The Department of Health and Human Services Meeting of the

Secretary's Advisory Committee on Human Research Protections (SACHRP) Monday, March 13 – Tuesday, March 14, 2006 The Radisson Hotel Old Town

901 North Fairfax Street Alexandria, VA

Monday, March 13, 2006

William 13, 2000	
8:30 am – 8:35 am	Welcome: Opening Remarks Introduction of New Members Ernest Prentice, Ph.D. Chairman, SACHRP
8:35 am – 8:50 am	Report of Issues Bernard Schwetz, D.V.M., Ph.D. Director, OHRP
8:50 am – 10:30 am	Subpart A Subcommittee report Felix Gyi, Pharm.D., M.B.A., CIP Dan Nelson, M.S., CIP, Co-Chairs
10:30 am – 10:45 am	BREAK
10:45 am – 12:00 noon	Subpart A Subcommittee report
12:00 noon – 1:00 pm	LUNCH
1:00 pm – 2:00 pm	Subpart A Subcommittee report
2:00 pm – 3:00 pm	Recognition of Departing Members/ Swearing in of new member Neil Powe, M.D., M.P.H., M.B.A. Admiral John O. Agwunobi, M.D., M.B.A., M.P.H., Assistant Secretary for Health, Department of Health and Human Services
3:00 pm – 3:15 pm	BREAK
3:15 pm – 4:15 pm	Discussion of IRB Workshop Dr. Ernie Prentice, SACHRP Chair Dr. Bernard Schwetz, Director, OHRP

4:15 pm – 4:30 pm

Public Comment

4:30 pm - 5:00 pm

Wrapup and adjourn

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8:30 am – 8:35 am Welcome: Opening Remarks

Ernest Prentice, Ph.D. Chairman, SACHRP

8:35 am – 10:30 am Report of Subcommittee on Research

Involving Children Celia Fisher, Ph.D.

Susan Kornetsky, M.P.H., Co-Chairs

10:30 am – 10:45 am BREAK

10:45 am – 12:00 noon Research

Involving Children

12:00 noon – 1:00 pm LUNCH

1:00 pm – 1:30 pm Public Comment

1:30 pm – 4:30 pm Panel on Status of Research Ethics/Training

Internationally

Moderator: Robert Levine, M.D.,

Professor, Yale University

School of Medicine

Melody Lin, Ph.D., Deputy Director, Office for Human Research Protections

David Lepay, M.D., Ph.D., Senior Advisor on Clinical Science, Office of Science and

Health Coordination, Office of the

Commissioner, FDA

Jean-Louis Saillot, Vice President and Head, Global Pharmacovigilance, Schering Plough

Maureen Power, RN, MPH, Nurse Consultant, Office for Policy in Clinical Research Operations/ Division of Acquired Immunodeficiency Syndrome, National Institute of Allergy and Infectious Diseases, NIH

Also attending: Karen Hansen, Institutional Review Officer, Fred Hutchinson Cancer Research Center

Barbara Sina, Ph.D., Fogarty International Center, NIH

Wrapup and adjourn

4:30 pm

Updated 3/10/06