41st MEETING NATIONAL BIOETHICS ADVISORY COMMISSION

Hyatt at Fisherman's Wharf 555 North Point Street San Francisco, CA 94133 June 5-6, 2000

DRAFT AGENDA

DAY ONE-Monday June 5, 2000

8:00 am Opening Remarks

Alexander M. Capron, LL.B.

ETHICAL ISSUES IN INTERNATIONAL RESEARCH

8:10 am Overview of Work to Date

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

8:20 am Chapter 5 – Enhancing International Collaborative Research

Discussion with Commissioners

10:15 am Break

10:30 am Chapter 2 – Informed Consent

Discussion with Commissioners

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 A. Speers, Ph.D.

1:40 pm Panel I: Informed Consent

Jeffrey P. Kahn, Ph.D., M.P.H., Director, Center for Bioethics, University of

Minnesota

2:10 pm Discussion with Commissioners

3:15 pm Break

3:30 pm Panel II: Private Sector Roundtable

Richard Schreck, Ph.D., Secretary, General Motors Human Research Committee, General Motors

DAY ONE-Monday June 5, 2000 (continued)

Henry B. Chin, Ph.D., Vice President, Center for Technical Assistance, National Food Processors Association Other panel members have been invited

5:00 pm Break

5:15 pm Panel III: Alternative Models

Donald Chalmers, LL.B, Chairman, Australian Health Ethics Committee, Faculty of Law, University of Tasmania (by conference call from Australia)

5:35pm Discussion with Commissioners

6:30 pm Adjournment



41st MEETING NATIONAL BIOETHICS ADVISORY COMMISSION Hyatt at Fisherman's Wharf 555 North Point Street San Francisco, CA 94133 June 5-6, 2000

DRAFT AGENDA

DAY TWO- Tuesday, June 6, 2000

8:00 am Opening Remarks

R. Alta Charo, J.D.

ETHICAL AND POLICY ISSUES IN THE OVERSIGHT OF HUMAN SUBJECTS RESEARCH

8:10 am Panel IV: Independent IRBs

Erica Heath, President, Independent Review Consulting, San Anselmo, CA Commissioned Paper: "The History, Function, and Future of Independent Institutional Review Boards

9:10 am Panel V: Purpose of Regulation

Harold Y. Vanderpool, Ph.D., Professor in the History and Philosophy of Medicine, Institute for the Medical Humanities, University of Texas Medical Branch, Galveston, TX

Commissioned Paper: "UNFULFILLED PROMISE: How The Belmont Report Can Amend The Code of Federal Regulations Title 45 Part 46: PROTECTION OF HUMAN SUBJECTS"

Jonathan D. Moreno, Ph.D., Kornfeld Professor and Director, Center for Biomedical Ethics, University of Virginia

Commissioned Paper: Protectionism in Research Involving Human Subjects

David Magnus, Ph.D., Assistant Professor and Director of Graduate Studies, Center for Bioethics, University of Pennsylvania

10:15 am Break

10:30 am Discussion with Commissioners

11: 30am Recommendations – Purpose and Structure

Discussion with Commissioners

12:30 pm Lunch

<u>DAY TWO- Tuesday, June 6, 2000</u> (continued)

ETHICAL ISSUES IN INTERNATIONAL RESEARCH

1:30 pm	Recommendations – Chapters 2, 3, 4, and 5 Discussion with Commissioners
3:30 pm	Break
3:45 pm	Chapter 1 – Introduction to Report Discussion with Commissioners
4:45 pm	Chapters 2, 3, 4, and 5, Revisited Discussion with Commissioners
5:15 pm	Wrap Up

Adjournment

5:30 pm