



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, the full meeting agenda, and instructions for linking to public access 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, March 23rd, 2021, from 11:00 a.m. until 4:30 p.m., and Wednesday, March 24, 2021, from 11:00 a.m. until 4:30 p.m. (times are tentative and subject to change). The confirmed times and agenda will be posted on the SACHRP web site when this information becomes available.

ADDRESSES: This meeting will be held via webcast. Members of the public may also attend the meeting via webcast. Instructions for attending via webcast will be posted one week prior to the meeting at <https://www.hhs.gov/ohrp/sachrp-committee/meetings/index.html>.

FOR FUTURE INFORMATION CONTACT: Julia Gorey, J.D., Executive Director, SACHRP; U.S. Department of Health and Human Services, 1101 Wootton Parkway,

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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 or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification or coordination.

The SACHRP meeting will open to the public at 11:00 a.m., on Tuesday, March 23, 2021, followed by opening remarks from Dr. Jerry Menikoff, Director of OHRP and Dr. Douglas Diekema, SACHRP Chair. The meeting will begin with presentation of recommendations on Justice as an Ethical Concept in 45 CFR 46, followed by an expert panel discussion of draft recommendations on Mandatory Exploratory Biopsies in Research. The day will conclude with discussion of a new SACHRP topic, IRB Authority to Restrict Use of Data in Research. March 24th will include presentation of Interactions between Sponsors, Clinical Trial Sites, and Research Subjects, and lastly, Consideration

of Risks to Bystanders in Research. Other topics may be added; for the full and updated meeting agenda, see <http://www.dhhs.gov/ohrp/sachrp-committee/meetings/index.html>.

The public will have an opportunity to send comments to SACHRP during the meeting's public comment session or to submit written public comments in advance. Persons who wish to provide public comments should review instructions at <https://www.hhs.gov/ohrp/sachrp-committee/meetings/index.html> and respond by midnight Wednesday, March 18th, 2021, ET. Individuals submitting written statements as public comment should submit their comments to SACHRP at SACHRP@hhs.gov. Comments are limited to three minutes each.

Time will be allotted for public comment on both days. Note that public comment must be relevant to topics currently being addressed by SACHRP.

Dated: February 22, 2021.

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Office for Human Research Protections.

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