I am very sorry that we missed 3 sessions of the 2013 course because of the closure of the government. We will have the next three scheduled sessions with some small changes (Oct. 23, Oct 30, and Nov. 6), and I am adding a session on Wednesday Nov. 13 to capture some of the lectures and activities that were missed.

Unfortunately, there is not enough time to make up all of the sessions and I have had to make some choices. Below are the topics, speakers, and readings, for the dates scheduled. Below that I have listed links to NIH Webcast lectures from last year’s course on topics that I cannot fit in so that you can view the content if interested.

For those in the intramural program who are trying to complete requirements for the Clinical Research Curriculum Certificate OR for HRPP training required by OHSRP, the requirement for successful completion of the class this year will be participation in 4 out of the 5 sessions. (instead of 6 out of 7)

Thank you for your understanding and patience.

October 23, 2013

Session 2: Risks and Benefits, Research with Children, and Conflicts of Interest.

8:30-9:15
Risks and Benefits
Dave Wendler, PhD
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: (CD)
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- 10:10  Ethical issues in research with children
Robert Nelson MD PhD
Pediatric Ethicist, Office of Pediatric Therapeutics
Food and Drug Administration

10:10- 10:20  Discussion

Readings: (book)
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: (CD)

10:20-10:35  Break

10:35- 11:20  Conflicts of Interest
Steve Joffe MD MPH
Associate Professor of Medical Ethics and Health Policy
University of Pennsylvania

11:20-11:30  Discussion

Readings: (book)
Chapter 72. Thompson D. “Understanding Financial Conflicts of Interest”
Chapter 75. Martin, JB and Kasper, DL. "In whose best interest? Breaching the academic-industrial wall."

Readings: (CD)
Krumholz HM et al. What have we learnt from Vioxx? *BMJ* 2007; 334:120-123
October 30, 2013  Session 3:  Informed Consent, Randomized Clinical Trials, and Participant Panel

8:30-9:15  Informed Consent  
Christine Grady RN PhD  
NIH Clinical Center Dept 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: (CD)  

9:25- 10:10  Ethics of Randomized Clinical Trials: Clinical Equipoise  
Robert Truog MD  
Professor of Medical Ethics & Anaesthesia (Pediatrics)  
Harvard Medical School

10:05-10:20  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

10:20- 10:35  Break

10:35-11:30  Participant/Investigator panel

November 6, 2013  Session 4:  Stored Tissues, 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

Readings: (CD)

9:25-10:10  How to think about Incidental Findings
Ben Berkman JD
NHGRI and NIH Clinical Center Department of Bioethics

10:10-10:20  Discussion

Readings: (CD)
F A Miller, R Christensen, M Giacomini, J S Robert. Duty to disclose what? Querying the putative obligation to return research results to participants *J Med Ethics* 2008. 34: 210-213
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

10:20- 10:35  Break

10:35- 11:30  MOCK IRB

PLEASE READ the Protocol and consent forms, found on the CD (under session 4)
Nov. 13, 2013  Session 5:

8:30- 9:10  Fair Subject Selection
Dave Wendler PhD
NIH Clinical Center Department of Bioethics

9:10-9:20  Discussion

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

9:20- 10:00  Research Involving Persons at Risk for Impaired Decision-Making
Scott Kim MD PhD
NIH Clinical Center Department of Bioethics

10:00- 10:10  Discussion

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

Supplementary readings

10:10-10:25  Break

10:25-11:10  Ethics of International Research
Seema Shah JD
NIH Clinical Center Department of Bioethics and DAIDS

11:10-11:20  Discussion

Readings:

Readings: (CD)
Excerpts from CIOMS

Supplementary
Chapter 65. Lurie P & Wolfe S. “Unethical Trials of Interventions to Reduce Perinatal Transmission of the Human Immunodeficiency Virus in Developing Countries”
Chapter 68. Participants in the 2001 conference on Ethical Aspects of Research in Developing Countries. Fair benefits for Research in Developing countries.

11:20-11:30 Post Test and Evaluations.

THANK YOU

FYI- to view the following missed topics (from last year’s NIH Videocast):

Purpose and Function of IRBs: Successes and Current Challenges

Coercion and Undue Inducement
   Alan Wertheimer PhD, middle third of video found at http://videocast.nih.gov/summary.asp?Live=11634

Exploitation
   Alan Wertheimer PhD, first third of video found at http://videocast.nih.gov/summary.asp?Live=11638

Ethics of Placebo Controlled Trials
   Frank Miller, PhD, first third of video found at http://videocast.nih.gov/summary.asp?Live=10686