

RESEARCH CURRICULUM

ETHICAL ISSUES IN CLINICAL RESEARCH

February 22, 2017 – April 12, 2017

This course will consist of 8 sessions beginning on Wednesday, February 22nd and ending on April 12th. We meet at 5pm in room MSB 2.103. The course will address both accepted and controversial aspects of the ethics of clinical research. It is intended to be both conceptually interesting and practically useful, particularly for young investigators.

Prior to the first class each participant is requested to read and comment (a one paragraph precis will do) on the following paper and submit it to the office.

Emanuel, E, Wendler, D, Grady, C: "What Makes Clinical Research Ethical" JAMA 2000, 283 : 2701-2711

To receive credit for the class attendance will ordinarily be required for no fewer than 7 of the 8 sessions. (Persons in extraordinary circumstances may be granted prior approval to view the video of the missed class. See course director)

The course is designed as a lecture course. However, there will be an honors section which will require additional reading and additional discussion time. You must sign up separately in order to participate in the honors section. If you do so, you will have additional papers to read or questions to consider. But, participation in small discussion groups immediately following the lecture is mandatory in order to earn the honors designation.

The lecture is designed to end at 5:45. Those enrolled in the honors section will stay for the small group discussion which will end at 6:30. Reading list will be provided for each lecture.

Lecture 1) **Unproved Therapies: Can We Better Serve our Patients?**
Feb. 22 **Jon E Tyson, MD, MPH & Susan H Wootton, MD**

Ethical Dilemmas in Medical Innovation & Research: Distinguishing Experimentation from Practice
Norman Fost, MD, Seminars in Perinatology, Vol 22, No 3, June 1998
pp 223-232

Wootton SH, Evans PW, Tyson JE. Unproven Therapies in Clinical Research And Practice: The Necessity to Change the Regulatory Paradigm. Pediatrics, 2013 Oct; 132(4): pp 599-601

Lecture 2) **Tuskegee and Its Aftermath**
March 1 **Simon Whitney, MD**
Reading to be provided

Lecture 3) **Financial Conflicts of Interest in Academic Medicine: Why This**

- March 8 **Matters More Now Than Ever**
Leonard Zwelling, MD
- Krimsky, Sheldon: Science in the Private interest: Has the Lure of Profits Corrupted Biomedical Research? 2003, Rowman & Littlefield
Read introductory chapter
- Lecture 4)
March 15 **Informed Consent- An Exploration**
Rebecca Lunstroth, J.D., M.A.
Readings to be provided
- Lecture 5)
March 22 **Conceptions and Misconceptions in Contemporary Research Ethics**
John Lantos, MD
- SUPPORT and the Ethics of Study Implementation: Lessons for Comparative Effectiveness Research from the Trial of Oxygen Therapy for Premature Babies
John D Lantos & Chris Feudtner, Hastings Center Report 45(2015):pp 1-11
- Learning the Right Lessons from the SUPPORT Controversy
Lantos JD, Arch Dis Child Fetal Neonatal Ed Jan 2014 vol 99, pp14-15
- Lecture 6)
March 29 **The Learning Health Care System and its Impact on Comparative Effectiveness Research**
Charles C. Miller, PhD
- Informed Consent, Comparative Effectiveness and Learning Health Care
Faden RR, Beauchamp TL and Kass NE, NEJM 370:8 Feb 20, 2014 pp 766-768
- Lecture 7)
April 5 **Flawed Clinical Research & its Aftermath: The Wakefield Case and Impact on Immunization Policy**
Susan H Wootton, MD
- Lancet Retracts 12 year old Article Linking Autism to MMR Vaccines
CMAJ: MARCH 9, 2010 pp 182(4)
- The Age Old Struggle Against the Antivaccinationists.
Poland GA, Jacobson RM. N Engl J Med. 2011 Jan 13; 364(2):97-9
- Lecture 8)
April 12 **Mock IRB**
cases to be provided
- Discussants: Kathleen Kennedy, MD, MPH
 Rebecca Lunstroth, JD
 Charles C. Miller, PhD