

COURSE SYLLABUS

Date	Topic	Instructor
January 24	Overview/Introduction/Requirements	Adkinson
	Introduction and Historical Review	Fost
January 31	Consent	Fost
February 7	Regulation of Clinical Research	Starklauf
February 14	Ethical Issues in the Design of Clinical Trials	Goodman
	RCTs: Equipoise and the Magic of .05 and Using a Person as a Means to an End	Fost
February 21	Good Clinical Practices for Clinical Investigation	Rocco
	Course Evaluation	
February 28	Special Populations: Children, Fetuses, and Prisoners	Fost
March 6	Confidentiality and Privacy Issues: Research on Medical Records and Stored Samples	Fost
	Ethical Obligations to Disclosure	Fost
March 13	Cultural Issues: Are Ethical Principles Relative?	Fost
	Research in Emergency Settings	Fost

Ethics & Regulation of Clinical Investigation
SOC1 – 3rd Quarter, 1999-00

(Ethics doc; revised 01/19/00)

Ethical and Regulatory Issues in Clinical Trials
Johns Hopkins Medical Institutions
January 24 – March 13, 2000

(Please note that at some point during the course, participants will need to read Appendix 1, “Department of Health and Human Services Rule and Regulations 45 CFR 46, pp. 393-412 in the Robert J. Levine book, *Ethics and Regulation of Clinical Research*, 2nd ed.)

Monday, January 24, 2000

Session 1: Overview/Introduction/Requirements
Introduction and Historical Review

5:30 Dr. N. Franklin Adkinson
5:45 Dr. Norman Fost
6:45 Break
7:00 Dr. Norman Fost

Readings

Chapter 2, “Ethical Norms and Procedures,” in Levine, Robert, *Ethics and Regulation of Clinical Research* (Yale University Press, 1988, pp. 19-35).

Fost, Norman. Ethical dilemmas in medical innovation and research: Distinguishing experimentation from practice. *Seminars in Perinatology* 1998 22 3(June): 223-232.

Ivy, Andrew, “Nazi War Crimes of a Medical Nature,” in Reiser, Stanley, Dyck, Arthur and Curran, William, eds., *Ethics in Medicine: Historical Perspectives and Contemporary Concerns* (The MIT Press, 1977, pp. 267-272).

“The Nuremberg Code,” in Reiser, Stanley, Dyck, Arthur and Curran, William, eds., *Ethics in Medicine: Historical Perspectives and Contemporary Concerns* (The MIT Press, 1977, pp. 272-273).

“How and by Whom Should Research Policy Be Formulated?” In Katz, Jay, *Experimentation with Human Beings* (Russell Sage Foundation, 1972, pp. 10-11).

Beecher, Henry, “Ethics and Clinical Research,” in Reiser, Stanley, Dyck, Arthur and Curran, William, eds., *Ethics in Medicine: Historical Perspectives and Contemporary Concerns* (The MIT Press, 1977, pp. 288-293).

Supplementary Reading: Jonas, Han, “Philosophical Reflections on Experimenting with Human Subjects, in Beauchamp, Tom and Walters, LeRoy, eds., *Contemporary Issues in Bioethics* (Wadsworth Publishing Company, 1989, pp. 432-440).

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Monday, January 31, 2000

Session 2: Consent

5:30 Dr. Norman Fost
6:45 Break
7:00 Dr. Norman Fost

Readings

Chapter 5, “Informed Consent,” in Levine, Robert, *Ethics and Regulation of Clinical Research* (Yale University Press, 1988, pp. 95-153).

- Fost, Norman, "When Patients Can't Provide Informed Consent." *The Chronicle of Higher Education*, A48, January 24, 1997
- Cardozo, Benjamin, "From Schloendorff v. New York Hospital," in Gorovitz, S., et al., *Moral Problems in Medicine* (Prentice-Hall, 1983, pp. 159).
- Roth Loren H, Meise Alan and Lidz, Charles W., "Tests of Competency to Consent to Treatment," in Gorovitz, S., et al., *Moral Problems in Medicine* (Prentice-Hall, 1983, pp. 172-179).
- Ingelfinger, Franz J., "From Informed (but Uneducated) Consent," in Gorovitz, S., et al., *Moral Problems in Medicine* (Prentice-Hall, 1983, pp. 179-181).
- Robinson, George and Meraz, Abraham, "Informed Consent: Recall by Patients Tested postoperatively," in Gorovitz, S., et al., *Moral Problems in Medicine* (Prentice-Hall, 1983, pp. 182-186).

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Monday, February 7, 2000

Session 3: Regulation of Clinical Research

- 5:30 Barbara Starklauf, MAS
 6:45 Break
 7:00 Barbara Starklauf, MAS

Readings

- Turkington, Richard C. Medical record confidentiality law, scientific research, and data collection in the information age. *Journal of Law, Medicine & Ethics* 1997; 25:113-129.
- Lind S.E. Financial Issues and Incentives Related to Clinical Research and Innovative Therapies in Vanderpool, Harold Y, ed, *The Ethics of Research Involving Human*, 185-201.
- Melton, L. Joseph, III. The threat to medical-records research. *N Engl J Med* 1997; 337(20):1466-1470.
- Shimm, David S. and Spece Roy G., Jr. An introduction to conflicts of interest in clinical research. *Clinical Research* 361-375.

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Monday, February 14, 2000

Session 4: Ethical Issues in the Design of Clinical Trials
 RCTs: Equipoise and the Magic of .05 and Using a Person as a Means to an End

- 5:30 Dr. Norman Fost (introduction)
 6:00 Dr. Stephen Goodman
 6:45 Break
 7:00 Dr. Norman Fost

Readings

- Chapter 8, "Randomized Clinical Trials," in Levine, Robert, *Ethics and Regulation of Clinical Research* (Yale University Press, 1988, pp. 185-212).

- Fost, Norman and Farrell, Philip M., "A Prospective Randomized Trial of Early Diagnosis and Treatment of Cystic Fibrosis: A Unique Ethical Dilemma." *Clinical Research*, 37:3, September 1989, pp. 495-500).
- Chalmers, Thomas, and Nadas, Alexander, "Randomized the First Patient!" *The New England Journal of Medicine*, 296:2, January 13, 1977, pp. 107).
- Truog, Bob, "Randomized Controlled Trials: Lessons from ECMO." *Clinical Research*, 40:3, October, 1992, pp. 519-527.
- Pocock, Stuart, "When to Stop a Clinical Trial." *British Medical Journal*, 305:6847, July 25, 1992, pp. 235-240.
- Freedman, Benjamin, "Equipose and the Ethics of Clinical Research," in Arras, John and Rhoden, Nancy, eds., *Ethical Issues in Modern Medicine* (Mayfield Publishing, 1989, pp. 452-457).

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Monday, February 28, 2000

Session 6: Special Populations: Children, Fetuses, and Prisoners

5:30 Dr. Norman Fost
6:45 Break
7:00 Dr. Norman Fost

Readings

- Chapter 10, "Children," in Levine, Robert, *Ethics and Regulation of Clinical Research* (Yale University Press, 1988, pp. 235-256)
- Chapter 13, "The Fetus and the Embryo," in Levine, Robert, *Ethics and Regulation of Clinical Research* (Yale University Press, 1988, pp. 297-320)
- Charo, Alta, "Protecting Us to Death: Women, Pregnancy, and Clinical Research Trials." *Saint Louis University Law Journal*, 38, 135, pp. 135-167)
- Fost, Norman, "Maternal-Fetal Conflicts: Ethical and Legal Considerations." *Annals of the New York Academy of Sciences*, Volume 562, June 30, 1989, pp. 248-254).
- Supplementary Reading: "Report of the Human Fetal Tissue Transplantation Research Panel," Consultants to the Advisory Committee to the Director, National Institutes of Health, December 1988, pp. 1-16 and pp. 27-71.

**Johns Hopkins Medical Institutions
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Monday, March 6, 2000

Session 7: Confidentiality and Privacy Issues: Research on
Medical Records and Stored Samples
Ethical Obligations to Disclosure

5:30 Dr. Norman Fost
6:45 Break
7:00 Dr. Norman Fost

Readings

- “The Hippocratic Oath,” in Arras, John d. and Steinbock, Bonnie, *Ethical Issues in Modern Medicine* (Mayfield Publishing Company, 1995, pp. 54).
- Chapter 7, “Privacy and Confidentiality,” in Levine, Robert, *Ethics and Regulation of Clinical Research* (Yale University Press, 1988, pp. 163-183).
- Kelsey, Karl T., Li, Frederick P., Polli, Anita M., and Clayton, Ellen Wright, “Informed Consent for Genetic Research.” *JAMA*, 275:14:1085-1086.
- Billings, Paul R., et al., “Discrimination as a Consequence of Genetic Testing.” *American Journal of Human Genetics*, 50:3:476-482, 1992 March (copy to follow).
- Clayton EW, Steinberg KK, Khoury MJ et al. Informed consent for genetic research on stored tissue samples. *JAMA* 274(22):1786-1792,1995(Dec 13).
- Letters from Kelsey KT; Li FP and Polli AM. Informed consent for genetic research (letter). *JAMA* 275(14):1085, 1996(Apr 10). Reply by Clayton EW. *JAMA* 275(14):1086, 1996(Apr 10).
- Knoppers BM, Laberge CM. Research and stored tissues: persons as sources, samples as person? *JAMA* 274(22):1806-1807,1995(Dec 13).
- Melton LJ. The threat to medical records research. *New Eng J Med* 337(20):1466-1470, 1997 (Nov 13)
- Veatch, RM. Consent Confidentiality and Research. *New Eng J Med* 33(12): 869-870.
- Giardiello, FM, Brensinger JD, Petersen, GM, Luce MC, Hyland LM, Bacon JA, Booker SV, Parker RD, Hamilton, SR. The use and interpretation of commercial APC gene testing for Familial adenomatous polyposis. *New Eng J Med* 1997336(12):823-827.

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Monday, February 21, 2000

Session 5: Good Clinical Practices for Clinical Investigation
Course Evaluation

5:30 L Rocco
6:45 Break
7:00 L. Rocco

Readings

To follow

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Monday, March 13, 2000

Session 8: Cultural Issues: Are Ethical Principles Relative?
Research in Emergency Settings

5:30 Dr. Norman Fost
6:45 Break
7:00 Dr. Norman Fost

Readings

- Angell, Marcia, "The Ethics of Clinical Research in the Third World." *New England Journal of Medicine* 337:12:847-849
- Lurie, Peter and Wolfe, Sidney, "Unethical Trials of Interventions to Reduce Perinatal Transmission of the Human Immunodeficiency Virus in Developing countries." *New England Journal of Medicine*, 337:12:853-855.
- Varmus, Harold and Satcher, David, "Ethical Complexities of Conducting Research in Developing Countries." *New England Journal of Medicine*, 337:14:1003-1005.
- Love, Richard R. and Fost, Norman C., "Ethical and Regulatory Challenges in a Randomized Control Trial of Adjuvant Treatment for Breast Cancer in Vietnam." *Journal of Investigative Medicine*, 45:9, October 1997, pp. 423-431.
- Council for International Organizations of Medical Sciences (CIOMS) and the World Health Organization (WHO), "International Ethical Guidelines for Biomedical Research Involving Human Subjects," (World Health Organization, Geneva, Switzerland, 1993, pp. 1-52).

Supplementary Reading:

- Barry, Michele and Molyneux, Malcolm, "Ethical Dilemmas in Malaria Drug and Vaccine Trials: A Bioethical Perspective." *Journal of Medical Ethics*, 1992, 19, pp. 189-192.
- Ekunwe, Ebun O. and Kessel, Ross. *Hastings Center Report*, June 1984, pp. 22-24.
- Maurice, John, "Malaria Vaccine Raises a Dilemma." *Science*, 267, January 20, 1995, pp. 320-323.
- Christakis, Nicholas a., "Ethics are Local" Engaging Cross-Cultural Variation in the Ethics for Clinical Research." *Soc. Sci. Med.*, 35:9, 1992, pp. 1079-1091.
- Christakis, Nicholas A. and Panner, Morris J., "Existing International Ethical Guidelines for Human Subjects Research: Some Open Questions." *Law, Medicine & Health Care*, 19:3-4, Fall-Winter, 1991, pp. 214-221.