

that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the 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All submissions received must include the Docket No. FDA-2015-D-4361 for “Gifts to FDA: Evaluation and Acceptance: Draft Guidance for the Public and FDA Staff; Availability”. Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” 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>.

Submit written requests for single copies of the draft guidance to the Office of Policy, Office of the Commissioner, Food and Drug Administration, Bldg. 32, Rm. 4235, 10903 New Hampshire Ave., Silver Spring, MD, 20993. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

#### **FOR FURTHER INFORMATION CONTACT:**

Aaron Zimmerman, Office of Policy, Office of the Commissioner, Food and Drug Administration, Bldg. 32, Rm. 4235, 10903 New Hampshire Ave., Silver Spring, MD, 20993. 301-796-0339, [aaron.zimmerman@fda.hhs.gov](mailto:aaron.zimmerman@fda.hhs.gov). Alternate contact: Office of Policy, 301-796-4830.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft guidance for the public and FDA staff entitled “Gifts to FDA: Evaluation and Acceptance.” The Secretary of HHS has the authority to accept conditional or unconditional gifts on behalf of the United States. The Secretary has delegated this gift authority to the Commissioner of Food and Drugs. This guidance provides the process and principles we will use in implementing this authority.

FDA will consider gifts from all sources on a case-by-case basis using a balancing test, described in the draft guidance. While any person may offer a gift, there are five reasons we should reject a gift without additional evaluation. We should not accept a gift if: (1) The donor imposes conditions that are illegal, are contrary to public policy, are unreasonable to administer, are contrary to FDA’s current policies and procedures, or are contrary to generally accepted public standards; (2) the donor requires us to provide the donor with some privilege, concession, or other present or future benefit in return for the gift; (3) a debarred entity offers the gift; (4) a different authority or financial mechanism applies; or (5) the total costs associated with acceptance are expected to exceed the cost of purchasing a similar item and the cost of normal care and maintenance.

This draft guidance is being issued consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent our current thinking on this matter. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

#### **II. Electronic Access**

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/RegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: June 23, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-15385 Filed 6-28-16; 8:45 am]

**BILLING CODE 4164-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **Center For Scientific Review; Notice of Closed Meetings**

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 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; Member Conflict: Transport Synapses and Cytoskeletal Dynamics.

*Date:* July 13, 2016.

*Time:* 1:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Joanne T Fujii, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4184, MSC 7850, Bethesda, MD 20892, (301) 435-1178, [fujii@csr.nih.gov](mailto:fujii@csr.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.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; US-China Program for Collaborative Biomedical Research.

*Date:* July 21, 2016.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Suzan Nadi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217B, MSC 7846, Bethesda, MD 20892, 301-435-1259, [nadis@csr.nih.gov](mailto:nadis@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Topics in Microbial Pathogenesis and Therapeutic Research.

*Date:* July 21, 2016.

*Time:* 1:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

*Contact Person:* Gagan Pandya, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, RM 3200, MSC 7808, Bethesda, MD 20892, 301-435-1167, [pandya@mail.nih.gov](mailto:pandya@mail.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; AREA: Oncological Sciences Grant Applications.

*Date:* July 22, 2016.

*Time:* 10:00 a.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

*Contact Person:* Svetlana Kotliarova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, Bethesda, MD 20892, 301-594-7945, [kotliars@mail.nih.gov](mailto:kotliars@mail.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; RM15-013: MoTrPAC Preclinical Animal Study Sites (U01).

*Date:* July 22, 2016.

*Time:* 11:30 a.m. to 4:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

*Contact Person:* Richard Ingraham, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4116, MSC 7814, Bethesda, MD 20892, 301-496-8551, [ingrahamrh@mail.nih.gov](mailto:ingrahamrh@mail.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR-13-327: Innovative Molecular Analysis Technology Development for Cancer Research and Clinical Care.

*Date:* July 26, 2016.

*Time:* 11:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

*Contact Person:* Zhang-Zhi Hu, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6186, MSC 7804, Bethesda, MD 20892, (301) 594-2414, [huzhuang@csr.nih.gov](mailto:huzhuang@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: June 23, 2016.

**Carolyn Baum,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2016-15320 Filed 6-28-16; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institutes of Health, Precision Medicine Initiative® (PMI) Cohort Program; Notice of Meeting

**ACTION:** Notice of Meeting.

**SUMMARY:** Pursuant to the NIH Reform Act of 2006 (42 U.S.C. 281(d)(4)), notice is hereby given that the National Institutes of Health (NIH), Precision Medicine Initiative® (PMI) Cohort Program will host two (2) teleconferences to enable public discussion of its proposal to align the authority and responsibility for the execution of PMI Cohort Program by establishing this program within the NIH Office of the Director, and reporting to the NIH Director.

**DATES:** Two (2) teleconferences will be held on the following days:

(1) Tuesday, July 5, 2016, 3:00-3:45 p.m. ET

(2) Wednesday, July 13, 2016, 2:00-2:45 p.m. ET

Any interested person may submit their written comments via the form provided at <http://grants.nih.gov/grants/rfi/rfi.cfm?ID=59> by Wednesday, July 13, 2016. The message should include the individual's name and organization/professional affiliation, when applicable.

**ADDRESSES:** Members of the public wishing to attend the July 5 teleconference are asked to Web RSVP by 12:00 p.m., Tuesday, July 5, 2016 at [https://www.mymeetings.com/emeet/rsvp/index.jsp?customHeader=mymeetings&Conference\\_ID=8723518&passcode=2802855](https://www.mymeetings.com/emeet/rsvp/index.jsp?customHeader=mymeetings&Conference_ID=8723518&passcode=2802855); Conference number: 8723518; Passcode: 2802855,

Teleconference number: 877-922-4780, Participant passcode: 2802855.

Members of the public wishing to attend the July 13 teleconference are asked to Web RSVP by 11:00 a.m. ET, Wednesday, July 13, 2016, at [https://www.mymeetings.com/emeet/rsvp/index.jsp?customHeader=mymeetings&Conference\\_ID=8723531&passcode=4607754](https://www.mymeetings.com/emeet/rsvp/index.jsp?customHeader=mymeetings&Conference_ID=8723531&passcode=4607754); Conference number: 8723531; Passcode: 4607754, Teleconference number 888-810-5910, Participant passcode: 4607754.

**FOR FURTHER INFORMATION CONTACT:** The PMI Cohort Program at [PrecisionMedicine@nih.gov](mailto:PrecisionMedicine@nih.gov) with subject line "PMI Cohort Program Office Organization."

**SUPPLEMENTARY INFORMATION:** The PMI Working Group of the Advisory Committee to the NIH Director (ACD) recommended that the authority and responsibility for the implementation and execution of the PMI Cohort Program be established in the NIH Office of the Director and that the PMI Cohort Program Director report to the NIH Director. On September 17, 2015, the NIH ACD supported the PMI Working Group Report with this recommendation and this report was subsequently accepted by the NIH Director. For additional information about the PMI Cohort Program, please visit the Web site at <https://www.nih.gov/precision-medicine-initiative-cohort-program>.

Dated: June 23, 2016.

**Lawrence A. Tabak,**

*Deputy Director, National Institutes of Health.*

[FR Doc. 2016-15395 Filed 6-28-16; 8:45 am]

**BILLING CODE 4140-01-P**

## ADVISORY COUNCIL ON HISTORIC PRESERVATION

### Notice of Advisory Council on Historic Preservation Quarterly Business Meeting

**AGENCY:** Advisory Council on Historic Preservation.

**ACTION:** Notice of Advisory Council on Historic Preservation Quarterly Business Meeting.

**SUMMARY:** Notice is hereby given that the Advisory Council on Historic Preservation (ACHP) will hold its next quarterly meeting on Thursday, July 14, 2016. The meeting will be held in Room SR325 at the Russell Senate Office Building at Constitution and Delaware Avenues NE., Washington, DC, starting at 10:30 a.m. DST.