Billing Code: 4150-36-P

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-ninth meeting. The meeting will be open to the public. Information about SACHRP and the full meeting agenda will be posted on the SACHRP web site at: http://www.hhs.gov/ohrp/sachrp/mtgings/index.html.

DATES: The meeting will be held on Tuesday, October 9, 2012 from 8:30 a.m. until 5:00 p.m. and Wednesday, October 10, 2012 from 8:30 a.m. until 4:30 p.m.

ADDRESSES: U.S. Department of Health and Human Services, 200 Independence Avenue, S.W., Room 705A, Washington, D.C. 20201.

FOR FUTHER 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, October 9, 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 revisions to the expedited review list, principal 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. Tuesday afternoon will be a discussion of informed consent issues in cluster randomized trials, featuring Dr. Andrew McRae, Research Director of the Division of Emergency Medicine, University of Calgary.

On the morning of October 10, the Subcommittee on Harmonization (SOH) will give a

report and discuss their recent work, including local context guidance recommendations. 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 will discuss a revised document on the issue of the use of the internet in human subjects research, drafted by Drs. Elizabeth Buchanan and Dean Gallant. Public Comment will be heard on both days.

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.

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. 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 October 1, 2012.

Dated: September 13, 2012

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Jerry Menikoff,

Director, Office for Human Research Protections

Executive Secretary, Secretary's Advisory Committee on

Human Research Protections

[FR Doc. 2012-23143 Filed 09/19/2012 at 8:45 am;

Publication Date: 09/20/2012]