

MSC 7892, Bethesda, MD 20892, 301-379-9351, [allen.richon@nih.hhs.gov](mailto:allen.richon@nih.hhs.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR14-247: Pharmacogenetics, Pharmacoeugenetics and Personalized Medicine in Children.

*Date:* April 16, 2015.

*Time:* 10:00 a.m. to 12:00 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:* Elaine Sierra-Rivera, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6184, MSC 7804, Bethesda, MD 20892, 301-435-1779, [riverase@csr.nih.gov](mailto:riverase@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Ocular Diseases Pathophysiology and Therapeutic Approaches.

*Date:* April 16, 2015.

*Time:* 10:00 a.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Alessandra C Rovescalli, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Rm. 5205 MSC7846, Bethesda, MD 20892, (301) 435-1021, [rovesca@mail.nih.gov](mailto:rovesca@mail.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR-13-190: Detection of Pathogen Induced Cancer.

*Date:* April 17, 2015.

*Time:* 12:00 p.m. to 6:00 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, [pandyaga@mai.nih.gov](mailto:pandyaga@mai.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: March 13, 2015.

**Anna Snouffer,**

*Deputy Director, Office of Federal Advisory Committee Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Heart, Lung, and Blood Institute; 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, contract proposal, 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 or contract proposal, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Heart, Lung, and Blood Institute Special Emphasis Panel; Clinical Research in HIV/HLB Diseases.

*Date:* April 13, 2015.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* The Dupont Circle Hotel, 1500 New Hampshire Avenue NW., Washington, DC 20036.

*Contact Person:* Stephanie L Constant, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7189, Bethesda, MD 20892, 301-443-8784 [constantsl@nhlbi.nih.gov](mailto:constantsl@nhlbi.nih.gov).

*Name of Committee:* National Heart, Lung, and Blood Institute Special Emphasis Panel; Improving Red Blood Cells for Transfusion.

*Date:* April 13, 2015.

*Time:* 12:00 p.m. to 2:00 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Room 7198, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Kristin Goltry, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7198, Bethesda, MD 20892, 301-435-0297, [goltrykl@mail.nih.gov](mailto:goltrykl@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: March 13, 2015.

**Michelle Trout,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-N-0620]

#### An Interactive Discussion on the Clinical Considerations of Risk in the Postmarket Environment; Public Workshop; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing a public workshop entitled "Clinical Considerations of Risk in the Postmarket Environment." The purpose of this workshop is to provide a forum for an interactive discussion on assessing changes in medical device risk as quality and safety situations arise in the postmarket setting when a patient, operator, or member of the public uses the device. FDA is interested in obtaining input from stakeholders about assessing risk postmarket when new hazards develop in the postmarket setting that were not present or not known at the time of clearance or approval or hazards were anticipated, but harm occurs at an unexpected rate or in unexpected populations or use environments. Comments and suggestions generated through this workshop will facilitate the assessment of risk in postmarket quality and safety situations.

*Date and Time:* The public workshop will be held on April 21, 2015, from 8:30 a.m. to 5 p.m.

*Location:* The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to: <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

*Contact Person:* Jean M. Cooper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5540, Silver Spring, MD 20993, 301-796-6141, email: [Jean.Cooper@fda.hhs.gov](mailto:Jean.Cooper@fda.hhs.gov).

*Registration:* Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register