Ethical and Regulatory Aspects of Clinical Research

NIH CC Department of Bioethics

Wednesdays, September 24- November 12, 2008

September 24, 2008	**Session 1: History, Guidance, and Framework for Ethical Clinical Research**
8:30-8:40	Pre-test
8:40-9:20	**Intro and Framework for the Ethics of Research with Human Subjects** Ezekiel Emanuel, M.D. Ph.D. NIH Clinical Center Dept of Bioethics
9:20-9:30	**Discussion**
9:30- 10:15	**History, Scandals and Tragedies: Beecher, Tuskegee, Willowbrook and the Rest** Susan E. Lederer Ph.D. University of Wisconsin
10:15- 10:25	**Discussion**
10:25-10:40	**Break**
10:40-11:20	**Do the Codes Apply to My Research? Nuremberg, Helsinki, the Belmont Report, CIOMS, and the Common Rule** Christine Grady, PhD NIH Clinical Center Dept of Bioethics
11:20-11:30	**Discussion**
October 1, 2008	**Session 2: IRB review ; Subject Selection and Recruitment**
8:30-9:15	**Purpose and Function of IRBs: Successes and Current Challenges** Jerry Menikoff, MD, JD Chief, OHSR/NIH
9:15-9:25	**Discussion**
9:25-10:10	**Fair Subject Selection** Dave Wendler PhD NIH Clinical Center Dept of Bioethics

1**0:10-10:20**	**Discussion**
10:20-10:35	**Break**
10:35-11:20	**Recruitment, Undue influence and Coercion** Alan Wertheimer, Ph.D. NIH Clinical Center Dept of Bioethics
11:20-11:30	**Discussion**
October 8, 2008	**Session 3: Ethical issues in study design and Conflicts of Interest**
8:30-9:15	**Ethics of Phase I Oncology Research and Consent template** Ezekiel Emanuel MD PhD NIH Clinical Center Dept of Bioethics
9:15-9:25	**Discussion**
9:25- 10:10	**Ethics of Randomized Clinical Trials: Clinical Equipoise** Robert Truog, M.D. Professor of Anesthesiology & Medical Ethics Harvard Medical School
10:10- 10:20	**Discussion**
10:20- 10:35	**Break**
10:35-11:20	**Conflicts of Interest** Cary Gross MD Yale University School of Medicine
11:20-11:30	**Discussion**
October 15, 2008	**Session 4: Placebo Controls and Research with Children**
8:30-9:15	**Ethics of Placebo Controlled Trials** Frank Miller, Ph.D. Department of Bioethics CC/NIH
9:15-9:25	**Discussion**
9:25- 10:10	**Ethical issues in research with children** Lainie Ross MD PhD University of Chicago School of Medicine

10:10- 10:20	**Discussion**
10:20- 10:35	**Break**
10:35- 11:30	**Mock IRB**
<u>October 22, 2008</u>	**Session 5: <u>Risks and Benefits; and special populations in research</u>**
8:30-9:15	**Assessment of Risks and Benefits** Dave Wendler PhD NIH Clinical Center Dept of Bioethics
9:15-9:25	**Discussion**
9:25-10:10	**Clinical Research with pregnant women** Maggie Little PhD Georgetown University
10:10-10:20	**Discussion**
10:20-10:35	**Break**
10:35- 11:30	**Research Involving Persons at Risk for Impaired Decision-Making** Don Rosenstein, M.D. National Institutes of Mental Health
<u>October 29, 2008</u>	**Session 6: <u>Informed Consent</u>**
8:30-9:15	**Informed Consent: Ethics and Contemporary Issues** John Arras PhD University of Virginia
9:15-9:25	**Discussion**
9:25- 10:10	**The Quality of Informed Consent: What do the data show?** Christine Grady PhD Department of Bioethics, CC/NIH
10:10- 10:20	**Discussion**
10:20- 10:35	**Break**
10:35- 11:30	**Participant panel**

November 5, 2008	**Session 7: Ethical issues in International Research**
8:30- 9:15	**Exploitation** Alan Wertheimer PhD NIH Clinical Center Dept of Bioethics
9:15-9:25	**Discussion**
9:25- 10:10	**Special issues in international research** Reidar Lie MD PhD NIH Clinical Center Dept of Bioethics
10:10-10:20	**Discussion**
10:20- 10:35	**Break**
10:35- 11:20	**International research ethics: Informed consent and post trial considerations** Seema Shah JD NIH Clinical Center Dept of Bioethics
11:20- 11:30	**Discussion**
November 12, 2008	**Session 8: Genetics and Stored Tissue**
8:30-9:15	**Ethical Issues in Genetics Research** Ben Wilfond MD Childrens Hospital Seattle
9:15-9:25	**Discussion**
9:25-10:10	**Ethical Issues in the Use of Stored Tissue** Sara Chandros Hull, Ph.D. NHGRI and Dept of Bioethics
10:10-10:20	**Discussion**
10:20- 10:35	**Break**
10:35 -11:15	**Case discussion/Mock IRB** Please read case provided on the CD
11:15- 11:30	**Post tests and evaluations**