DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

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

ACTION: Notice.

SUMMARY: Pursuant to Section 10(a) of the Federal Advisory Committee Act, U.S.C. Appendix 2, 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 Monday, July 21, 2014, from 8:30 a.m. until 5:00 p.m. and Tuesday, July 22, 2014, from 8:30 a.m. until 4:00 p.m.

ADDRESSES: NOTE NEW LOCATION! Fisher's Lane Conference Center, Terrace Level, 5635 Fisher Lane, Rockville, MD 20852.

FOR FUTHER INFORMATION CONTACT: Jerry Menikoff, M.D., J.D., Executive Secretary, SACHRP and 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: Julia.Gorey@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 Monday, July 21. Following opening remarks from Dr. Jerry Menikoff, Executive Secretary, SACHRP and OHRP Director, and Dr. Jeffrey Botkin, SACHRP Chair, the Subpart A Subcommittee (SAS) will give their initial report on the new SAS initiative examining informed consent. A panel of speakers will discuss comprehension and tools for validating comprehension in informed consent. SAS 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; this subcommittee was established by SACHRP in October 2006.

On the afternoon of July 21, the Subcommittee on Harmonization (SOH) will present their initial work on the topic of the intersection of the HHS and FDA regulations and "big data"; this presentation will be highlighted by a special expert panel discussion. The morning of July 22, the SOH will present their work to date on the topic of return of general results, also assisted by a special expert panel discussion. 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.

A public comment session will be offered on 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 the SACHRP at the address/phone 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 or by contacting the Executive Director, SACHRP, by COB July 17. Individuals who would like to submit written statements should email or fax their comments to SACHRP at least five business days prior to the meeting.

DATED: June 27, 2014.

Julia Gorey, J.D.

Executive Director, Secretary's Advisory Committee on

Human Research Protections.

Billing Code: 4150-36-P

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