**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:

Miller F., & Rosenstein D. *The Therapeutic Orientation to Clinical Trials*. *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:
The Common Rule, at [https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML)


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.; Emanuel, 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:

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):
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:


