



Presidential Commission *for the Study of Bioethical Issues*

Amy Gutmann, Ph.D.
Commission Chair



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Agenda for Meeting Five: May 18-19, 2011, in New York, N.Y.

Warwick New York Hotel
65 W. 54th Street
New York, NY 10019

Wednesday, May 18

9:30 – 9:45 a.m. Welcome and Opening Remarks

Amy Gutmann, Ph.D.
Commission Chair

James Wagner, Ph.D.
Commission Vice-Chair

9:45 – 10 a.m. Executive Director's Report

Valerie H. Bonham, J.D.
Executive Director

10 – 10:30 a.m. Session 1: Federal Standards - Introduction

Christine Grady, R.N., Ph.D.
Commission Member

10:30 – 10:45 a.m. Break

10:45 – 11:45 a.m. Session 2: Implementing Federal Standards

Connie Celum, M.D., M.P.H.
Professor of Medicine
Professor of Global Health
Adjunct Professor of Epidemiology
Director, International Clinical Research Center, Department of Global Health
University of Washington

David A. Borasky, Jr., M.P.H., C.I.P.

IRB Manager
Office of Research Protection
RTI International

Sergio Litewka, M.D., M.P.H.
International Programs Director
Research Assistant Professor
University of Miami Ethics Programs

11:45 a.m. – 1:15 p.m. Lunch Break

1:15 – 2 p.m. Session 3: Implementing Federal Standards – International Efforts

Murray M. Lumpkin, M.D., M.Sc.
Deputy Commissioner for International Programs
U.S. Food and Drug Administration (FDA)

Jerry Menikoff, M.D., J.D.
Director, Office for Human Research Protections
U.S. Department of Health & Human Services

2 – 2:45 p.m. Session 4: Implementing Federal Standards – Ethics Issues

Ronald Bayer, Ph.D.
Professor and Co-Chair, Center for the History and Ethics of Public Health
Mailman School of Public Health
Columbia University

Joseph J. Fins, M.D., F.A.C.P.
E. William Davis, M.D., Jr. Professor of Medical Ethics
Chief, Division of Medical Ethics
Professor of Medicine, Professor of Public Health, and Professor of Medicine in Psychiatry
Weill Cornell Medical College

2:45 – 3:45 p.m. Session 5: Roundtable

3:45 – 4 p.m. Break

4 – 4:45 p.m. Session 6: Public Comment

4:45 – 5 p.m. Closing Remarks

Amy Gutmann, Ph.D.
James Wagner, Ph.D.

Thursday, May 19

9 – 9:05 a.m. Opening Remarks

Amy Gutmann, Ph.D.
James Wagner, Ph.D.

9:05 – 10:30 a.m. Session 7: Transnational Standards**John R. Williams, Ph.D.**

Consultant, World Medical Association (WMA)
Adjunct Professor, Department of Medicine
University of Ottawa
Adjunct Research Professor, Department of Philosophy
Carleton University (Ottawa)

Johannes J. M. van Delden, M.D., Ph.D.

President, Council for International Organizations of Medical Sciences (CIOMS)
Professor of Medical Ethics
Utrecht University Medical Center

Dafna Feinholz, Ph.D.

Chief of the Bioethics Section
Division of Ethics of Science and Technology
Sector for Social and Human Services
United Nations Educational, Scientific and Cultural Organization (UNESCO)

Francis P. Crawley

Executive Director, Good Clinical Practice Alliance – Europe (GCPA)

10:30 – 10:45 a.m. Break**10:45 – 11:30 a.m. Session 8: European Perspectives****Linda Nielsen, J.D.**

Vice President, European Group on Ethics in Science and New Technologies (EGE)
Professor of Global Law and Governance
University of Copenhagen, Denmark

Maurizio Salvi, Ph.D.

Policy Advisor (Ethics) to the President of the European Commission
Head of the EGE Secretariat
Member of the Bureau of European Policy Advisors (BEPA)

11:30 a.m. – 12:30 p.m. Session 9: Roundtable**12:30 – 12:45 p.m. Concluding Remarks****Amy Gutmann, Ph.D.****James Wagner, Ph.D.****Tags**

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[meetings](#)

[human subjects protection](#)

Topic

Human Subjects Protection

Share Your Views

This meeting is free and open to the public on a first come, first served basis. The Commission welcomes input from anyone wishing to provide public comment on any issue before it. Individuals who wish to present at the public meeting must register by email to info@bioethics.gov on or before May 10, 2011, and provide complete contact information, including name, title, affiliation, address, email, and phone number.

The Commission will do its best to accommodate requests to speak, and will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin. To accommodate as many speakers as possible, the time for public comments may be limited to no more than one or two minutes each. If the number of individuals wishing to speak is greater than can reasonably be accommodated during the scheduled meeting, the Commission may randomly select speakers from among those who register to speak.

Written comments will also be accepted and are especially welcome. Please address written comments by e-mail to info@bioethics.gov, or by mail to the following address:

Public Commentary

The Presidential Commission for the Study of Bioethical Issues
1425 New York Ave. NW, Suite C-100
Washington, DC 20005.

Comments will be publicly available, including any personally identifiable or confidential business information that they contain. Trade secrets should not be submitted.

Special Assistance

If you need special accommodations because of disability, please contact Esther Yoo at info@bioethics.gov or via phone at 202-233-3960 at least seven days before the meeting.

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