

**3<sup>rd</sup> AFRICA CONFERENCE ON ETHICAL ASPECTS OF  
CLINICAL RESEARCH IN DEVELOPING COUNTRIES**

**March 19-21, 2003  
Kampala, Uganda**

**Tuesday, March 18, 2003**

Evening                      Welcome Reception

**Wednesday, March 19, 2003**

8:30-9:00 am              Formal Welcome

9:00-9:45 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.  
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.  
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.

9:45-10:00 am            Case about Randomization and Placebo Controls  
                                  Banson Barugahare, M.Phil.  
                                  Makerere University, Uganda

10:00-10:45 am        The Ethics of Randomization and Placebo Controls  
                                  Reidar K. Lie, MD, PhD  
                                  NIH

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.

10:45-11:00 am        Break

11:00-11:15 am        Case about Risks and Benefits  
                                  Joseph Ochieng , MD

Makerere University, Uganda

11:15-12:00 pm      The Ethics of Risks and Benefits  
Reidar K. Lie, MD, 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.

12:00-1:30 pm      Lunch

1:30-1:45 pm      Case about Recruitment and Incentives  
**TBA**

1:45-2:30 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.

2:30-3:00      Break

3:00-3:45 pm      The Ethics of Conflicts of Interest  
Ambrose Talisuma, MD  
Ministry of Health, Uganda

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.

3:45- 4:00 pm Case about Stored Biological Samples  
4:00-4:45 pm The Ethics of Research with Stored Biological Samples  
Diana Atwine, MD  
JCRC, Uganda

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.

### Thursday, March 20, 2003

8:30-8:45 am Case About Individual Informed Consent  
**TBA**  
8:45-9:30 am The Ethics of Informed Consent  
David Wendler, PhD  
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, 2<sup>nd</sup> 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 - 10.00 am	Break
10:00 - 10:30 am	Case about Community Mobilization and Consent Vickey Tallo, PhD Research Institute for Tropical Medicine, The Philippines
10:30-12:00 pm	Community Mobilization and Consent Hanna Nohynek, MD, PhD, Finland
12:00	Lunch
Afternoon and Evening	Free Time and Optional Excursion

### **Friday, March 21, 2003**

8:30-9:15 am	Function and Performance of Ethical Review Reidar K. Lie, MD, Ph.D 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. <i>The Milbank Quarterly</i> , 2000; 73:489-507.
9:15-10:30 am	Mock IRB Ezekiel Emanuel, MD, PhD NIH
10:30-11	Break

11-11:45	Access to Treatment in Clinical Trials Cathy Slack
11:45-12:30	Access to Treatment in Clinical Trials Henry Richardson, PhD NIH
Readings	Glantz L, Annas G, et al. Research in Developing Countries: Taking “Benefit” Seriously. <i>The Hastings Center Report</i> 1998;28(6):38-42. Shapiro HT, Meslin EM. Ethical Issues In the Design and Conduct of Clinical Trials in Developing Countries. <i>New England Journal of Medicine</i> 2001; 345:139-141 Participants in the 2001 Conference on Ethical Aspects of Research in Developing Countries. Fair Benefits for Research in Developing Countries <i>Science</i> Dec 13 2002: 2133-2134
12:30-13:30	Lunch
13:30-15:00	Community Consent: Should the idea be abandoned? Reidar K. Lie, MD, PhD.
Evening	Concluding Reception and Dinner