



Ethics of Human Subject Research

Holly Taylor
Reading List

Lecture: Introduction to Ethical Analysis

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, "The Belmont Report"(1979)

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady. Johns Hopkins University Press 2003, pp. 33-38.

Ezekiel Emanuel, David Wendler, and Christine Grady. 2000. What Makes Clinical Research Ethical? JAMA 283(20): 2701-11.

Lecture: Cases and Codes

Cases:

Henry K. Beecher, "Ethics and Clinical Research" (1966)

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady. Johns Hopkins University Press 2003. pp. 16-20

Allan Brandt, "Racism and Research: The Case of the Tuskegee Syphilis Study"

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady. Johns Hopkins University Press 2003, pp. 20-23.

Vanessa Northington Gamble, "Under the Shadow of Tuskegee: African Americans and Health Care", American Journal of Public Health, 1997;87(11):1773-1778.

Codes:

"The Nuremberg Code" (1949)

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady. Johns Hopkins University Press 2003, p. 29.

World Medical Association, "Declaration of Helsinki" (1964, rev. 2000)

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady.

Johns Hopkins University Press 2003. pp. 30-32

RECOMMENDED READING

Council for International Organizations of Medical Sciences (CIOMS), in collaboration with the World Health Organization (WHO), "International Ethical Guidelines for Biomedical Research Involving Human Subjects" (2002)

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady. Johns Hopkins University Press 2003, pp. 56-80.

Lecture: Assessment of Risks and Benefits

Charles Weijer, Gary Goldsand and Ezekiel Emanuel. "Protecting Communities in Research: Current Guidelines and Limits of Extrapolation." (1999)

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady. Johns Hopkins University Press 2003, pp. 340-341.

Charles Weijer and Ezekiel Emanuel. "Protecting Communities in Biomedical Research." (2000)

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady. Johns Hopkins University Press 2003, pp. 342-343.

Neal Dickert and Christine Grady. "What's the Price of a Research Subject? Approaches to Payment for Research Participation." (1999)

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady. Johns Hopkins University Press 2003, pp. 179-183.

Ruth Grant and Jeremy Sugarman. 2004. Ethics in Human Subjects Research: Do Incentives Matter? *Journal of Medicine and Philosophy* 29(6): 717-738.

Lecture: Respect for Persons and Informed Consent

Robert J. Levine, "Consent Issues in Human Research" (1995)

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady. Johns Hopkins University Press 2003, pp. 197-201.

Franz J. Ingelfinger, "Informed (But Uneducated) Consent" (1972)

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady. Johns Hopkins University Press 2003, pp. 202-203.

Jay Katz, "Human Experimentation and Human Rights" (1993)

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady. Johns Hopkins University Press 2003, pp. 210-213.

Lecture: Informed Consent and Cultural Relativism

Nicholas A. Christakis. "Ethics are Local: Engaging Cross-Cultural Variation in Ethics Research." (1992)

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady. Johns Hopkins University Press 2003, pp. 358-363.

Macklin R, "International Research and Ethical Imperialism," Chapter 8 in *Against Relativism: Cultural Diversity and the Search for Ethical Universals in Medicine*, New York: Oxford University Press (1999): 188-217

RECOMMENDED READING

Meade, Cathy D. Improving Understanding of the Informed Consent Process and Document. *Seminars in Nursing Oncology* 1999; 15(2): 124-37.

Lecture: Institutional Review Boards

Harold Edgar and David J. Rothman, "The Institutional Review Board and Beyond: Future Challenges to the Ethics of Human Experimentation" (1995)

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady. Johns Hopkins University Press 2003, pp. 436-440.

Department of Health and Human Services, National Institutes of Health, Office for Protection from Research Risks, Code of Federal Regulations, Title 45, Part 46 "Protection of Human Subjects"(1991)

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady. Johns Hopkins University Press 2003, pp. 39-55.

Charles Weijer, Stanley H. Shapiro, Abraham Fuks, Kathleen Cranley Glass and Myriam Skrutkowska, "Monitoring Clinical Research, An Obligation Unfulfilled" (1995)

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady. Johns Hopkins University Press 2003. pp. 425-429.

Lecture: Protection and Access

Dresser, Rebecca, "Wanted. Single, White Male for Medical Research"(1992)

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited

by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady. Johns Hopkins University Press 2003, pp. 166-171.

Charles Weijer and Robert A. Crouch, "Why Should we Include Women and Minorities in Randomized Controlled Trials?" (1999)

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady. Johns Hopkins University Press 2003, pp. 171-174.

The National Bioethics Advisory Commission. "Research Involving Persons with Mental Disorders that May Affect Decision-Making Capacity."

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady. Johns Hopkins University Press 2003, pp. 229-233.

RECOMMENDED

Jonathan Moreno. "Convenient and Captive Populations." (1998)

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady. Johns Hopkins University Press 2003, pp. 258-262.

Carl Cohen. "Medical Experimentation on Prisoners." (1978)

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady. Johns Hopkins University Press 2003, pp. 262-266.

Lecture: Justice in Research Ethics: International Issues

Council for International Organizations of Medical Sciences (CIOMS), in collaboration with the World Health Organization (WHO), "International Ethical Guidelines for Biomedical Research Involving Human Subjects" (2002)

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady. Johns Hopkins University Press 2003, pp. 56-80.

Richard Love and Norman Fost. "Ethical and Regulatory Challenges in a Randomized Controlled Trial of Adjuvant Treatment in Vietnam."

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady. Johns Hopkins University Press 2003, pp. 363-367.

Lecture 13: Research Ethics and Human Rights

Christopher Beyrer and Nancy Kass. Human rights, Politics and Research Ethics Review. *Lancet* 2002; 360(9328):246-51.

Additional Recommended Readings

Ethical Issues in Study Design

Samuel Hellman and Deborah S. Hellman, "Of Mice But not Men: Problems of the Randomized Clinical Trial" (1991)

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady. Johns Hopkins University Press 2003, pp.113-116.

Benjamin Freedman, "Equipoise and the Ethics of Clinical Research" (1987)

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady. Johns Hopkins University Press 2003. pp. 117-120.

Peter Lurie and Sidney Wolfe. "Unethical Trials of Interventions to Reduce Perinatal Transmission of the Human Immunodeficiency Virus in Developing Countries." (1997).

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady. Johns Hopkins University Press 2003, pp. 343-346.

Robert A. Crouch and John D. Arras. "AZT Trials and Tribulations." (1998).

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady. Johns Hopkins University Press 2003, pp. 348-353.

Privacy and Confidentiality

Office for Protection from Research Risks. "Privacy and Confidentiality" in Protecting Human Research Subjects: Institutional Review Board Guidebook (1993).

Jeffrey Botkin. "Protecting the Privacy of Family Members in Survey and Pedigree Research." (2001)

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady. Johns Hopkins University Press 2003, pp. 302-305.

HIPAA and Research

Helpful Reference: Clinical Research and the HIPAA Privacy Rule.
http://privacyruleandresearch.nih.gov/clin_research.asp

Conflict of Interest

Dennis F. Thompson. "Understanding Conflicts of Interest." (1993)

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady. Johns Hopkins University Press 2003, pp. 375-377.

Baruch Brody. "Conflicts of Interest and the Validity of Clinical Trials." (1996)

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady. Johns Hopkins University Press 2003, pp. 378-381.

Case Study Lecture: Pediatrics

Carol Tauer. "The NIH Trials of Growth Hormone for Short Stature."(1994)

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady. Johns Hopkins University Press 2003, pp. 240-247.

Benjamin Freedman, Abraham Fuks, and Charles Weijer. "In Loco Parentis: Minimal Risk as an Ethical Threshold for Research Upon Children." (1993)

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady. Johns Hopkins University Press 2003, pp. 247-252.

Sanford Leiken. "Minor's Assent, Consent or Dissent to Medical Research." (1993)

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady. Johns Hopkins University Press 2003, pp. 252-258.

Case Study Lecture: Genetics

Kathleen Cranley Glass, Charles Weijer, Roberta M. Palmour, et al. "Structuring the Review of Human Genetics Protocols: Gene Localization and Identification Studies" (1996)

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady. Johns Hopkins University Press 2003, pp. 285-291.

Kathleen Cranley Glass, Charles Weijer, Trudo Lemmens et al. "Structuring the Review of Human Genetics Protocols, Part II: Diagnostic and Screening Studies" (1997)

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady. Johns Hopkins University Press 2003, pp. 291-297.

The American Society of Human Genetics. "Statement on Informed Consent for Genetic Research" (1996)

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited

by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady. Johns Hopkins University Press 2003, pp. 305-307.

Ellen Wright Clayton, Karen K. Steinberg, Muin J. Khoury et al. "Informed Consent for Genetic Research on Stored Tissue Samples" (1995)

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady. Johns Hopkins University Press 2003, pp. 308-311.

Eric T. Juengst. "Groups as Gatekeepers to Genomic Research: Conceptually Confusing, Morally Hazardous, and Practically Useless" (1998)

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady. Johns Hopkins University Press 2003, pp.337-340.

Charles Weijer, Gary Goldsand, Ezekiel Emanuel. Protecting Communities in Research: Current Guidelines and Limits of Extrapolation" (1999)

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Edited by: Ezekiel Emanuel, Robert Crouch, John Arras, Jonathan Moreno and Christine Grady. Johns Hopkins University Press 2003, pp.340-341.

Research After Natural/Man-made Disasters

Jonathan Moreno. Detainee Ethics: Terrorists and Research Subjects. The American Journal of Bioethics 2003; 3(4): W32-33.

Jennifer Learning. Ethics of Research in Refugee Populations. The Lancet 2001; 357: 1432-3