

Ethical and Regulatory Aspects of Clinical Research
NIH CC Department of Bioethics
Wednesdays, September 27-November 8, 2017

- September 27, 2017 Session 1: History and Framework for Ethical Clinical Research**
- 8:30-8:40 Introduction**
- 8:40-9:25 Framework for the Ethics of Research with Human Subjects**
Christine Grady RN PhD
NIH Clinical Center Department of Bioethics
- 9:25-9:35 Discussion**
- 9:35-9:50 Break**
- 9:50- 10:35 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
- 10:35- 10:45 Discussion**
- 10:45- 11:30 What we can learn about research ethics from experienced subjects**
Rebecca Dresser JD
Professor Emerita, Washington University School of Law
Visiting Scholar NIH CC Bioethics
- October 4, 2017 Session 2: IRBs, the Common Rule, and Subject Selection**
- 8:30-9:15 Purpose and Function of IRBs: Successes and Current Challenges**
Sara Hull PhD
Chair, NHGRI IRB
- 9:15-9:25 Discussion**
- 9:25-10:10 Common Rule Changes**
Yvonne Lau MBBS, MBHL, PhD
Director, Division of Education and Development,
Office for Human Research Protection (OHRP)
- 10:10-10:20 Discussion**

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

10:35- 11:20 **Fair Subject Selection**
Dave Wendler PhD
NIH Clinical Center Department of Bioethics

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

October 11, 2017 **Session 3: Risks and Benefits, Research with Pregnant Women
and Research Participant Panel**

8:30-9:15 **Risks and Benefits**
Dave Wendler PhD
NIH Clinical Center Department of Bioethics

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

9:25-10:10 **Ethics of Research with Pregnant Women**
Maggie Little BPhil PhD
Director of the Kennedy Institute of Ethics,
Professor of Philosophy, Georgetown University

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

10:20-10:35 **BREAK**

10:35- 11:30 **Participant panel**

October 18, 2017 **Session 4: Informed consent, Research with those with
Impaired Capacity for Consent, and Conflicts of Interest**

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

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

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
10:20- 10:35	Break
10:35- 11:20	Conflicts of Interest
	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
<u>October 25, 2017</u>	Session 5: Ethics of Research with Children, Ethics of Randomized Clinical Trials, and Ethics of Pragmatic Trials
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
9:25- 10:10	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
10:10-10:20	Discussion
10:20-10:35	Break
10:35-11:20	Ethics of Pragmatic trials Scott Kim MD PhD Senior Investigator NIH Clinical Center Department of Bioethics
11:20- 11:30	Discussion

Nov. 1, 2017 Session 6: Ethical issues in International Research and Mock IRB

- 8:30-9:15** **Ethical Issues in International research: Standard of Care**
Reidar Lie MD PhD
Head, Department of Philosophy,
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**
- 10:20- 10:35** **Break**
- 10:35-11:30** **Mock IRB**

November 8, 2017 Session 7: Stored Tissue, Big Data, and Incidental Findings

- 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** **Research with Big Data**
Jeff Kahn PhD
Andreas C. Dracopoulos Director
Johns Hopkins University Berman Institute of Bioethics
- 10:10- 10:20** **Discussion**
- 10:20-10:35** **Break**
- 10:35- 11:20** **Incidental and secondary Findings**
Ben Berkman JD MPH
NHGRI Bioethics Core and NIH Clinical Center Department of
Bioethics
- 11:20-11:30** **Discussion**