Tuesday, January 21, 2003

8:30-9:15 am  Formal Welcome. Presentation of participants

9:15-10:00 am  A Framework for the Ethics of Clinical Research

Ezekiel J. Emanuel, M.D., Ph.D.
NIH, USA

Readings:
- Emanuel E, Wendler D, Grady C. What Makes Clinical Research Ethical?


The Nuremberg Code
The Belmont Report
International Ethical Guidelines for Biomedical Research Involving Human Subjects, CIOMS 1993

10:00-10:30 am  Break
10:30-10:45 am  Case about Randomization and Placebos

TBA
10:45-11:30 am  The Ethics of Randomization and Placebo Controls  
Dr. Isabelle Moulon  
EMEA

Readings:  

11:30-11:45 am  Case about Risks and Benefits  
TBA

11:45-12:30 pm  Evaluation of Risks and Benefits  
Reidar K. Lie, M.D., PhD  
NIH

Readings:  
12:30-2:00 pm  Lunch

2:00-2:15 pm  Case about Recruitment and Incentives
TBA

2:15-3:00 pm  The Ethics of Subject Recruitment
David Wendler, PhD
NIH


3:00-3:30 pm  Break

3:30-4:30 pm  The Ethics of Conflicts of Interests
Ezekiel J. Emanuel, MD, PhD
NIH


4:30-4:45 pm  Case about Stored Biological Samples
TBA

4:45-5:30 pm  The Ethics of Research with Stored Biological Samples
David Wendler, PhD
NIH


**Wednesday January 22, 2003**

8:30-8:45 am Case About Individual Informed Consent TBA

8:45-9:30 am Individual Informed Consent
Samia Hurst, MD
NIH


Guidelines for Writing Informed Consent Documents, OHSR, NIH. Recommendations for the Development of Informed Consent Documents for Cancer Clinical Trials, NCI, NIH.
9:30-9:45 am  Case about International Collaboration
TBA

9:45-10:30 am  Ethical issues in research partnership in international co-
operation
Mamadou Traore, MD, PhD
European Commission/INRSP

10:30-11:00 am  Break

11:00-noon  Measuring Benefits of Clinical Research
Ezekiel J. Emanuel, M.D., Ph.D.
NIH, USA

Readings:  Glantz L, Annas G, et al. Research in Developing Countries: Taking
Beyond Reasonable Availability: An ethical framework for determining
benefits of research in developing countries
Shapiro HT, Meslin EM. Ethical Issues In the Design and Conduct of
Clinical Trials in Developing Countries. New England Journal of Medicine 2001;
345:139-141

12-1:30 pm Lunch

1:30 Function and Performance of Ethical Review
Reidar K. Lie, MD, PhD.
NIH

Readings:  Operational Guidelines for Ethics Committees That Review Biomedical
Lemmens T and Freedman B. Ethics Review for Sale: Conflict of
Interest and Commercial Research Review Boards. The Milbank Quarterly,

2.15-2.45  Break

2:45- 4.30 pm  Mock IRB
Reidar K. Lie, MD, PhD
NIH

Evening  Concluding Reception and Dinner