PHIL 543 / EPID 679: Medical Ethics  
Topic for 2014: Human Experimentation Ethics  
Professor: Jonathan Kimmelman, Biomedical Ethics Unit  
Time: Monday, 10:35 a.m.–1:25 p.m.  
Room: 3647 Peel, Room 102

Reading Materials for 2014:*

Week 1 (January 6)  
Introduction to Human Experimentation Ethics  
Themes: Why do we worry about experimenting in human beings? What is research ethics, and how did it arise? How has medical research evolved? How have human protections evolved? Do policies protect all that is ethically at stake in medical research?

• Moreno JD. Goodbye to All That: The End of Moderate Protectionism in Human Subjects Research. *Hastings Cent Rep* 2001; 31: 9-17
• Belmont Report (see: http://ohsr.od.nih.gov/guidelines/belmont.html)
• Declaration of Helsinki (see: http://www.wma.net/e/policy/b3.htm)

Week 2 (Jan 13)  
What is Research?  
Themes: What is the difference between research and medical care? Why is research “special?” How do we demarcate? Why is this distinction important for establishing ethical policies? How important is it that human subjects understand this difference?

Week 3 (Jan 20)

Informed Consent
Themes: What vision of autonomy does informed consent support? How is informed consent obtained in different circumstances? Is it always necessary? Are current practices too restrictive, or are they too limited?


Week 4 (Jan 27)

Equipoise
Themes: when is it ethical for physicians—or the state—to allow invitation to research? How do we establish norms of risk and benefit, and what are the proper goals of research?


Week 5 (Feb 3)

Risk:
Themes: How should investigators analyze risk? What counts as acceptable risk? How should risk be disclosed? How do we resolve tensions between paternalism and autonomy in risk?


**Week 6 (Feb 10)**

**Value and Validity**
Themes: what do we mean by value and validity? How do we prospectively evaluate it? How are is value attained in research? How should policy-makers establish a research agenda?


**Week 7 (Feb 17)**

**Inducement and Financial Interest Conflicts**
Themes: Do incentives jeopardize important ethical values, like voluntariness or value, in research? What are appropriate inducement measures?


**Week 8 (Feb 24)**

**Placebos and Sham Procedures**
Themes: What is a placebo, and what is a placebo effect? Why are they used in research, and why do major controversies persist around placebo use? Is use of active placebo—sham—ethical?
• Marcus A. Fighting Cancer With a Sugar Pill—Move to Give Some Patients Instead of Drugs Causes Rift. *Wall Street Journal* 8 June 2004; D1
• Flum DR. Interpreting Surgical Trials Involving Subjective Outcomes: Avoiding UnSPORTSman Conduct. *JAMA* 296: 2483-5.

--------------------------------------- Reading Week ------------------------------------------

**Week 9 (Mar 10)**
Midterm Exam (1 hr)

**Deception**
Themes: What is deception, lying, and manipulation? What are the effects and consequences of deception? When is deception and manipulation acceptable? Are single blind run-in phases deceptive? Is use of sham control deceptive?

• APA Ethical Principles of Psychologists. 2003. 8.07: Deception in Research.

**Week 10 (March 17)**

**Children**
Themes: what is the moral status of children, and how do we protect their interests in medical experimentation? What are the consequences of not experimenting on children? How do standards of risk change when minors are involved?

Week 11 (Mar 24)

Disadvantaged Populations
Themes: To what extent should deprivations of low-income countries drive the research agenda? Can research be considered a type of economic transaction, subject to the same rules and norms of other economic transactions between advantaged and disadvantaged countries? What counts as exploitative research? What counts as unjust research?


Week 12 (Mar 31)

Public Health and Epidemiology
Themes: in what ways does the moral appraisal of public health activities and research overlap? Do public health studies represent a special category of research- bound by different rules? What about research aimed at assessing the implementation of research findings?

• Carrel M, Rennie S. Demographic and Health Surveillance: Longitudinal Ethical Considerations. Bull World Health Assoc 2008; 86: 612-6

Week 13 (Apr 8)

What is “Human”??
Themes: So far, this class has viewed the category “human subjects” as fixed and well demarcated. This session takes up the question of whether human protections ought to be extended to categories of “research subjects” that lack full human status, including embryos, animals, and future generations.


* Students are expected to familiarize themselves w/ major policy documents, including:

  
  
  
  • Declaration of Helsinki: [http://www.wma.net/e/policy/b3.htm](http://www.wma.net/e/policy/b3.htm)

*In accord with McGill University’s Charter of Students’ Rights, students in this course have the right to submit in English or in French any written work that is to be graded.*

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