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:

September 30, 2015  Session 1: History and Framework for Ethical Clinical Research

8:30-8:40  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):

9:40-9:55  Break

9:55-10:40  History, Scandals and Tragedies: Beecher, Tuskegee, Willowbrook and the Rest
Susan E. Lederer PhD
10:40- 10:50  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)

10:50- 11:30  Update on Federal Regulations
Carrie Wolinetz PhD
Director, NIH Office of Science Policy

Notice of Proposed Rulemaking (NPRM) available at

October 7, 2015  Session 2: Fair subject selection, community engagement and voices

8:30-9:15  Fair Subject Selection
Dave Wendler PhD
NIH Clinical Center Department of Bioethics

9:15-9:25  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


9:25-9:40 Break

9:40-11:00 Ethics of Community Engagement
(NIMHD Sponsored Session)
CBPR Investigators and Community Partners

(9:40-10:10) Carol Horowitz MD, MPH
Associate Professor
Co-Director, Center of Health Equity and Community Engaged Research
Department of Population Health Science and Policy Department of Medicine
Icahn School of Medicine at Mount Sinai

Crispin Noelle Goytia, BA
Community and Patient Engagement Specialist
East Harlem Diabetes Center of Excellence
Icahn School of Medicine at Mount Sinai

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(10:10-10:35) Brian Mustanski, PhD
Associate Professor, Department of Medical Social Sciences
Director, IMPACT Program
Co-Director, Third Coast Center for AIDS Research (CFAR)
Northwestern University, Feinberg School of Medicine

Dr. Héctor Torres
Director of Behavioral Health
Center on Halsted

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(10:36-11:00) Moon S. Chen Jr. MPH, PhD
Professor, Div. of Hematology & Oncology, Department of Internal Medicine,
Principal Investigator, AANCART: The National Center for Reducing Asian American Cancer Health Disparities
Associate Director for Cancer Control, UC Davis Comprehensive Cancer Center
Ms. Kendra Thao
Executive Director
Hmong Women’s Heritage Association

11:00-11:30  Panel Q&A

READINGS


October 14, 2015  Session 3: IRBs, Risk and Benefits, and Informed Consent

8:30- 9:15  Purpose and Function of IRBs: Successes and Current Challenges
Sara Hull PhD
Chair, NHGRI IRB
9:15-9:25  Discussion

Readings: Textbook
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  Risks and Benefits
Dave Wendler, PhD
NIH Clinical Center Department of Bioethics

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.

Readings: (CD)
Rid A; Emanuel E; Wendler D Evaluating the Risks of Clinical Research.  *JAMA*. 2010; 304(13):1472-1479


10:20-10:35  Break

10:35-11:20  Informed Consent
Christine Grady RN PhD
NIH Clinical Center Dept of Bioethics
11:20-11:30 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 (CD)


October 21, 2015

Session 4: Research involving persons at risk for impaired decision making, Ethical issues in stored tissue research, and incidental findings

8:30-9:15 Research Involving Persons at Risk for Impaired Decision-Making
Scott Kim MD PhD
NIH Clinical Center Department of Bioethics

9:15-9:25 Discussion

Readings: (book and online)
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](http://cc-internal.cc.nih.gov/policies/PDF/M87-4.pdf)

Readings: (CD)

Supplementary readings

9:25-10:10 **Ethical Issues in the Use of Stored Tissue and Data**  
Sara Chandros Hull PhD  
NHGRI and NIH Clinical Center Department of Bioethics

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

**Readings:**


10:20-10:35 **Break**

10:35-11:20 **How to think about Incidental Findings**  
Ben Berkman JD  
NHGRI Bioethics Core and NIH Clinical Center Department of Bioethics

11:20-11:30 **Discussion**

**Readings:** (CD)  
F A Miller, R Christensen, M Giacomini, J S Robert. Duty to disclose what? Querying the putative obligation to return research results to participants *J Med Ethics* 2008. 34: 210-213  
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

**October 28, 2015**  
**Session 5: International Research Ethics and Conflicts of Interest**

**8:30-9:15**  
**Ethical Issues in International research**  
Joe Millum PhD  
NIH Clinical Center Department of Bioethics and Fogarty International Center

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

**9:25-10:10**  
**Ethical issues in International Research**  
Seema Shah JD  
NIH Clinical Center Department of Bioethics and NIAID Division of AIDS

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

**Readings on International Research Ethics:**


**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**  
**Conflicts of Interest**  
Steve Joffe MD MPH
Deputy Director 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)
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

Nov. 4, 2015  Session 6: Ethics of Research with Children, Ethics of Randomized Trials, and mock IRB

8:30-9:15  Ethics of Research with Children
Robert “Skip” Nelson MD
Director of Ethics and Deputy Director,
Office of Pediatric Therapeutics
US Food and Drug Administration

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,”
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):

9:25 - 10:10  Ethics of Randomized Clinical Trials: Clinical Equipoise
Robert Truog MD
Professor of Medical Ethics, Anesthesiology & Pediatrics at Harvard Medical School
Harvard University Program in Ethics and Health

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

10:35-11:30  Mock IRB
Christine Grady

PLEASE READ the Protocol on the CD before Nov. 4

November 11, 2015- FEDERAL HOLIDAY, NO CLASS

November 18, 2015  Session 7: Special Topics in Research Ethics

8:30-9:15  The Ethics of Challenge Studies
Seema Shah JD
NIH Clinical Center Department of Bioethics and NIAID Division of AIDs

9:15-9:25  Discussion

Readings (CD):


Letters to the Editor regarding Willowbrook. Lancet. 1991

9:25-10:10  Ethics of Research with Pregnant women
Maggie Little PhD
Director of the Kennedy Institute of Ethics, and Associate Professor of Philosophy

10:10-10:20 Discussion

Readings:
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):

10:20- 10:35 Break

10:35- 11:30 Pragmatic Trials Case Discussion
Scott Kim MD PhD
NIH Clinical Center Department of Bioethics

Readings:


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