

Office for Human Research Protections (OHRP)

The Department of Health and Human Services
Meeting of the Secretary's Advisory Committee on Human Research Protections
(SACHRP)
Tuesday, July 21, 2009 — Wednesday, July 22, 2009
The Sheraton National Hotel
900 South Orme Street, Arlington, Virginia

AGENDA

**Tuesday, July 21,
2009**

8:30 am — 8:35 am Welcome: Opening remarks
Barbara Bierer, M.D.
SACHRP Chair

8:35 am — 8:45 am Report of Issues/Remarks
Jerry Menikoff, M.D., J.D.,
Director, OHRP

8:45 am — 10:45 am ANPRM: Holding External IRBs Accountable
Julie Kaneshiro, MA
Team Leader, Division of Policy and Assurances, OHRP

Felix Gyi, PharmD, M.B.A.
Chief Executive Officer,
Chesapeake Research Review, Inc.

Darrell Wilson, M.D., Stanford University
Professor and Chief of Pediatric Endocrinology and Diabetes,
Stanford University and the Lucile Packard Children's Hospital at
Stanford

David Wynes, Ph.D.
Vice President for Research Administration
Emory University

Susan Loess-Perez, M.S.
Director, Office of Research Protections
DePaul University

10:45 am — 11:00 am BREAK

- 11:00 am — 12:00 am CTSA Pediatric Multisite IRB Issues
Steven Hirschfeld, M.D., Ph.D.
 Captain, U.S. Public Health Service
 Associate Director for Clinical Research
 National Institute of Child Health and Human Development
- 12:05 pm — 1:00 pm LUNCH
- 1:00 pm — 1:45 pm Summary of Comment: Education Requirements RFI
Elyse Summers, J.D.
 Acting Director, Division of Education Development OHRP
- 1:45 pm — 3:15 pm SACHRP Future Planning
- 3:15 pm — 3:30 pm BREAK
- 3:30 pm — 5:30 pm Panel: How to Measure IRB Effectiveness?
Holly Taylor, M.P.H., Ph.D.
 Assistant Professor, Johns Hopkins Bloomberg School of Public Health and Core Faculty, Johns Hopkins Berman Institute of Bioethics
- Steve Joffe, M.D., M.P.H.**
 Assistant Professor, Pediatrics, Harvard Medical School
 Pediatric hematologist/oncologist, Dana-Farber Cancer Institute (DFCI) and Children's Hospital, Boston
- Norm Fost, M.D., M.P.H.**
 Professor, Pediatrics and Medical History and Bioethics
 Director, Program in Bioethics
 University of Wisconsin
- 5:30 pm — 5:45 pm Public Comment
- 5:45 pm — 6:00 pm Wrap-up discussion and Adjourn

Wednesday, July 22, 2009

- 8:30 am — 8:45 am Remarks
Barbara Bierer, M.D.
SACHRP Chair
- 8:45 am — 9:00 am Remarks of Acting Assistant Secretary for Health
Howard K. Koh, M.D., M.P.H.
- 9:00 am — 10:30 am Report of Subpart A Subcommittee (SAS)
Dan Nelson, M.S., CIP
Elizabeth A. Bankert, M.A.
SAS Co-chairs
- 10:30 am — 10:45 am BREAK
- 10:45 am — 11:45 pm Report of Subpart A Subcommittee (SAS), cont'd

11:45 pm — 12:45 pm

12:45 pm — 3:00 pm

LUNCH

Conflict of Interest in Human Subjects Research

Marilyn Field, Ph.D.

Senior Program Officer, Institute of Medicine

Ross McKinney, Jr., M.D.

Director, Trent Center for Bioethics, Humanities,
and History of Medicine, Duke University School
of Medicine

Guy Chisolm, Ph.D.

Vice Chairman of the Lerner Research Institute of
Cleveland Clinic, Director of Cleveland Clinic's
Innovation Management and Conflict of Interest
Program

Jack Harris, M.D.

Vice President, US Medical Division
Lilly USA, LLC

3:00 pm — 3:15 pm

3:15 pm — 3:30 pm

Public Comment

Wrap-up Discussion and Adjourn