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

October 25, 2017 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
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| 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 |                                                                                                 |
| 10:35-11:30 | Mock IRB |                                                                                                 |
| 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 |                                                                                                 |
| 10:35-11:20 | Incidental and secondary Findings | Ben Berkman JD MPH  
NHGRI Bioethics Core and NIH Clinical Center Department of Bioethics |
| 11:20-11:30 | Discussion |                                                                                                 |