

*mackenzie.robertson@hhs.gov*. Please call the contact person for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice.

**Agenda:** The committee will hear reports from its workgroups and updates from ONC and other Federal agencies. ONC intends to make background material available to the public no later than two (2) business days prior to the meeting. If ONC is unable to post the background material on its Web site prior to the meeting, it will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on ONC's Web site after the meeting, at <http://healthit.hhs.gov>.

**Procedure:** ONC is committed to the orderly conduct of its advisory committee meetings. Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. Written submissions may be made to the contact person on or before two days prior to the Committee's meeting date. Oral comments from the public will be scheduled in the agenda. Time allotted for each presentation will be limited to three minutes. If the number of speakers requesting to comment is greater than can be reasonably accommodated during the scheduled public comment period, ONC will take written comments after the meeting until close of business on that day.

Persons attending ONC's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

ONC welcomes the attendance of the public at its advisory committee meetings. Seating is limited at the location, and ONC will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact MacKenzie Robertson at least seven (7) days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (Pub. L. 92-463, 5 U.S.C., App. 2).

Dated: June 13, 2012.

**MacKenzie Robertson,**

*FACA Program Lead, Office of Policy and Planning, Office of the National Coordinator for Health Information Technology.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Secretary's Advisory Committee on Human Research Protections

**AGENCY:** Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

**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 SW., Hubert H. Humphrey Building, Room 705A, Washington, DC 20201.

**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; 240-453-8141; fax: 240-453-6909; email address: [Julia.Gorey@hhs.gov](mailto: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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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### HIT Standards Committee Advisory Meeting; Notice of Meeting

**AGENCY:** Office of the National Coordinator for Health Information Technology, HHS.

**ACTION:** Notice of meeting.