

43rd MEETING
NATIONAL BIOETHICS ADVISORY COMMISSION
U.S. Chamber of Commerce
Anheuser-Busch Briefing Center
1615 H Street, NW
Washington, DC 20062
September 12-13, 2000

A G E N D A

DAY ONE-Tuesday, September 12, 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.

10:00 am Break

10:15 am Discussion of Draft Report Continues

12:00 pm Lunch

1:00 pm Discussion of Draft Report Continues

2:30 pm Public Comment

ETHICAL AND POLICY ISSUES IN THE OVERSIGHT OF HUMAN SUBJECTS RESEARCH

3:00 pm Overview of Work to Date
Marjorie A. Speers, Ph.D.

3:10 pm New Directions for the Office for Human Research Protections
Greg Koski, Ph.D., M.D., Director

3:30 pm Break

3:45 pm Panel I: Alternatives/Supplements to Local IRB Review

Steven Peckman, Associate Director, Human Subjects Research, Office for Protection of Research Subjects, University of California, Los Angeles
Commissioned Paper, entitled "Local Institutional Review Boards"

Soren Holm, M.D., Ph.D., Reader in Bioethics Center for Social Ethics and Policy, University of Manchester, England
Commissioned Paper, entitled "The Danish Research Ethics Committee System –

Overview and Critical Assessment”

DAY ONE-Tuesday, September 12, 2000 (continued)

Daniel P. Schuster, M.D., Professor of Medicine, Washington University in St. Louis

4:15 pm **Discussion with Commissioners**

5:00 pm **Adjournment**

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AGENDA

DAY TWO- Wednesday, September 13, 2000

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

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

8:10 am **Discussion of Chapter 1**
Marjorie A. Speers, Ph.D.

9:10 am **Panel II: Privacy/Confidentiality**

Joan E. Sieber, Ph.D., Professor of Psychology, California State University, Hayward
Commissioned Paper, entitled "Privacy and Confidentiality: As Related to Human
Research in Social & Behavioral Science"

Janlori Goldman, J.D., Director, Health Privacy Project, Georgetown University,
Institute for Health Care Research and Policy
Commissioned Paper, entitled "Privacy and Confidentiality in Health Research"

9:40 am **Discussion with Commissioners**

10:30 am **Break**

10:45 am **Panel III: Quality Control: assurances, site inspections, accreditation,
certification, and licensure**

Greg Koski, Ph.D., M.D., Director, Office for Human Research Protections, DHHS

David A. Lepay, M.D., Ph.D., Acting Senior Advisor on Clinical Science,
Office of the Commissioner and Director, Division of Scientific Investigations,
Office of Medical Policy, Center for Drug Evaluation and Research, US Food and Drug
Administration

DAY TWO- Wednesday, September 13, 2000 (continued)

Michael S. Hamm, Principal, Michael Hamm & Associates

11:30 am Discussion with Commissioners

12:00 pm Wrap-up

12:15 pm Adjournment