PHIL 543 EPID 679: Medical Ethics

Topic for 2013: The Ethics of Human Experimentation

Time: Monday, 1:00 p.m.–4:00 p.m.
Room: 3647 Peel, Room 102

Instructor: Jonathan Kimmelman
Office: 3647 Peel St., Room 302
Tel: 398-3306
E-mail: jonathan.kimmelman@mcgill.ca
Office Hours: by appointment

Course Overview

Some of the earliest and foundational debates in bioethics grew out of revelations about abuses in human experimentation. This class provides an introduction to the ethics of conducting research involving human beings. Though there is a particular focus on clinical trials, the course surveys ethical issues in public health research, experimental psychology, and animal experimentation. Areas covered include: (1) scandals involving research with humans; (2) ethical and regulatory guidelines and structures; (3) ethical theory and principles of human research ethics; (4) empirical literature on ethical practice.

Required Readings

All readings will be available in a course packet, available for purchase at the McGill Bookstore. In addition, students will be expected to read key research ethics documents / policies the Tricouncil Policy Statement, 45 CFR 46, and CIOMS. These are easily accessible over the web.

Course Requirements

1. *In-class participation*: One of the most important skills as scholar in bioethics is the ability to identify important gaps or contradictions in an argument, and to formulate a research program deriving from a body of work. Students are expected arrive at class prepared with several critical questions that point to tensions within or between papers or that identify major unresolved issues in the materials. Students can take a holiday for submitting questions for two sessions (plus the introductory class, of course). These questions must be submitted at the start of class. Students should also be able to describe scholarly approaches or analogies that might inform analysis of a particular issue. Students will be expected to occasionally bring in materials from outside the assigned readings. **Contribution to final grade: 32.5%**.

2. *Presentation*: Each student will be responsible for a short presentation- 15 minutes, and not a minute more. Students should identify a topic within the subject of the session. For example, for the week of “Risk,” a student could give a presentation on Risk Perception and Informed Consent; for the week of “International Research,” students could give a presentation on competing definitions of exploitation. In addition to reading and absorbing the assigned readings, students will need to further background research.
and access material not covered in the readings. The student must be prepared to critically engage both the assigned as well as presented material, and raise questions for class discussion. Students can use powerpoint if they wish. Students must provide me a one page outline of their presentation. **Contribution to final grade: 20%.**

3. **Final paper:** This involves a well researched, well argued, and focused essay (3000-4000 words) due the last class of the term. Papers must list wordcount on coverpage; >4000 words is not accepted. You must discuss your topic with me beforehand. These papers should be written as if they were to be submitted for publication; you should aim to absorb the style and structure of argument used in the assigned readings. Final papers should not be summaries of the published literature; instead, they should strive to make a contribution to the literature on research ethics. This means that you should perform literature searches using standard scholarly databases, (e.g.,PubMed or Philosopher’s Index), and spend a considerable amount of time identifying key gaps in the literature that you might try to tackle. The paper must involve ethical analysis, and should not simply provide a summary of what others have said. I will encourage students who write outstanding papers to submit their articles for publication. **Contribution to final grade: 32.5%.**

4. **Midterm Exam:** Students will receive a midterm exam lasting 1 hour. The exam will cover material from each session up to then, including the first session. The exam will consist of several short answer questions about the history, policies, and practices in research ethics, and several short essay questions that test recall of various topics discussed or require you to apply principles already discussed to new questions. **Contribution to final grade: 15%.**

5. **Extra Credit (2010):** Each year, I offer the class the opportunity to perform an extra credit project. Precise parameters of project will be clarified by mid Feb. All students who “volunteer” for this extra credit project are expected to work together by discussing and reviewing each other’s entries. A single grade for extra credit will be assigned to the entire group. **Potential contribution to final grade: 5%**
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Reading Materials for 2013:

**Week 1 (January 7)**

**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
- Declaration of Helsinki (see: http://www.wma.net/e/policy/b3.htm)

**Week 2 (Jan 14)**

**The Research-Treatment Distinction:**

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 21)

**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 28)

**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 4)

**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 11)

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?

• Kuehn BM. Clinical Trials Registry Expands. JAMA 2009; 302: 22.

Week 7 (Feb 18)

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

• Chambers T. Participation as Commodity, Participation as Gift. AJOB 2001; 1: 48.

Week 8 (Feb 25)

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 UnSPORTSmanship Conduct. JAMA 296: 2483-5.

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

Week 9 (Mar 11)
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 Pediatric Research (March 18)

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 25)

**International Studies and Research Involving Disadvantage**
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 (Apr 1)

**Public Health and Epidemiology Research**
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)

**Special Topics 2: Really Marginal Research “Subjects”**
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.

McGill University values academic integrity. Therefore all students must understand the meaning and consequences of cheating, plagiarism and other academic offences under the Code of Student Conduct and Disciplinary Procedures (see [www.mcgill.ca/integrity](http://www.mcgill.ca/integrity) for more information).