DATES: The meeting will be held on Tuesday, July 21, 2015, from 8:30 a.m. until 5:00 p.m. and Wednesday, July 22, 2015, from 8:30 a.m. until 4:30 p.m.

ADDRESSES: Fishers Lane Conference Center, Terrace Level, 5635 Fishers Lane, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Jerry Menikoff, M.D., J.D., Director, Office for Human Research Protections (OHRP), or Julia Gorey, J.D., Executive Director, SACHRP; U.S. Department of Health and Human Services, 1101 Wooton Parkway, Suite 200, Rockville, Maryland 20852; 240–453–8141; fax: 240–453–6909; email address: SACHRP@hhs.gov.

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 meeting will open to the public at 8:30 a.m. on Tuesday, July 21, 2015. Following opening remarks from Dr. Jerry Menikoff, Executive Secretary of SACHRP and OHRP Director, and Dr. Jeffrey Botkin, SACHRP Chair, the Subpart A Subcommittee (SAS) will present their report on informed consent for minimal risk research. 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. In the afternoon of July 21, the Subcommittee on Harmonization (SOH) will present their report, including recommendations pertaining to waiver of consent in cluster randomized trials, the application of the HHS regulations to data registries, and the topic of “benchmarking” in human subjects research. SOH was established by SACHRP at its July 2009 meeting and is 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. On July 22, the SOH will discuss the return of individual research results with special considerations regarding HIPAA and CLIA.

In the afternoon special guest speaker Dr. Robert Klitzman will present on his recent work, The Ethics Police. The meeting will adjourn at 4:30 p.m. on July 22, 2015. Time for public comment sessions will be allotted both days. 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. Pre-registration is required for participation in the on-site public comment session; individuals may preregister the day of the meeting. Individuals who would like to submit written statements should email or fax their comments to SACHRP at SACHRP@hhs.gov at least five business days prior to the meeting.

Dated: June 17, 2015.

Jerry Menikoff,
Executive Secretary, Secretary’s Advisory Committee on Human Research Protections, Director, Office for Human Research Protections.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

National Institute on Drug Abuse; 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 materials, 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 on Drug Abuse Special Emphasis Panel, Developing Technologies and Tools to Monitor HIV Brain Reservoirs and How They May Be Altered by Exposure to Substances of Abuse (R21/R33).

Date: July 16, 2015.

Time: 1:30 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Susan O. McGuire, Ph.D., Scientific Review Officer, Office of Extramural Affairs, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Blvd., Room 4245, Rockville, MD 20852, 301–435–1426, mcguireso@mail.nih.gov.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, NIAID Clinical Trial Planning Grants (R34) and NIAID Clinical Trial Implementation Cooperative Agreement (U01).

Date: July 17, 2015.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Trial Planning Grants (R34) and NIAID Clinical Trial Implementation Cooperative Agreement (U01).

Date: July 22, 2015.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Trial Planning Grants (R34) and NIAID Clinical Trial Implementation Cooperative Agreement (U01).

Date: July 17, 2015.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

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