

**SUPPLEMENTARY INFORMATION:** Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services, through the Assistant Secretary for Health, on issues and topics pertaining to or associated with the protection of human research subjects.

The Subpart A Subcommittee (SAS) was established by SACHRP in October 2006 and is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment.

The Subcommittee on Harmonization (SOH) was established by SACHRP at its July 2009 meeting and charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination. The SACHRP meeting will open to the public at 8:30 a.m., on Wednesday, March 15, 2017, followed by opening remarks from Dr. Jerry Menikoff, Director of OHRP and Executive Secretary of SACHRP, and Dr. Stephen Rosenfeld, SACHRP Chair. Dr. Menikoff will then lead a discussion focusing on selected sections of the new Common Rule, which was published January 19, 2017, with an effective date of January 19, 2018 (see <https://www.gpo.gov/fdsys/pkg/FR-2017-01-19/html/2017-01058.htm>).

The SOH will present their recommendations for considerations of the new Common Rule's compliance dates and transition provisions, as well as for the interpretation and implementation of the new broad consent provision. The SAS will discuss their report on the interpretation of the new exemption involving benign behavioral interventions.

The Wednesday meeting will adjourn at approximately 5:00 p.m.

The Thursday, March 16, meeting will begin at 8:30 a.m. with

recommendations from the SOH on the FDA Draft Guidance "Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices," issued July 27, 2016. SOH will also present recommendations on the return of incidental findings to research subjects. The SAS will present recommendations surrounding the new Common Rule's expedited review requirements.

The meeting will adjourn at 4:30 p.m. March 16, 2017. Time for public comment sessions will be allotted both

days. Note that public comment must be relevant to issues being addressed by the SACHRP.

Public attendance at the meeting is limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify one of the designated SACHRP points of contact at the address/phone number listed above at least one week prior to the meeting. On-site registration is required for participation in the live public comment session. Individuals who would like to submit written statements as public comment should email or fax their comments to SACHRP at [SACHRP@hhs.gov](mailto:SACHRP@hhs.gov) at least five business days prior to the meeting.

Dated: February 23, 2017.

**Julia G. Gorey,**

*Executive Director, Secretary's Advisory Committee on Human Research Protections.*

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## 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; Clinical Trial Implementation Cooperative Agreement (U01).

*Date:* March 22, 2017.

*Time:* 2:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate cooperative agreement applications.

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

*Contact Person:* Zhuqing (Charlie) Li, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room # 3G41B, National Institutes

of Health/NIAID, 5601 Fishers Lane, MSC9823 Bethesda, MD 20892-9823, (240) 669-5068, [zhuqing.li@nih.gov](mailto:zhuqing.li@nih.gov).

(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: February 23, 2017.

**Natasha M. Copeland,**

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

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## 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; Molecular and Imaging Dynamics in Psychiatry.

*Date:* March 14, 2017.

*Time:* 2:00 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, (Telephone Conference Call).

*Contact Person:* Julius Cinque, MS., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5186, MSC 7846, Bethesda, MD 20892, (301) 435-1252, [cinquej@csr.nih.gov](mailto:cinquej@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; Member Conflict: Learning and Memory.

*Date:* March 20, 2017.

*Time:* 9:00 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, (Virtual Meeting).