

Topic for 2021: Human Experimentation Ethics
Professor: Jonathan Kimmelman, Biomedical Ethics Unit
Time: Monday, 8:35 AM–11:25 PM
Room: <https://mcgill.zoom.us/j/4735285921>

Themes: Why is research on human beings ethically fraught? What is research ethics, and how did it arise? How has medical research evolved? How have human research policies 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* :q~~500~~

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? Are there ways of conducting randomized trials without obtaining informed consent?

- Begley S. ER Patients given Ketamine, other powerful drugs, In Clinical Trials Without Their Consent, FDA Says. *STAT News* Oct 29 2018.
<https://www.statnews.com/2018/10/29/er-patients-given-ketamine-powerful-drugs-without-consent/>
- Berg JW, Appelbaum PS, Lidz CW, Parker LS. The Concept and Ethical Justification of Informed Consent. In: *Informed Consent: Legal Theory and Practice*, 2d edition. New York: Oxford University Press (2001).

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?

- Branswell, H. Ethics Panel Blocks proposed Zika Vaccine Research. *STAT News* 2017; Feb 28. <https://www.statnews.com/2017/02/28/zika-vaccine-ethics-panel/>

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and methodological myths. *J Law Med Ethics*. 1996 Fall;24(3):243-51.

Midterm Exam (1 hr)

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?

- Data Research. Bioeth Inquiry 2017.
- Weijer CW et al. Ethical Issues posed by cluster randomized trials in health research. Trials 2011; 12: 100.

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.