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 twentieth meeting. The meeting will be open to the public.

DATE: The meeting will be held on Tuesday, July 21, 2009 from 8:30 a.m. until 5 p.m. and Wednesday, July 22, 2009 from 8:30 a.m. until 5 p.m.


FOR FURTHER 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; 240–453–8114; fax: 240–453–6909; e-mail address: sachrp@osophs.dhhs.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.

On July 21, 2009, the Committee will discuss a summary of comments from the recent OHRP-issued advance notice of proposed rulemaking on institutional review board (IRB) accountability, as well as hear a summary of Clinical and Translational Science Awards pediatric research issues. SACHRP will also spend time focusing on long-range future planning regarding new subcommittees and areas of focus. The day will conclude with a panel discussion addressing the question of how to evaluate IRB effectiveness.

On July 22, 2009, the Committee will hear a report from the Subpart A Subcommittee focusing on issues surrounding consent for future use of specimens or data. This subcommittee was established by SACHRP at its October 4–5, 2006 meeting and is charged with developing recommendations for consideration by SACHRP about the application of Subpart A of 45 CFR part 46 in the current research environment. SACHRP will then hear a presentation of the recent National Academy of Sciences report entitled “Conflict of Interest in Medical Research, Education and Practice,” followed by a panel discussion.

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 Friday, July 17, 2009. Information about SACHRP and the draft meeting agenda will be posted on the SACHRP Web site at: http://www.hhs.gov/ohrp/sachrp/index.html.

Dated: June 29, 2009.
Jerry Menikoff,
Director, Office for Human Research Protections Executive Secretary, Secretary’s Advisory Committee on Human Research Protections.

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