Billing Code: 4150-36-P

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, 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-committee/meetings/index.html.

DATES: The meeting will be held on Tuesday, October 25, 2016, from 8:30 a.m. until 5:00 p.m. and Wednesday, October 26, 2016, 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: Julia Gorey, J.D., Executive Director, SACHRP or Jerry Menikoff, M.D., J.D., Director, Office for Human Research Protections (OHRP); U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; telephone: 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, October 25, followed by 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will then present their report, including recommendations regarding single IRB review and the draft joint OHRP-FDA draft guidance, "Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs." This will be followed by the Subcommittee on Harmonization's (SOH) report, including recommendations involving clustered randomized trials, benchmarking, and the "NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules," Appendix M.

SAS was established by SACHRP in October 2006. The subcommittee 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.

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. On Wednesday, October 26, 2016, SACHRP will discuss 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.

The meeting will adjourn at 4:30 p.m. October 26, 2016. 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. Registration is required for participation in the on-site public comment session; individuals may register on the day of the meeting. Individuals who would like to submit written statements as public comment should email or fax their comments to SACHRP at SACHRP@hhs.gov at least five business days prior to the meeting. Note that public comment must be relevant to agenda topics.

Dated: October 3, 2016.

_____

Julia Gorey, J.D.

Executive Director, Secretary's Advisory Committee on

Human Research Protections

[FR Doc. 2016-24251 Filed: 10/5/2016 8:45 am; Publication Date: 10/6/2016]