



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

<https://www.hhs.gov/ohrp/sachrp-committee/meetings/index.html>

DATES: The meeting will be held on Wednesday, July 21, from 11:00 a.m. until 4:30 p.m., and Thursday, July 22, 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 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 11:00 a.m., on Wednesday, July 21, 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 on the impact of artificial intelligence algorithms on Institutional Review Board considerations for human subjects protections. The day will conclude with discussion of a new SACHRP charge addressing the current system of engagement and the interpretation of HHS support in 45 CFR 46. The second day, July 22, will include discussion of consideration of risks to third parties in research, and continue discussion of topics from the first day's agenda. Other topics may be added; for the full and updated

meeting agenda, see <https://www.dhhs.gov/ohrp/sachrp-committee/meetings/index.html>.

The meeting will adjourn by 4:30 p.m. July 22.

The public will have an opportunity to send comment to SACHRP during the meeting's public comment session or to submit written public comment in advance. Persons who wish to provide public comment should review instructions at

<https://www.hhs.gov/ohrp/sachrp-committee/meetings/index.html>

and respond by midnight July 16th, 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: June 14, 2021.

Julia G. Gorey,

Executive Director,

Secretary's Advisory Committee on Human Research Protections,

Office for Human Research Protections.

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