The Department of Health and Human Services Meeting of the Secretary's Advisory Committee on Human Research Protections (SACHRP) Monday, July 31-Tuesday, August 1, 2006 The North Bethesda Marriott Hotel and Conference Center 5701 Marinelli Road, (Enter through Salon C, Main level) North Bethesda, MD 20852

DRAFT AGENDA

Monday, July 31, 2006

| 8:00 am – 8:15 am | Welcome: Opening Remarks Introduction of New Members Ernest Prentice, Ph.D. Chairman, SACHRP |
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| 8:15 am – 8:30 am | Report of Issues Bernard Schwetz., D.V.M., Ph.D. Director, OHRP |
| 8:30 am – 8:45 am | Remarks John Agwunobi, M.D. Assistant Secretary for Health |
| 8:45 am – 9:00 am | Swearing in of new members John Agwunobi, M.D. Assistant Secretary for Health |
| 9:00 am – 10:00 am | Federal Adverse Events Task Force update Amy Patterson, M.D., NIH Michael Carome, M.D., OHRP |
| 10:00 am – 10:15 am | BREAK |
| 10:15 am – 12:00 noon | Report of Subpart A subcommittee Daniel Nelson, M.S., CIP Felix Gyi, Pharm D., M.B.A., CIP, Co-Chairs |
| 12:00 noon – 1:00 pm | Working lunch/Ethics training for new members Presenter from OGC TBD |

| 1:00 pm – 2:30 pm | Report of Subcommittee on Research Involving Children (SRIC) Celia Fisher, Ph.D. Susan Kornetsky, M.P.H., Co-Chairs |
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| 2:30 pm – 2:45 pm | BREAK |
| 2:45 pm – 4:00 pm | SRIC report continued |
| 4:00 pm – 4:30 pm | Public Comment |
| 4:30 pm – 5:00 pm | Discussion and wrap-up |
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Tuesday, August 1, 2006

| 8:00 am – 8:15 am | Welcome: Opening Remarks Ernest Prentice, Ph.D. Chairman, SACHRP |
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| 8:15 am – 10:00 am | Presentation of IOM Prisoner Report/ Committee discussion IOM Presenter TBD |
| 10:00 am – 10:15 am | BREAK |
| 10:15 am – 12:30 pm | Panel on Research Involving Individuals With Impaired Decision-making Capacity |
| | David Strauss, M.D., NY State Psychiatric Institute - Moderator and IRB perspective |
| | Dr. Charles MacKay, NIH - Historical context from National Commission Report |
| | David Shore, M.D., NIMH - NBAC report, NHRPAC recommendations |
| | Laurie Flynn, Columbia University - Advocate and informed consent issues |
| | Myra Christopher, Practical Bioethics - Recommendations on federal regulations protecting research subjects with diminished capacity |
| 12:30 pm -12:45 pm | Public Comment |
| 12:45 pm – 1:15 pm | Discussion and wrap-up |