



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 17, 2017, from 8:30 a.m. until 5:00 p.m., and Wednesday, October 18, 2017, from 8:30 a.m. until 4:00 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; 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 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 Tuesday, October 17, 2017, followed by opening remarks from Dr. Jerry Menikoff, Director, Office for Human Research Protections (OHRP) and Dr. Stephen Rosenfeld, SACHRP Chair.

The SAS will present their recommendations regarding the revised Common Rule's (<https://www.gpo.gov/fdsys/pkg/FR-2017-01-19/html/2017-01058.htm>) expedited review requirements, followed by a discussion of the meaning of "context" when considering requirement for single IRB review. This will be followed by a discussion of SOH

recommendations on the revised Common Rule's HIPAA exemption, section 104(d) (4) (iii), and a panel discussion with a representative of the Office for Civil Rights. The day will conclude with a presentation by OHRP staff on a new public outreach website, *About Participation*. The Tuesday meeting will adjourn at approximately 5:00 p.m.

The Wednesday, October 18, meeting will begin at 8:30 a.m. with a presentation and discussion led by FDA staff on a recent FDA experience with IRB review under 21 CFR 50.54, and the lessons learned. Time is allotted for review of the previous day's recommendations. The meeting will adjourn at approximately 4:00 p.m., October 18, 2017.

Time for public comment sessions will be allotted both days. On-site registration is required for participation in the live public comment session. Note that public comment must be relevant to issues currently being addressed by the SACHRP. Individuals submitting 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.

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.

Dated: September 21, 2017.

Julia G. Gorey, J.D.

Executive Director

Secretary's Advisory Committee on Human Research Protections

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