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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 web site at: http://www.dhhs.gov/ohrp/sachrp/mtgings/index.html.

DATES: The meeting will be held on Wednesday, July 10, 2013 from 8:30 a.m. until 5:00 p.m. and Thursday, July 11, 2013 from 8:30 a.m. until 4:30 p.m.

ADDRESSES: U.S. Department of Health and Human Services, 200 Independence Avenue, S.W., Hubert H. Humphrey Building, Room 800, 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

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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 meeting will open to the public at 8:30 a.m., Wednesday, July 10. Following opening remarks from Dr. Jerry Menikoff, OHRP Director, and Dr. Jeffrey Botkin, SACHRP Chair, the Subcommittee on Harmonization (SOH) will give their report.

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. The SOH report will be followed by an expert panel discussion of informed consent issues in cluster randomized trials. After lunch, there will be a special expert panel discussing Certificates of Confidentiality (COCs).

Following opening remarks on the morning of July 11, the Subpart A Subcommittee (SAS) will give their report. This will be followed by a discussion of the concept of engagement in human subjects research. 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 day will conclude with a panel discussion of issues surrounding electronic informed consent.

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 July 5, 2013.

Dated: June 12, 2013

Jerry Menikoff,

Director, Office for Human Research Protections

Executive Secretary, Secretary's Advisory Committee on

Human Research Protections

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