Ethical and Regulatory Aspects of Clinical Research
NIH CC Department of Bioethics
Wednesdays, September 26-November 7, 2018

September 26, 2018  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: (book)
Chapter 5. The Nuremberg Code
Chapter 6. The Declaration of Helsinki
Chapter 7. The Belmont Report

Readings:

9:30-9:45  Break

9:45- 10:30  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

10:30- 10:40  Discussion

Readings:


Miller F, Rosenstein D. The Therapeutic Orientation to Clinical Trials. NEJM 1993
10:40-11:20  Purpose and Function of IRBs: Successes and Current Challenges
Sara Hull PhD
Chair, NHGRI IRB
Director, NHGRI Bioethics Core

11:20-11:30  Discussion

Readings: Textbook
Chapter 8. The Common Rule

Readings:


October 3, 2018  Session 2: Risks and Benefits, and the Ethics of Research with Children

8:30-9:15  Risks and Benefits
Dave Wendler PhD
Head of Section on Ethics and Research
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:
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- 9:40          Break

9:40-10:25          Ethics of Research with Children
                  Alan Fleischman MD
                  Professor, Department of Pediatrics (Neonatology)
                  Professor, Department of Epidemiology & Population Health
                  Albert Einstein College of Medicine

10:25-10:35          Discussion

Readings:

Readings: (these are from the Emanuel, Crouch, et al. anthology 2003)
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:
Fleischman, A.R. and Collogan, L.: Research with Children, in: The Oxford Textbook of
Clinical Research Ethics. (eds) EJ Emanuel, C Grady, RA Crouch, R Lie, F Miller, and D
Wendler, Oxford University Press, 446-460, 2008

10:40- 11:30          Review of a protocol
                  Alan Fleischman MD
                  Professor, Department of Pediatrics (Neonatology)
                  Professor, Department of Epidemiology & Population Health
                  Albert Einstein College of Medicine

October 10, 2018          Session 3: Research with Samples and Data, Big Data, and
Incidental Findings

8:30-9:15          Incidental and secondary Findings
                  Ben Berkman JD MPH
                  NHGRI Bioethics Core and NIH Clinical Center Department of
                  Bioethics

9:15-9:25          Discussion

Readings:
Wolf S et al. Managing Incidental Findings in Human Subjects Research: Analysis and

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)

9:25-10:10 Research with Biospecimens and Data Under the Revised Common Rule

Holly Fernandez Lynch, JD, MBe
John Russell Dickson MD Presidential Assistant Professor of Medical Ethics
Assistant Faculty Director of Online Education
Department of Medical Ethics and Health Policy
Perelman School of Medicine, University of Pennsylvania

10:10-10:20 Discussion

Readings:


SACHRP Broad Consent Recommendations and Template
https://www.hhs.gov/ohrp/sachrp-committee/recommendations/sachrp-recommendations/index.html

10:20-10:35 BREAK
10:35- 11:30  Research with Big Data
Jeff Kahn PhD
Andreas C. Dracopoulos Director
Johns Hopkins University Berman Institute of Bioethics

11:20-11:30  Discussion

Readings:


October 17, 2018  Session 4: Fair Subject Selection, the History of Research Ethics, Research with Native Americans and Alaskan Natives

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

9:15-9:25  Discussion

Readings:
Wendler D. When should ‘riskier’ subjects be excluded from research? *Kennedy Institute of Ethics Journal* 1998; 8:307-327.


9:25-10:10  History, Scandals and Tragedies: Beecher, Tuskegee, Willowbrook and the Rest
Jonathan D. Moreno PhD
David and Lyn Silfen University Professor
Department of Medical Ethics and Health Policy
Department of History and Sociology of Science
University of Pennsylvania

10:10-10:20 Discussion

Readings:

Readings: (our 2003 book)

Readings:


10:20- 10:35 Break

10:35- 11:20 Community Based Research with American Indian and Alaskan Native Tribes
David R. Wilson, Ph.D.
Director, Tribal Health Research Office (THRO)
NIH

11:20-11:30 Discussion

Readings:

October 24, 2018 Session 5: Ethics of Randomized Clinical Trials, and Ethics of Pragmatic Trials, AND Ethical issues in *All of Us*

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: (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

10:35-11:20 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:

October 31, 2018

Session 6: Informed consent, research with those with impaired capacity for consent, and participant panel

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:


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


November 7, 2018  Session 7:  Ethical issues in international research

8:30-9:15  Ethical Issues in International research: Introduction and Standard of Care
Annette Rid MD  
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

10:20- 10:35  Break

10:35-11:30  Case discussion
Joe Millum and Annette Rid

Readings:


Standard of care


**Post-trial obligations / ancillary care**

CIOMS guideline 6


**Responsiveness & Reasonable Availability**

CIOMS guideline 2
