



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, July 30, 2019, from 9 a.m. until 4:45 p.m., and Wednesday, July 31, 2019, from 9 a.m. until 3:30 p.m.

ADDRESSES: National Institutes of Health, Vaccine Research Center Rooms 1201/1203, 40 Convent Drive, Bethesda, Maryland 20892.

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 or coordination.

The SACHRP meeting will open to the public at 9 a.m., on Tuesday, July 30, 2019, followed by opening remarks from Dr. Jerry Menikoff, Director of OHRP and Dr. Stephen Rosenfeld, SACHRP Chair. New SACHRP members will be welcomed and introduced.

The SOH subcommittee will present its recommendations on End User Licensing Agreements and Terms of Service, and Charging Subjects to Participate in Clinical

Trials. This will be followed by a discussion of site monitoring under single IRB review, with a review of possible recommendations, and finally a discussion of guidance for institutions affected by the end of the voluntary check-the-box option to extend a federalwide assurance to all research regardless of funding.

Wednesday will begin with a discussion of questions newly posed to SACHRP regarding Deceased Organ Intervention Research (DDIR), with a particular focus on recipient informed consent. There will be a panel presentations from leading experts in the field of DDIR, followed by SACHRP discussion. This will be followed by a discussion of ethical and regulatory issues surrounding reconsent of subjects for human subjects research. The meeting is scheduled to end at approximately 3:30 p.m.

Time will be allotted for public comment on both days. On-site registration is required for participation in the live public comment session. Note that public comment must be relevant to topics 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 the designated SACHRP point of contact at the address/phone number listed above at least one week prior to the meeting.

Dated: July 3, 2019.

Julia G. Gorey,

Executive Director, Secretary's Advisory Committee on Human Research Protections.

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