38th MEETING
NATIONAL BIOETHICS ADVISORY COMMISSION
Hilton Washington Dulles Airport
13869 Park Center Rd
Herndon, VA
February 29-March 1, 2000

DRAFT AGENDA

DAY ONE-Tuesday, February 29, 2000

8:30 am **Opening Remarks**
Harold T. Shapiro, Ph.D.

ETHICAL ISSUES IN INTERNATIONAL RESEARCH

8:40am Overview of Work to Date

Ruth Macklin, Ph.D.; Alice Page, J.D., M.P.H.

9:00 am **Panel I: Perspectives from Other Countries**

- Jean W. Pape, M.D., Institut National de Laboratoire, Port-au-Prince, Haiti
- Grace Malenga, M.D., Queen Elizabeth Central Hospital and University of Malawi College of Medicine, Blantyre, Malawi, Africa
- Dr. Ogobara Doumbo, University of Mali, Barmako, Mali, West Africa
- Christopher Plowe, M.D., M.P.H., University of Maryland, Baltimore, MD

10:30 am **Break**

10:45 am **Discussion with Commissioners**

12:00 pm **Lunch**

1:00 pm **PUBLIC COMMENT**

ETHICAL ISSUES IN INTERNATIONAL RESEARCH (continued)

1:30 pm **Discussion with Commissioners**
Ruth Macklin, Ph.D., Alice Page, J.D., M.P.H.
Obligations to Research Subjects (Draft of Chapter 4)

3:30 pm **Break**

4:00 pm **Discussion with Commissioners continues**
Choosing a Research Design (Draft of Chapter 3)

5:00 pm **Adjournment**

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DRAFT AGENDA

DAY TWO- Wednesday, March 1, 2000

8:00 am **Opening Remarks**
Harold T. Shapiro, Ph.D.

ETHICAL AND POLICY ISSUES IN THE OVERSIGHT OF HUMAN SUBJECTS RESEARCH

8:10am **Overview of Work to Date**
Marjorie A. Speers, Ph.D.

8:20 am **Panel I: Oversight of Human Gene Therapy Research**

- Lana Skirboll, Ph.D., Director, Office of Science Policy, National Institutes of Health
- Kathryn C. Zoon, Ph.D., Director, Center for Biologics Evaluation and Research, Food and Drug Administration
- Claudia Mickelson, Ph.D., Chair, Recombinant DNA Advisory Committee

8:50 am **Discussion with Commissioners**

9:30 am **Panel II: Implementation of the Common Rule – The Case of Revising the Expedited Review Categories and the Case of the Classified Research Rule**

- Michele Russell-Einhorn, J.D., Director for Regulatory Affairs, Office for Protection from Research Risks

9:45 am **Discussion with Commissioners**

10:15 am **Break**

10:30 am **Panel III: Alternative Federal Regulatory Systems**

- Diane Flack, M.S., Senior Health Physicist, Rulemaking and Guidance Branch Office of Nuclear Material Safety and Safeguards, Nuclear Regulatory Commission

- Jane Ley, J.D., Deputy Director for Government Relations and Special Projects, Office of Government Ethics

DAY TWO- Wednesday, March 1, 2000 (continued)

11:00 am **Discussion with Commissioners**

11:30 am **Lunch**

12:45 pm **Panel IV: Definition of Research**

- Andrew Nelson, Executive Director, HealthPartners and President HMO Research Network
- Mary Durham, Ph.D., Vice President for Research, Kaiser Foundation Hospitals

1:15 pm **Discussion with Commissioners**

1:45 pm **Panel V: Update on Congressional Initiatives**

- Paul T. Kim, J.D., Counsel, Congressman Henry A. Waxman, United States House of Representatives
- Anne Phelps, M.A., Staff Director, Senate Subcommittee on Public Health, Chairman Bill Frist, M.D., United States Senate
- Souheila Al-Jadda, Legislative Aide, Congressman Dennis J. Kucinich, United States House of Representatives

2:30 pm **Next Steps**
Harold T. Shapiro, Ph.D.

3:00 pm **Adjournment**