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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Secretary's Advisory Committee on Human Research Protections

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

ACTION: Notice.

SUMMARY: Pursuant to Section 10(a) of the Federal Advisory Committee Act, 5 U.S.C., notice is hereby given that the Secretary's Advisory Committee on Human Research Protections (SACHRP) will hold a meeting that will be open to the public. Information about SACHRP and the full meeting agenda will be posted on the SACHRP website at: http://www.dhhs.gov/ohrp/sachrp/mtgings/index.html.

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 FUTHER 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 Wootton Parkway, Suite 200, Rockville, Maryland 20852; 240-453-8141; fax: 240-453-6909; e-mail 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 pre-register 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

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Jerry Menikoff, M.D., J.D.

Executive Secretary, Secretary's Advisory Committee on

Human Research Protections

Director, Office for Human Research Protections

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