

Ethical and Regulatory Aspects of Clinical Research
NIH CC Department of Bioethics
Wednesdays, September 23- November 4, 2009

September 23, 2009 **Session 1: History, Guidance, and Framework for Ethical Clinical Research**

- 8:30-8:40** Pre-test
- 8:40-9:20** **Intro and Framework for the Ethics of Research with Human Subjects**
Ezekiel Emanuel MD, PhD (Grady backup)
NIH Clinical Center Dept of Bioethics
- 9:20-9:30** **Discussion**
- 9:30- 10:15** **History, Scandals and Tragedies: Beecher, Tuskegee, Willowbrook and the Rest**
Susan E. Lederer Ph.D.
University of Wisconsin
- 10:15- 10:25** **Discussion**
- 10:25-10:40** **Break**
- 10:40-11:20** **Do the Codes Apply to My Research? Nuremberg, Helsinki, the Belmont Report, CIOMS, and the Common Rule**
Jerry Menikoff MD JD
Director, Office of Human Research Protections
- 11:20-11:30** **Discussion**

Sept. 30, 2009 **Session 2: IRB review, Conflicts of Interest and Fair Subject Selection**

- 8:30-9:15** **Purpose and Function of IRBs: Successes and Current Challenges**
Barbara Karp MD
Chair of CNS and NIDA IRBs/NIH
- 9:15-9:25** **Discussion**
- 9:25-10:10** **Conflicts of Interest**
Cary Gross MD
Yale University School of Medicine

10:10-10:20 Discussion

10:20-10:35 Break

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

11:20-11:30 Discussion

October 7, 2009 Session 3:

8:30-9:15 Recruitment, Undue influence and Coercion
Alan Wertheimer, Ph.D.
NIH Clinical Center Dept of Bioethics

9:15-9:25 Discussion

9:25- 10:10 Clinical Research with pregnant women
Maggie Little PhD
Georgetown University

10:10- 10:20 Discussion

10:20- 10:35 Break

10:35-11:30 Mock IRB

October 14, 2009 Session 4:

8:30-9:15 Ethical issues in research with children
Robert Nelson MD PhD
FDA

9:15-9:25 Discussion

9:25- 10:10 Research Involving Persons at Risk for Impaired Decision-Making
Don Rosenstein, M.D.
University of North Carolina Medical Center

10:10- 10:20 Discussion

10:20- 10:35 Break

10:35- 11:30 Informed Consent

Christine Grady RN PhD
NIH Clinical Center Department of Bioethics

October 21, 2009

Session 5: Risks and Benefits;

8:30-9:15

Assessment of Risks and Benefits

Dave Wendler PhD

NIH Clinical Center Dept of Bioethics

9:15-9:25

Discussion

9:25-10:10

Ethical Issues in the Use of Stored Tissue and Data

Sara Chandros Hull, Ph.D.

NHGRI and Dept of Bioethics

10:10-10:20

Discussion

10:20-10:35

Break

10:35- 11:30

Investigator Panel

Crystal Mackall MD (pediatrics)

Jorge Tavel MD (HIV/ international/ flu vaccine)

Tito Fojo MD (medical oncology)

? NIMH

October 28, 2009

Session 6: Study design, Randomization, Placebos

8:30-9:15

Ethics of Randomized Clinical Trials: Clinical Equipoise

Robert Truog, M.D.

Professor of Anesthesiology & Medical Ethics

Harvard Medical School

9:15-9:25

Discussion

9:25- 10:10

Ethics of Placebo Controlled Trials

Frank Miller, Ph.D.

Department of Bioethics CC/NIH

10:10- 10:20

Discussion

10:20- 10:35

Break

10:35- 11:30

Participant panel

November 4, 2009

Session 7: Ethical issues in International Research

- 8:30- 9:10** **Exploitation**
Alan Wertheimer PhD
NIH Clinical Center Dept of Bioethics
- 9:10-9:20** **Discussion**
- 9:20- 10:05** **Special issues in international research**
Joe Millum PhD
NIH Clinical Center Dept of Bioethics
- 10:05-10:15** **Discussion**
- 10:15- 10:25** **Break**
- 10:25- 11:10** **International research ethics: Informed consent and post trial considerations**
Seema Shah JD
NIH Clinical Center Dept of Bioethics
- 11:10- 11:20** **Discussion**
- 11:20- 11:30** **Post tests and evaluations**

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