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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 website at: <http://www.dhhs.gov/ohrp/sachrp/mtgings/index.html>.

DATES: The meeting will be held on Tuesday, March 24, 2015, from 8:30 a.m. until 5:00 p.m. and Wednesday, March 25, 2015, from 8:30 a.m. until 4:30 p.m.

ADDRESSES: Fishers Lane Conference Center, Terrace Level, 5635 Fishers Lane, Rockville, Maryland 20852.

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: 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 meeting will open to the public at 8:30 a.m., on Tuesday, March 24. Following opening remarks from Dr. Jerry Menikoff, Executive Secretary of SACHRP and OHRP Director, and Dr. Jeffrey Botkin, SACHRP Chair, Dr. Botkin and invited speakers will discuss issues surrounding the use of newborn dried bloodspots in research. The Subpart A Subcommittee (SAS) report will follow; SAS will discuss draft recommendations on the research uses of newborn dried bloodspots and the Newborn Screening Saves Lives Reauthorization Act of 2014. 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.

In the afternoon of March 24, the Subcommittee on Harmonization (SOH) will present their report; 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. SOH will present

recommendations on the research use of “big data” and the intersection of the HHS and FDA regulations.

On March 25, the SOH will discuss the return of individual research results with special considerations regarding HIPAA and CLIA; this will be followed by presentation of SOH recommendations on the FDA draft guidance “General Clinical Pharmacology Considerations for Pediatric Studies for Drugs and Biologics.” The meeting will adjourn at 4:30 p.m. March 25, 2015. Time for public comment sessions will be allotted both days.

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 one of the designated SACHRP points of contact at the address/phone number listed above at least one week prior to the meeting. Pre-registration is required for participation in the on-site public comment session; individuals may pre-register the day of the meeting. Individuals who would like to submit written statements should email or fax their comments to SACHRP at SACHRP@hhs.gov at least five business days prior to the meeting.

Dated: February 23, 2015.

Jerry Menikoff,
Executive Secretary, Secretary’s Advisory Committee on
Human Research Protections,
Director, Office for Human Research Protections.

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