advancing Translational Sciences Advisory Council.

Date: January 14, 2016.

Open: 8:30 a.m. to 4:30 p.m.

Agenda: Report from the Institute Director and other staff.

Place: National Institutes of Health, Building 31, Conference Room 10, 31 Center Drive, Bethesda, MD 20892.

Closed: 3:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, Conference Room 10, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Anna L. Ramsey-Ewing, Ph.D., Executive Secretary, National Center for Advancing Translational Sciences, 1 Democracy Plaza, Room 1072, Bethesda, MD 20892, 301-435-0809, anna.ramseyewing@nih.gov.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, 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.

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology,

Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: December 10, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–31547 Filed 12–15–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 Allergy and Infectious Diseases Special Emphasis Panel; NIAID Peer Review Meeting.
Date: January 5, 2016.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 3F30A, 5601 Fishers Lane, Rockville, MD 20892, (Telephone Conference Call).

Contact Person: Ellen S. Buczek, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room # 3F30A, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–9823, (240) 669–5028, ebuczek1@niaid.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. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 10, 2015.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–31549 Filed 12–15–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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 next 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: January 12, 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 the next update 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: <http://videocast.nih.gov/>.

Conference Call Access: Dial: 800–988–9744, Access code: 3700810.

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

Registration: 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. To register, please visit: www.iacc.hhs.gov.

Deadlines: Notification of intent to present oral comments: Monday, January 4, 2016 by 5:00 p.m. ET. Submission of written/electronic statement for oral comments: Tuesday, January 5, 2016 by 5:00 p.m. ET. Submission of written comments: Tuesday, January 5, 2016 by 5:00 p.m. ET. For IACC Public Comment guidelines please see: <http://iacc.hhs.gov/public-comment/index.shtml>.

Access: Medical Center Metro Station (Red Line).

Contact Person: Ms. Lina Perez, Office of Autism Research Coordination, National Institute of Mental Health, NIH, 6001 Executive Boulevard, Room 6182A, Bethesda, MD 20892–9669,

Phone: 301–443–6040, 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 Monday, January 4, 2016, with their request to present oral comments at the meeting. Interested individuals and representatives of organizations must submit a written/electronic copy of the oral presentation/statement including a brief description of the organization represented by 5:00 p.m. ET on Tuesday, January 5, 2016. Statements submitted will become a part of the public record. Only one representative of an organization will be allowed to present oral comments and presentations will be limited to three to five minutes per speaker, depending on the number of speakers to be accommodated within the allotted time. Speakers will be assigned a time to speak in the order of the date and time when their request to speak is received, along with the required submission of the written/electronic statement by the specified deadline.

In addition, any interested person may submit written public comments to the IACC prior to the meeting by sending the comments to the Contact Person listed on this notice by 5:00 p.m. ET on Tuesday, January 5, 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, Tuesday, January 5, 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. EST, January 5, 2016 deadline through January 11, 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.

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