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 Wednesday, March 11, 2020, from 11 a.m. until 4 p.m., and Thursday, March 12, 2020, from 11 a.m. until 4 p.m. (times are tentative and subject to change). The confirmed times and agenda will be posted at https://cms-drupal-hhs-ohrp-prod.cloud.hhs.gov/ohrp/sachrp-committee/meetings/index.html 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 about one week prior to the meeting at https://cms-drupal-hhs-ohrp-prod.cloud.hhs.gov/ohrp/sachrp-committee/meetings/index.html.
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 11 a.m., on Wednesday, March 11, 2020, followed by opening remarks from Dr. Jerry Menikoff, Director of OHRP and Dr.
Stephen Rosenfeld, SACHRP Chair. The meeting will focus on regulatory and ethical issues surrounding Deceased Donor Intervention Research, with a particular focus on recipient informed consent. An additional agenda topic will be a discussion of ethical and regulatory issues surrounding re-consent of subjects for humans subjects research. Other topics will be addressed. For the full meeting agenda, see https://cms-drupal-hhs-ohrp-prod.cloud.hhs.gov/ohrp/sachrp-committee/meetings/index.html

The public will have an opportunity to comment to the SACHRP during the meeting’s public comment session or by submitting written public comment. Persons who wish to provide public comment should review instructions at https://cms-drupal-hhs-ohrp-prod.cloud.hhs.gov/ohrp/sachrp-committee/meetings/index.html and respond by midnight Wednesday, March 4, 2020, ET. Individuals submitting written statements as public comment should submit their comments to SACHRP at SACHRP@hhs.gov. Verbal comments will be 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 the SACHRP.


Julia G. Gorey,
Executive Director,
Secretary’s Advisory Committee on Human Research Protections.

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