There is no fee for this course, but a textbook, *The Ethical and Regulatory Aspects of Clinical Research (JHU Press)* is required. The book is available in the FAES Bookstore in Building 10 and also can be ordered from commercial bookstores and websites.

**September 25, 2019**  Session 1: Ethical Framework, Bench to Bedside, and IRB Function/Purpose

8:30 - 8:40  Introduction

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

9:20 - 9:30  Discussion

Readings (textbook):

Readings:

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 and Chair, Medical History and Bioethics
University of Wisconsin

10:30 - 10:40  Discussion

Readings (textbook):
Chapter 1. US Medical Researchers and Nuremberg
Chapter 4. Brandt, A.M. “Racism and Research: The Case of the Tuskegee Syphilis Study.”


10:40 - 11:20  **Bench to Bedside or Bedside to Bench: The Ethics of the Investigator-Participant Relationship**
Steve Joffe MD MPH
Chief, Division of Medical Ethics
Emanuel and Robert Hart Professor of Medical Ethics and Health Policy
Professor of Pediatrics
University of Pennsylvania Perelman School of Medicine

11:20 - 11:30  Discussion

Readings (textbook):

Readings:
*Hastings Center Report*, March April 2008

Miller F., & Rosenstein D. [The Therapeutic Orientation to Clinical Trials](https://www.nejm.org/doi/full/329/8/1363)
*NEJM* 1993

**October 2, 2019**  Session 2: IRBs, Risks and Benefits, and the Ethics of Research with Children

8:30 - 9:15  **Purpose and Function of IRBs: Successes and Current Challenges**
Sara Hull PhD
Director, NHGRI Bioethics Core
Faculty, NIH CC Department of Bioethics

9:15 - 9:25  Discussion

Readings (textbook):

Readings:


9:25 - 10:10 ***Risks and Benefits***
Dave Wendler PhD
Head of Section on Ethics and Research
NIH Clinical Center Department of Bioethics

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

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

***Readings (textbook):***
Chapter 42. Freedman B., Fuks A., and Weijer C. “*In loco parentis*: Minimal Risk as an Ethical Threshold for Research upon Children.”

***Readings:***
King, N. *Defining and Describing Benefit Appropriately in Clinical Trials*  

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


10:35 - 11:20 ***Ethics of Research with Pregnant Women***
Maggie Little PhD
Senior Research Scholar, Professor of Philosophy, Director of Ethics Lab
Georgetown University

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 9, 2019 - NO CLASS YOM KIPPUR

October 16, 2019  Session 3: Ethics of Pragmatic Trials, Ethics of Randomized Clinical Trials, and Ethics of Vaccine Research

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

9:15 - 9:25  Discussion

Readings:


9:25 - 9:40  Break

9:40 - 10:25  Ethics of Randomized Clinical Trials: Clinical Equipoise
Robert Truog MD
Director, Harvard Center for Bioethics
Frances Glessner Lee Professor of Legal Medicine,
Professor of Anaesthesia (Pediatrics)
Harvard Medical School
10:25 - 10:35  Discussion

Readings (textbook):
Chapter 11. Levine R. "Research and Practice."
Chapter 13. Hellman S. and Hellman DS. “Of Mice but Not Men: Problems of the Randomized Clinical Trial.”
Chapter 15. Truog R. “Randomized Controlled Trials: Lessons from ECMO”

10:35 - 11:20  Ethics of Vaccine Research
Holly Taylor PhD MPH
NIH Clinical Center Department of Bioethics

11:20 - 11:30  Discussion

Readings:


October 23, 2019  Session 4: Fair Subject Selection, Recruitment and Retention, and Participant Panel

8:30 - 9:15  Fair Subject Selection
Holly Taylor PhD MPH
NIH Clinical Center Department of Bioethics

Readings (textbook):
Chapter 4. Brandt, A.M. “Racism and Research: The Case of the Tuskegee Syphilis Study.” (assigned for Session 1)
Chapter 25. Weijer, C. and Crouch, R.A. “Why Should We Include Women and Minorities in Randomized Controlled Trials?”

9:15 - 9:25  Discussion

9:25 - 10:10  Recruitment and Retention
Dave Wendler PhD
NIH Clinical Center Department of Bioethics
10:10 - 10:20  Discussion

Readings (textbook):
Chapter 27. Dickert, N. and Grady, C. “What’s the Price of a Research Subject?
Approaches to Payment for Research Participation.”
Chapter 29. McNeil, P. “Paying People to Participate: Why Not?”
Chapter 73. Lind, S.E. “Finder’s Fees for Research Subjects.”

10:20 - 10:35  Break

10:35 - 11:30  Participant Panel

October 30, 2019  Session 5: Informed Consent, Research with Those with Impaired
Capacity for Consent, and Research Ethics Consultation

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

9:15 - 9:25  Discussion

Readings (textbook):
Chapter 30. Levine, R.J. “Consent Issues in Human Research.”
Chapter 31. Ingelfinger, F.J. “Informed (But Uneducated) Consent.”
Chapter 33. Truog R., et al. «Is Informed Consent Always Necessary for Randomized,
Controlled Trials?»

Readings:
Grady C. Enduring and Emerging Challenges of Informed Consent, New Eng J Med,

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

10:10 - 10:20  Discussion

Readings (textbook):
Persons with Mental Disorders That May Affect Decisionmaking Capacity.”
Readings:
NIH SOP 14E: Research Involving Adults Who Are or May Be Unable to Consent Available at [https://ohsr.od.nih.gov/public/SOP_14E_v2_05-26-16.pdf](https://ohsr.od.nih.gov/public/SOP_14E_v2_05-26-16.pdf)


10:20 - 10:35 Break

10:35 - 11:20 Research Ethics Consultation
Marion Danis MD

Readings:


November 6, 2019 Session 6: Ethical Issues in International Research

8:30 - 9:15 Ethical Issues in International Research: Introduction and Standard of Care
Annette Rid MD, PhD
NIH Clinical Center Department of Bioethics and Georgetown University

9:15 - 9:25 Discussion

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

10:10 - 10:20 Discussion
Readings:


Optional readings:

Standard of Care


Post-trial Obligations / Ancillary Care
CIOMS guideline 6


Responsiveness & Reasonable Availability
CIOMS guideline 2

10:20 - 10:35  Break

10:35 - 11:30  Mock IRB- Ebola Treatment Trial
Annette Rid, MD, PhD

**November 13, 2019**  Session 7: Ethics of Genetics Research and Incidental Findings, and Ethical Issues in *All of Us*

8:30 - 9:15  Ethics of Genetics Research and Incidental Findings
Leila Jamal PhD
NIAID, and NIH Clinical Center Dept of Bioethics

9:15 - 9:25  Discussion

9:25 - 10:10  Ethics of Genetics Research and Incidental Findings
Ben Berkman JD MPH
NHGRI Bioethics Core and NIH Clinical Center Dept of Bioethics

10:10 - 10:20  Discussion

**Readings:**

10:20 - 10:35  Break

10:35 - 11:20  Ethical Issues in the *All of Us* Research Program
Katherine Blizinsky, Ph.D
Policy Director, *All of Us* Research Program
NIH

11:20 - 11:30  Discussion

**Readings:**


