**Course Readings:**
Readings are listed under each topic below. The list includes both readings assigned for each session and some additional recommendations.
Assigned readings are found either in the following course textbook (listed by chapter) or on the supplemental course CD provided.

**Course Textbook:**

**October 1, 2014  Session 1: History, Guidance, and Framework for Ethical Clinical Research**

8:30-8:40 Pre-test and Introduction

8:40-9:30 Framework for the Ethics of Research with Human Subjects
Christine Grady RN PhD
NIH Clinical Center Dept of Bioethics

9:30-9:40 Discussion

**Readings: (book)**
Chapter 5. The Nuremberg Code
Chapter 6. The Declaration of Helsinki
Chapter 7. The Belmont Report

**Readings (CD):**

9:40-10:00 Break

10:00-10:50 History, Scandals and Tragedies: Beecher, Tuskegee, Willowbrook and the Rest
Susan E. Lederer PhD
Robert Turell Professor of Medical History and Bioethics, Chair
University of Wisconsin

10:50-11:00 Discussion
Readings: (book)
Chapter 1. Faden et al. “US medical researchers, the Nuremberg Doctors Trial, and the Nuremberg Code.”
Chapter 4. Brandt, A. “Racism and Research: The case of the Tuskegee Syphilis Study.”

Readings: (CD)

11:00-11:30 The DHHS Secretary’s Advisory Committee for Human Research Protections
Jeffrey R. Botkin, MD, MPH
Chair, SACHRP
Professor of Pediatrics and Medical Ethics
Associate Vice President for Research
University of Utah

October 8, 2014 Session 2: IRB review, Randomized Clinical Trials, and Research with Children

8:30-9:15 Purpose and Function of IRBs: Successes and Current Challenges
Richard Cannon MD
Chair, NHLBI IRB

9:15-9:25 Discussion

Chapter 8. The Common Rule

Readings: (CD)


Emanuel E, Menikoff J. Reforming the Regulations Governing Research with Human Subjects NEJM ; 2011 Jul 25

9:25-10:10 Ethics of Randomized Clinical Trials: Clinical Equipoise
Robert Truog MD
10:10-10:20 Discussion

Readings: (book)
Chapter 11. Levine R. "Research and practice,"
Chapter 14. Freedman B. “Equipoise and the ethics of clinical research.”
Chapter 15. Truog R. “Randomized Controlled Trials: Lessons from ECMO

10:20-10:45 Break

10:45-11:20 Research with Children
Sara Goldkind MD
Research & Clinical Bioethics Consultant

11:20-11:30 Discussion

Readings: (book)
Chapter 42. Freedman B, Fuks A, Weijer C. "In loco parentis: Minimal risk as an ethical threshold for research upon children,”
Chapter 41. Tauer C. “The NIH trials of growth hormone for short stature.”
Chapter 43. Leikin S. “Minors assent, consent, or dissent to medical research.”

October 15, 2014 Session 3: Fair Subject Selection

8:30-9:10 Fair Subject Selection
Dave Wendler PhD
NIH Clinical Center Department of Bioethics

9:10-9:20 Discussion

Readings: (CD)
Wendler D. When should ‘riskier’ subjects be excluded from research? Kennedy Institute of Ethics Journal 1998; 8:307-327.
Rid A, Emanuel EJ. Ethical considerations of experimental interventions in the Ebola outbreak. Published Online August 21, 2014 http://dx.doi.org/10.1016/S0140-6736(14)61315-5
9:20- 10:05    Coercion and Undue Inducement
Alan Wertheimer PhD
NIH Clinical Center Department of Bioethics

10:05-10:15    Discussion

Readings: (book)
Chapter 27, Dickert N, Grady C. “What’s the price of a research subject”?

Readings: (CD)

Supplementary readings
Chapter 28, Lemmens T, Elliott C. “Justice for the professional guinea pig”
Chapter 29, McNeill P. “Paying people to participate: why not?”

10:15-10:30    Break

10:30-11:30    MOCK IRB

Readings: (CD)
Protocol and consent forms

October 22, 2014    Session 4: Risks and Benefits, Research involving persons at risk for impaired decision making

8:30-9:15    Risks and Benefits
Dave Wendler, PhD
NIH Clinical Center Department of Bioethics

9:15-9:25    Discussion

Readings: (book)
Chapter 42. Freedman B, Fuks A, Weijer C. “In loco parentis: Minimal risk as an ethical threshold for research upon children.

Readings: (CD)
King N, Defining and Describing Benefit Appropriately in Clinical Trials
Rid A; Emanuel E; Wendler D Evaluating the Risks of Clinical Research.
JAMA. 2010; 304(13):1472-1479


**9:25- 10:10** Research Involving Persons at Risk for Impaired Decision-Making
Scott Kim MD PhD
NIH Clinical Center Department of Bioethics

**10:10- 10:20** Discussion

**Readings:** *(book)*
Chapter 38. National Bioethics Advisory Commission, excerpts from “Research Involving Persons with Mental Disorders That May Affect Decision-making Capacity”

**Readings:** *(CD)*

**Supplementary readings**

**10:20- 10:30** Break

**10:30- 11:30** Participant panel

**October 29, 2014** Session 5: Informed Consent, Comparative Effectiveness Trials, and Conflicts of Interest

**8:30-9:15** Informed Consent
Christine Grady RN PhD
NIH Clinical Center Department of Bioethics

**9:15-9:25** Discussion

**Readings**
Chapter 31 Inglefinger, F. Informed (but uneducated) consent
Chapter 32 Freedman, B. A moral theory of informed consent
Chapter 33. Truog R, et al. Is Informed Consent Always Necessary for Randomized, Controlled Trials?
Supplementary readings not on CD


9:25- 10:10  Comparative Effectiveness Trials and Informed Consent
Frank Miller PhD
NIH CC Department of Bioethics

10:10- 10:20  Discussion

Readings CD


Kim S and Miller F. Informed Consent for Pragmatic Trials — The IntegratedConsent Model *N ENGL J MED* 370;8: 769-772

10:20-10:35  Break

10:35- 11:20  Conflicts of Interest
Steve Joffe MD MPH
Associate Professor of Medical Ethics and Health Policy
University of Pennsylvania

11:20-11:30  Discussion

Readings: (book)
Chapter 72. Thompson D. “Understanding Financial Conflicts of Interest”
Chapter 75. Martin, JB and Kasper, DL. "In whose best interest? Breaching the academic-industrial wall."

Readings (CD)

Krumholz HM et al. What have we learnt from Vioxx? *BMJ* 2007; 334:120-123

**Nov 5, 2014  Session 6: Ethics of International Research**

8:30-9:15  Exploitation
Alan Wertheimer PhD
NIH Clinical Center Department of Bioethics

9:15-9:25  Discussion

9:25 - 10:10  Post trial Obligations and reasonable availability
Seema Shah JD
NIH Clinical Center Department of Bioethics and NIAID Division of AIDs

10:10-10:20  Discussion

10:20-10:35  Break

10:35-11:20  Case discussion
Joe Millum PhD
NIH Clinical Center Department of Bioethics and Fogarty International Center

11:20-11:30  Discussion

Readings:

Readings: (CD)
Excerpts from CIOMS

Supplementary
Chapter 65. Lurie P & Wolfe S. “Unethical Trials of Interventions to Reduce Perinatal Transmission of the Human Immunodeficiency Virus in Developing Countries”

Chapter 68. Participants in the 2001 conference on Ethical Aspects of Research in Developing Countries. Fair benefits for Research in Developing countries.

**November 12, 2014  Session 7: Ethics and Genetics Research**

**8:30-9:15**  Ethical Issues in the Use of Stored Tissue and Data  
Sara Chandros Hull PhD  
NHGRI and NIH Clinical Center Department of Bioethics

**9:15-9:25**  Discussion

**Ethical Issues in the Use of Stored Tissue and Data**

**Readings: (CD)**  


**9:25-10:10**  How to think about Incidental Findings  
Ben Berkman JD  
NHGRI and NIH Clinical Center Department of Bioethics

**10:10-10:20**  Discussion

**Readings: (CD)**  

American College of Medical Genetics and Genomics, ACMG Recommendations for Reporting of Incidental Findings in Clinical Exome and Genome Sequencing, available at: [https://www.acmg.net/docs/ACMG_Releases_Highly-Anticipated_Recommendations_on_Incidental_Findings_in_Clinical_Exome_and_Genome_Sequencing.pdf](https://www.acmg.net/docs/ACMG_Releases_Highly-Anticipated_Recommendations_on_Incidental_Findings_in_Clinical_Exome_and_Genome_Sequencing.pdf)


10:20- 10:35 Break

10:35- 11:20 Case

11:20- 11:30 Post tests and evaluations