

**The Department of Health and Human Services
Meeting of the
Secretary's Advisory Committee on Human Research Protections (SACHRP)
Tuesday, November 1 – Wednesday, November 2, 2005
The Radisson Hotel Old Town Alexandria
901 North Fairfax Street
Alexandria, VA**

AGENDA

Tuesday, November 1, 2005

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|-----------------------|---|
| 8:30 am – 8:35 am | Welcome: Opening Remarks Introduction of New Members Ernest Prentice, Ph.D. Chairman, SACHRP |
| 8:35 am – 8:45 am | Report of Issues Bernard Schwetz, D.V.M., Ph.D. Director, OHRP |
| 8:45 am – 9:00 am | Recognition of Departing Members/Swearing in of new member Dr. James Powell Ernest Prentice, Ph.D. Bernard Schwetz, D.V.M., Ph.D. |
| 9:00 am – 9:05 am | Overview of Charges to Subcommittees Approval of Minutes from Aug 1-2, 2005 meeting Ernest Prentice, Ph.D. |
| 9:05 am – 10:35 am | Children's Subcommittee Report Celia Fisher, Ph.D. Susan Kornetsky, M.P.H., Co-Chairs |
| 10:35 am – 10:45 am | BREAK |
| 10:45 am – 12:00 noon | Children's Subcommittee Report |
| 12:00 noon – 1:00 pm | LUNCH |
| 1:00 pm – 1:30 pm | Public Comment |
| 1:30 pm – 2:15 pm | OHRP's Draft Guidance on Adverse Events and Unanticipated Problems Michael A. Carome, M.D., OHRP |
| 2:15 pm - 3:00 pm | Subpart A Subcommittee Report Felix Gyi, Pharm.D., M.B.A., CIP Daniel Nelson, M.S., CIP, Co-Chairs |
| 3:00 pm – 3:15 pm | BREAK |
| 3:15 pm – 4:30 pm | Subpart A Subcommittee Report |
| 4:30 pm – 5:00 pm | Wrap-up and adjourn |

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Wednesday, November 2, 2005

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| 8:30 am – 8:35 am | Welcome: Opening Remarks Ernest Prentice, Ph.D. Chairman, SACHRP |
| 8:35 am – 9:30 am | IOM update: Report on Research Involving Prisoners Larry Palmer, LL.B. |
| 9:30 am - 10:15 am | Update of FDA/OHRP Joint 407 Review Process Sara Goldkind, M.D., Ph.D., FDA Kevin Prohaska, D.O., CDR-PHSC, OHRP |
| 10:15 am – 10:30 am | BREAK |
| 10:30 am – 12:30 pm | Identification of Future SACHRP Priorities; International Research Multi-Center Studies Evidence-Based Practice Exemptions SACHRP Ex-Officios |
| 12:30 pm – 1:30 pm | LUNCH |
| 1:30 pm – 3:00 pm | Identification of Future SACHRP Priorities SACHRP Members |
| 3:00 pm – 3:15 pm | Break |
| 3:15 pm – 4:15 pm | Identification of Future SACHRP Priorities; Opportunity for Individual Agency Comment SACHRP Ex-Officios |
| 4:15 pm – 4:45 pm | Public Comment |
| 4:45 pm - 5:00 pm | Wrap-up and adjourn |