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

Course Textbook:

September 28, 2016 Session 1: History and Framework for Ethical Clinical Research

8:30-8:40 Introduction

8:40-9:20 Framework for the Ethics of Research with Human Subjects
Christine Grady RN PhD
NIH Clinical Center Department of Bioethics

9:20-9:30 Discussion

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

Readings (CD):

9:30-9:45 Break

9:45- 10:30 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

10:30- 10:40 Discussion
Readings: (book)

Readings: (CD)


Supplementary:
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.”.

10:40- 11:20 Changes to the Common Rule
Ivor Pritchard, OHRP

11:20-11:30 Discussion

Readings:

October 5, 2016 Session 2: IRBs, Fair subject selection, and participant perspectives

8:30-9:110 Purpose and Function of IRBs: Successes and Current Challenges
Sara Hull PhD
Chair, NHGRI IRB

9:10-9:20 Discussion

Readings: Textbook
Chapter 8. The Common Rule
Readings: (CD)


9:20-10:15 Fair Subject Selection
Dave Wendler PhD
NIH Clinical Center Department of Bioethics

10:05-10:15 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](http://dx.doi.org/10.1016/S0140-6736(14)61315-5)


10:15-10:30 Break

10:30-11:30 Panel of research perspectives

October 12- NO CLASS –YOM KIPPUR

October 19, 2016 Session 3: Risk and Benefits, Research with Children, and Research with Pregnant Women

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 Ethics of Research with Children
Robert “Skip” Nelson MD
Director of Ethics and Deputy Director, Office of Pediatric Therapeutics
US Food and Drug Administration

10:10-10:20 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.”

Readings (CD):

10:20-10:35 Break

10:35-11:20 Ethics of Research with Pregnant women
Maggie Little PhD
Director of the Kennedy Institute of Ethics, and Associate Professor of Philosophy

11:20-11:30 Discussion

Readings (book)
Chapter 24. Dresser, R. Wanted: Single, White Male for Medical Research
Chapter 25. Weijer, C and Crouch R. Why Should We Include Women and Minorities in Randomized Controlled Trials.

Readings (CD):

October 26, 2016  Session 4: Informed consent, research with adults with impaired decision making, and the ethics of research with big data

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

9:15-9:25  Discussion

Readings (book)
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?

Readings (CD):


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
NIH Policy M87-4 Research involving adults who are or may be unable to consent. Available at http://cc-internal.cc.nih.gov/policies/PDF/M87-4.pdf

Readings: (CD)

Supplementary readings

10:20-10:35 Break

10:35-11:20 Research with Big Data
Jeff Kahn PhD
Berman Institute of Bioethics, JHU

11:20- 11:30 Discussion

Readings (CD):


Nov. 2, 2016 Session 5: Ethics of Randomized Trials, Research with Stored Tissue and Data, and Conflicts of Interest

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

9:25 - 10:10  Ethics of Randomized Clinical Trials: Clinical Equipoise
Robert Truog MD
Professor of Medical Ethics, Anaesthesiology & Pediatrics at Harvard Medical School
Director of the Center for Bioethics Harvard Medical School

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- 10:35  Break

10:35-11:20  Conflicts of Interest
Steve Joffe MD MPH
Deputy Director Medical Ethics and Health Policy
University of Pennsylvania Perelman School of Medicine

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)
Loewenstein G, Sah S, Cain D. The Unintended consequences of conflict of interest disclosure JAMA 2012; 307(7): 669-70


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


November 9, 2016   Session 6: International Research Ethics and Mock IRB

8:30-9:15   Ethical Issues in International research: Standard of Care
Reidar Lie MD PhD
University of Bergen

9:15-9:25   Discussion

9:25-10:10   Ethical issues in International Research: Post-trial obligations
Joe Millum PhD
NIH Clinical Center Department of Bioethics and Fogarty International Center

10:10-10:20   Discussion

Readings:

Readings (book)
Chapter 68. Fair benefits for Research in Developing countries.

Readings: (CD)
Excerpts from CIOMS


10:20-10:35   Break

10:35-11:20   Community Engagement and Research with Alaskan Natives
Stacy Rasmus
Billy Charles
Readings (CD):


November 16, 2016 Session 7: Ethics of Pragmatic Trials and Incidental Findings

8:30-9:15 Ethics of Pragmatic trials
Scott Kim MD PhD
NIH Clinical Center Department of Bioethics

9:15-9:25 Discussion

Readings:


Collaboratory Case Study, available at ➤https://www.nihcollaboratory.org/demonstration-projects/Pages/regulatory-ethics.aspx

9:25-9:45 Break

9:45-10:20 How to think about Incidental Findings
Ben Berkman JD MPH
NHGRI Bioethics Core and NIH Clinical Center Department of Bioethics

10:20-10:30 Discussion

Readings

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

Catherine Gliwa & Benjamin E. Berkman, Do Researchers Have an Obligation to Actively Look for Genetic Incidental Findings? The American Journal of Bioethics, 13:2, 32-42 (2013)

10:3- 11:30 Case Discussion
Ben Berkman