



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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 its twenty-eighth meeting. The meeting will be open to the public. Information about SACHRP and the meeting agenda will be posted on the SACHRP web site at: <http://www.dhhs.gov/ohrp/sachrp/mtgings/index.html>.

DATES: The meeting will be held on Tuesday, July 10, 2012 from 8:30 a.m. until 5:00 p.m. and Wednesday, July 11, 2012 from 8:30 a.m. until 4:30 p.m.

ADDRESSES: U.S. Department of Health & Human Services, 200 Independence Avenue S.W., Hubert H. Humphrey Building, Room 705A, Washington, D.C. 20201.

FOR FUTURE INFORMATION CONTACT: Jerry Menikoff, M.D., J.D., Director, Office for Human Research Protections (OHRP), or Julia Gorey, J.D., Executive Director, SACHRP; U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; 240-453-8141; fax: 240-453-6909; e-mail address: Julia.Gorey@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 and the Assistant Secretary for Health on issues and topics pertaining to or associated with the protection of human research subjects.

The meeting will open Tuesday, July 10, with remarks from SACHRP Chair Dr. Barbara Bierer and OHRP Director Dr. Jerry Menikoff, followed by a report from the Subpart A Subcommittee (SAS). SAS will discuss their recent work, including considerations for investigator responsibilities and informed consent waiver criteria. SAS 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; this subcommittee was established by SACHRP in October 2006. The topic for discussion Tuesday afternoon will be the internet in human subjects research, with a series of FAQs drafted by Dr. Elizabeth Buchanan and Dean Gallant presented for consideration.

On the morning of July 11, SACHRP and representatives from OHRP will discuss the requirements surrounding local context in human subjects research, and considerations for new HHS guidance. This discussion will help inform the report and recommendations to follow from the Subcommittee on Harmonization (SOH). SOH was established by SACHRP at its July 2009 meeting, and is 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. Wednesday afternoon, SACHRP member Drs. Lainie Friedman-Ross and Daniel Hausman will discuss IRB issues concerning community engagement in research.

Public comment will be heard on both days. Members of the public will have the opportunity to provide comments on both days of the meeting. Public comment will be limited to five minutes per speaker.

Public attendance at the meeting is limited to space available. Individuals who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the designated contact persons. Any members of the public who wish to have printed materials distributed to SACHRP members for this scheduled meeting should submit materials to the Executive Director, SACHRP, prior to the close of business July 3, 2012.

Dated: June 15, 2012

Jerry Menikoff,

Director, Office for Human Research Protections

Executive Secretary, Secretary's Advisory Committee

on Human Research Protections

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