MALI CONFERENCE ON ETHICAL ASPECTS OF CLINICAL RESEARCH IN DEVELOPING COUNTRIES

January 21-22, 2003
Bamako, Mali

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? *Journal of the American Medical Association* 2000;283(20):2701-2711.
Lederer SE. Doctors, Patients and Medical Research, pp21-23; Human Experimentation in an Age of Medical Progress, pp 132-135. *Subjected To Science*, Johns Hopkins University Press, Baltimore, MD, 1995.
Taylor T. Opening Statement of the Prosecution December 9, 1946, Chapter 5, pp 67-93, *The Nazi Doctors and the Nuremberg Code*, George Annas, Michael Grodin, eds. Oxford University Press, 1992.

Stephens J. As Drug Testing Spreads, Profits and Lives Hang in Balance. The Body Hunters: Article I, *The Washington Post*, December 17, 2000.
Flaherty MP, Nelson D, Stephens J. Overwhelming the Watchdogs. The Body Hunters: Article II, *The Washington Post*, December 18, 2000.
LaFraniere S, Flaherty MP, Stephens J. The Dilemma: Submit or Suffer. The Body Hunters: Article III, *The Washington Post*, December 19, 2000.
Pomfret J, Nelson D. In Rural China, A Genetic Mother Lode. The Body Hunters: Article IV, *The Washington Post*, December 20, 2000.
DeYoung K, Nelson D. Latin America Is Ripe For Trials and Fraud. The Body Hunters: Article V, *The Washington Post*, December 21, 2000.
Flaherty MP, Struck D. Life By Luck Of The Draw. The Body Hunters: Article VI, *The Washington Post*, December 22, 2000.

Revised Declaration of Helsinki 2000.
The Nuremberg Code
The Belmont Report
CFR-45: Protection of Human Subjects, DHHS, Revised June 1991.
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:
Freedman B. Equipoise and the Ethics of Clinical Research. *New England Journal of Medicine* 1987; 317(3):141-145.
Passamani E. Clinical Trials – Are They Ethical? *New England Journal of Medicine* 1991; 324(22):1589-1592.
Hellman S, Hellman D. Of Mice But Not Men: Problems Of The Randomized Clinical Trial. *New England Journal of Medicine* 1991; 324(22): 1585-1589.
Troug R. Randomized Controlled Trials: Lessons from ECMO. *Clinical Research* 1992;40(3):519-527.
Schafer A. The Ethics of the Randomized Clinical Trial. *New England Journal of Medicine* 1982; 307(12):719-724.
Miller F, Emanuel E. The Ethics of Placebo-Controlled Trials – A Middle Ground. *New England Journal of Medicine* 2001; 345(12):915-919.
Freedman B. Placebo-Controlled Trials and the Logic of Clinical Purpose. *IRB* 1990;12(6):1-6.
Beecher H. Surgery As Placebo. *Journal of the American Medical Association* 1961; 176(13):1102-1107.
Temple R, Ellenberg S. Placebo-Controlled Trials and Active-Control Trials in the Evaluation of New Treatments: Ethical and Scientific Issues. *Annals of Internal Medicine* 2000; 133(6):455-463.
Ellenberg S, Temple R. Placebo-Controlled Trials and Active-Control Trials in the Evaluation of New Treatments: Practical Issues and Specific Cases. *Annals of Internal Medicine* 2000; 133(6):464-470.
Rothman J, Michels K. The Continuing Unethical Use of Placebo Controls. *New England Journal of Medicine* 1994; 331(6):394-398.
Weijer C. Placebo-Controlled Trials in Schizophrenia: Are They Ethical? Are They Necessary?. *Schizophrenia Research* 1999;35:211-218.
Levine R. The Use of Placebos in Randomized Clinical Trials. *IRB* 1985; 7(2):1-4.

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:
King N. Defining and Describing Benefit Appropriately In Clinical Trials. *Journal of Law, Medicine & Ethics* 2000;28:332-343.
Meslin E. Protecting Human Subjects from Harm Through Improved Risk Judgements. *IRB* 1990;12(1):7-10.

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

Readings: Jonas H. Philosophical Reflections on Experimenting With Human Subjects. *Philosophical Reflections on Human Experimentation* pp1-31.
Council on Ethical and Judicial Affairs, AMA, Subject Selection for Clinical Trials. *IRB* 1998;20(2):12-15.
Weijer C. Evolving Ethical Issues in Selection of Subjects For Clinical Research. *Cambridge Quarterly* 1996;5:334-345.
Dickert N, Grady C. What's the Price of a Research Subject? Approaches To Payment for Research Participation. *New England Journal of Medicine* 1999; 341(3):198-203.
Office of Inspector General, DHHS. Recruiting Human Subjects: Pressures In Industry-Sponsored Clinical Research; OEI-01-97-00195, June 2000.

3:00-3:30 pm Break

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

Readings: Rothman K. Conflict of Interest: The New McCarthyism In Science. *Journal of the American Medical Association* 1993;269(21):2782-2784.
Thompson D. Understanding Financial Conflicts of Interest. *New England Journal of Medicine* 1993;329(8):573-576.
Thompson D. Ethics in Congress: From Individual to Institutional Corruption. *Corrupt Connections* The Brookings Institute 1995, Pp 124-130.
Emanuel E, Steiner D. Institutional Conflict of Interest. *New England Journal of Medicine* 1995;332(4):262-267.

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

Readings: Clayton EW, et al. Informed Consent for Genetic Research On Stored

Tissue Samples. *Journal of the American Medical Association* 1995;274(22):1786-1792.
National Bioethics Advisory Commission, Research Involving Human Biological Materials: Ethical Issues and Policy Guidance, Executive Summary And Chapter 1, August 1999.
American Society of Human Genetics, ASHG Report: Statement Of Informed Consent for Genetic Research. *American Journal of Human Genetics* 1996;59:471-474.
American Society of Human Genetics, Ad Hoc Committee on DNA Technology; DNA Banking and DNA Analysis: Points To Consider. *American Journal of Human Genetics* 1988;42:781-783.
Merz J, Sankar P, et al. Use of Human Tissues in Research: Clarifying Clinician and Researcher Roles and Information Flows. *Journal of Investigative Medicine* 1997;45(5):252-257.
Glass KC, Weijer C, et al. Structuring the Review of Human Genetics Protocols: Gene Localization and Identification Studies. *IRB* 1996;18(4):1-9.

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

Readings:

Appelbaum P, Roth L, Lidz C, Benson P, Winslade W. False Hopes And Best Data: Consent To Research and The Therapeutic Misconception. *The Hastings Center Report* pp 20-23, April 1987.
Levine R. Informed Consent in Research and Practice. *Archives of Internal Medicine* 1983; 143:1229-1231.
Berg JW, et al. The Legal Requirements for Disclosure and Consent: History and Current Status. From *Informed Consent: Legal Theory and Clinical Practice, 2nd Edition*. pp 41-74. Oxford University Press, New York 2001.
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 "Benefit" Seriously. *The Hastings Center Report* 1998;28(6):38-42.
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 Research, WHO, Geneva 2000.
Lemmens T and Freedman B. Ethics Review for Sale: Conflict of Interest and Commercial Research Review Boards. *The Milbank Quarterly*, 2000; 73:489-507.

2.15-2.45	Break
2:45- 4.30 pm	Mock IRB Reidar K. Lie, MD, PhD NIH
Evening	Concluding Reception and Dinner