

**LATIN AMERICA CONFERENCE ON ETHICAL ASPECTS OF  
INTERNATIONAL COLLABORATIVE RESEARCH**

**June 16-18, 2003  
Iguazu, Argentina**

**Sunday, June 15, 2003**

Evening                      Welcome Reception and Dinner

**Monday, June 16, 2003**

9:00 – 9.45am              Formal Welcome. Presentation of participants

9:45-10:30am              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.  
Henry K. Beecher. Ethics and Clinical Research. *New England Journal of Medicine* 1966: 274: 1354-1360  
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.

10.30-11.00 Break

11:00-12:00 noon The Ethics of Randomization and Placebo Controls  
Reidar K. Lie MD, PhD  
NIH, USA

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.  
Trough 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.

12:00-1:30 pm Lunch

1:30-1:45 pm Case about Risks and Benefits

1:45-2:30 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.**  
                                 Van Luijn et al. Assessment of the risk benefit ratio of phase II cancer clinical trials by Institutional Review Board Members. *Annals of Oncology* 2002; 13: 1307-1313

2:30-3:00 pm            Break

3:00-3:15 pm            Case about Recruitment and Incentives  
                                 **TBA**

3:15-4:00 pm            The Ethics of Subject Recruitment  
                                 Christine Grady, RN, 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.

4:00 – 4:15              Case about conflicts of interest

4:15-5:00 pm            The Ethics of Conflicts of Interest  
                                 Ezekiel 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.

Evening Free

## Tuesday, June 17, 2003

9:00-9:15 am Case About Individual Informed Consent  
**TBA**

9:15-10:00 am The Ethics of Informed Consent  
Florencia Luna, PhD

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.

10:00 - 10.30 am Break

10:30-10:45 am Case about Stored Biological Samples

10:45 -11:30 am 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.

11:30 – 11:45 Case Ethics of Research with children

11:45-12:30 Research with Children  
 David Wendler, PhD  
 NIH, USA

Readings: **Dan Brock. Ethical issues in exposing children to risks in research In *Children as Research Subjects: Science, Ethics and Law*, Michal Grodin and Leonard Glantz, eds. New York, Oxford University Press, pp. 81-101**  
 Sanford Leikin. Minors' assent, consent or dissent to research. *IRB* 1993 15(2) , 1-7  
 Freedman, B, Fuks, A, Weijer C. In loco parentis: Minimal risk as an ethical threshold for research upon children. *Hastings Center Report*, 1993; 32: 13-19

12:30- 14.00 Lunch

14.00-14.15 pm Case about Fair Benefits to Research

14.15 pm-15.00 Fair Benefits to Research  
 Ruth Macklin, PhD  
 Albert Einstein College of Medicine, NY

Solomon R. Benatar, "Distributive Justice and Clinical Trials in the Third World," *Theoretical Medicine* 22: 169-176: 169, 2001.

Solomon R. Benatar, "Justice and International Research: A Response to Reidar K. Lie," Levine, Gorovitz, and Gallagher (eds), 41-50.

D.R. Cooley, "Distributive Justice and Clinical Trials in the Third World," *Theoretical Medicine* 22: 151-167: 2001.

**Glantz, Leonard H., Annas, George J., Grodin, Michael A., and Mariner, Wendy K. 1998. Research in Developing Countries: Taking 'Benefit' Seriously. *Hastings Center Report* 28 (6): 38-42.**

Reidar K. Lie, "Justice and International Research," Levine, Gorovitz, and Gallagher (eds), 27-50.

National Bioethics Advisory Commission 2000. *Ethical and Policy Issues in International Research*, Chapter 4.

Nuffield Council on Bioethics, *The Ethics of Research Related to Healthcare in Developing Countries*, Chapter 9 (London: Nuffield Council on Bioethics, 2002).

David Orentlicher, "Universality and its Limits: When Research Ethics Can Reflect Local Circumstances," *Journal of Law, Medicine & Ethics*, 30 (2002): 403-410.

15.00 – 15.30

Break

15.30 – 16.15

Obligations to provide ancillary care  
Leah Belsky  
NIH, USA

Readings:

Baier A. Trust and Antitrust. *Ethics* 1986; 96:231-60.

**Miller FG, Rosenstein DL, DeRenzo EG. Professional Integrity in Clinical Research. *JAMA* 1998; 280:1449-54.**

Pellegrino ED. Nonabandonment: An old obligation revisited. *Annals of Internal Medicine* 1995; 122(5):377-378.

Evening

Reception and Dinner

**Wednesday, June 18, 2003**

9-9:30 am                      Function and Performance of Ethical Review  
   Reidar K. Lie

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.

9:30-10:45 am                Mock IRB  
   Ezekiel Emanuel, MD, PhD  
   NIH

10:45-11:15 am              Break

11.15-12.00                    Closing and evaluation