

**42nd MEETING
NATIONAL BIOETHICS ADVISORY COMMISSION
Hyatt Regency Bethesda
One Bethesda Metro Center
Wisconsin Ave. at Old Georgetown Rd.
Bethesda, MD 20814
July 10-11, 2000**

DRAFT AGENDA

DAY ONE--Monday July 10, 2000

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

ETHICAL ISSUES IN INTERNATIONAL RESEARCH

8:40 am Discussion of Draft Report
Harold T. Shapiro, Ph.D., Ruth Macklin, Ph.D., Alice Page, J.D., M.P.H.

10:30 am Break

10:45 am Discussion continues

12:00 pm Lunch

1:00 pm PUBLIC COMMENT

**ETHICAL AND POLICY ISSUES IN THE OVERSIGHT OF HUMAN SUBJECTS
RESEARCH**

1:30 pm Overview of Work to Date
Marjorie Speers, Ph.D.

1:40 pm Panel I: Community-Based Research

Vincent T. Francisco, Ph.D., Associate Director, Work Group on Health Promotion
and Community Development, University of Kansas

Edison J. Trickett, Ph.D., Professor of Psychology, University of Maryland

2:15 pm Discussion with Commissioners

2:45 pm Break

3:00 pm Panel II: Individuals Who Have Participated in Research as Subjects

Darnell Williams, Chicago, Illinois

Timmecca Wilson, Washington, DC

DAY ONE--Monday July 10, 2000 (continued)

Susan May, Atlanta, Georgia

Linda Smith, Perris, California

3:30 pm Discussion with Commissioners

4:00 pm Panel III: Vulnerable Populations

Kenneth Kipnis, Ph.D., Professor of Philosophy, University of Hawaii at Manoa
Commissioned Paper: "Vulnerability in Research Subjects: An Ethical Taxonomy"

4:30 pm Discussion with Commissioners: Recommendation on Vulnerable Populations

5:00 pm Adjournment

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DRAFT AGENDA

DAY TWO- Tuesday, July 11, 2000

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

ETHICAL ISSUES IN INTERNATIONAL RESEARCH

8:10 am **Discussion of Draft Report (cont'd)**
Harold T. Shapiro, Ph.D.

ETHICAL AND POLICY ISSUES IN THE OVERSIGHT OF HUMAN SUBJECTS RESEARCH

9:10 am **Panel IV: Identification and Assessment Risk and Benefit**

Ernest D. Prentice, Ph.D., Associate Dean for Research, Co-chair, IRB
Office of Regulatory Affairs, University of Nebraska Medical Center
Commissioned Paper: "Institutional Review Board Assessment of Risks and Benefits
Associated with Research"

9:50 am **Discussion with Commissioners: Risk/Benefit Assessment**

10:45 am **Break**

11:00 am **Panel V: Perspectives of Oversight System from IRBs**

Daniel K. Nelson, M.S., Director, Human Research Studies, and Associate Professor
of Social Medicine and Pediatrics, School of Medicine, University of North Carolina-
Chapel Hill

Maira A. Keane, M.A., Director, Research Subjects' Protection Program
IRB/IACUC, University of Minnesota Health Center

E. Ray Stinson, Ph.D., Assistant Vice President for Research, Wayne State University

DAY TWO- Tuesday, July 11, 2000 (continued)

Robert Nelson, M.D., Ph.D., Assistant Professor of Anesthesia and Pediatrics,
Director, Research Regulatory Affairs Office, Chair, Institutional Review Board, The
Children's Hospital of Philadelphia

11:40 am Discussion with Commissioners

12:30 pm Lunch

1:30 pm Panel VI: Perspectives of the Oversight System from Researchers

Sharon B. Murphy, M.D., Professor of Pediatrics, Northwestern University School of
Medicine

William Burman, M.D., Attending Physician, Denver Department of Public Health

Monica M. Farley, M.D., Professor of Medicine, Emory University, School of
Medicine, Atlanta VA Medical Center

Samuel A. Wells, Jr., M.D., Director of Clinical Trials and Evidence-Based Medicine,
American College of Surgeons

2:30 Discussion with Commissioners: IRB Functioning

4:00pm Adjournment