

PHL 5000W Topics in Philosophy: Global Bioethics

Wed 2:35-4:25 TB 431

Professor Vida Panitch

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Paterson 3A55 Wed 1-2:30

Course Description

Nearly 25% of all new drugs released on the North American market contain results obtained from phase three clinical trials conducted in the developing world. While moral guidelines exist to protect human subjects from undue risks in research participation, there is legitimate concern that these traditional guidelines are inadequate to protect subjects in contexts where poverty, low education levels and a lack of access to health care resources make them acutely vulnerable to exploitation. The exploitation worry arises specifically in response to perceived injustices in the quality of treatment and/or the distribution of post-trial benefits, and inadequacies in the quality of the participants' consent. We will begin the course with a brief discussion of health as a problem of global justice, and then turn to the issues of consent, quality of care, and transactional fairness by way of evaluating competing principles of non-exploitation in international clinical research.

Course Text:

- *Exploitation and Developing Countries: The Ethics of Clinical Research*, eds Jennifer Hawkins and Ezekiel Emanuel (Princeton 2008). Available at the Carleton Bookstore and MacOdrum reserves.
- All other readings are available through the library journal catalogue.

Course Evaluation (Masters)

- Mid term paper, 10 pages in length, worth 35%
- End of term *research* paper, 15-20 pages in length, worth 50%
- Class participation, worth 15%

Course Schedule

Week 1: January 4 - Introduction to the course

Week 2: January 11

- Thomas Pogge, "Eradicating Systemic Poverty: Brief for a Global Resources Dividend," *Journal of Human Development* 2 (2001)
- Thomas Pogge, Priorities of Global Justice, *Metaphilosophy* 32/1-2

(2001)

Week 3: January 18

- Thomas Pogge, “Responsibilities for Poverty Related Ill Health,” *Ethics and International Affairs* 16/2 (2002)
- Gopal Sreenivasan, “International Justice and Health: A Proposal,” *Ethics and International Affairs* 16/2(2002)
- Gopal Sreenivasan, “Health and Justice in our Non Ideal World,” *Politics, Philosophy and Economics* 6/2 (2007)

Week 4: January 25

- “The Body Hunters,” *The Washington Post*, December 2000 **
- Declaration of Helsinki
<http://www.wma.net/en/30publications/10policies/b3/>
- Nuremberg Code <http://ohsr.od.nih.gov/guidelines/nuremberg.html>
- Jennifer Hawkins and Ezekiel Emanuel, “Case Studies: The Havrix Trial and The Surfaxin Trial,” Course Text

Week 5: February 1

- Ezekiel Emanuel et al., “What Makes Clinical Research in Developing Countries Ethical?” *Journal of Infectious Diseases* 189/5 (2004)
- Jennifer Hawkins and Ezekiel Emanuel, “Clinical Research, Developing Countries and Exploitation: A Primer,” Course Text

Week 6: February 8

- Robert Levine, “Informed consent: Challenges to the Universal Validity of the Western Model,” *Law, Medicine and Ethics* 19/3-4 (1991)
- Carel Ijsselmuiden and Ruth Faden, “Research and Informed Consent in Africa,” *New England Journal of Medicine* 326/12 (1992). **
- D. W. Fitzgerald et al., “Comprehension During Informed Consent in a Less Developed Country,” *The Lancet* 360/9342 (2002)
- Gopal Sreenivasan, “Does Informed Consent to Research Require Comprehension?” *The Lancet* 362/9400 (2003)

Week 7: February 15

- Peter Lurie and Sidney Wolfe, “Unethical Trials of Intervention,” *The New England Journal of Medicine* 337/12 (1997).
http://columbiauniversity.net/itc/hs/pubhealth/p9408/readings/lurie-wolfe_1997.pdf
- Robert Crouch and John Arras, “AZT Trials and Tribulations,”

Hastings Center Report 28/6 (1998)

- Jennifer Hawkins, “Exploitation and Placebo Controls” Course Text

Week 8: February 29

- Alan Wertheimer, “Exploitation,” *Stanford Encyclopedia of Philosophy*
<http://plato.stanford.edu/entries/exploitation/>
- Alan Wertheimer, “Exploitation in Clinical Research,” Course Text

Week 9: March 7

- Leonard Glantz et al., “Research in Developing Countries: Taking Benefit Seriously,” *Hastings Center Report* 28/6 (1998)
- Ezekiel Emanuel, “Addressing Exploitation: Reasonable Availability vs. Fair Benefits,” Course Text

Week 10: March 14

- Richard Arneson, “Broadly Utilitarian Theories of Exploitation and Multinational Clinical Research,” Course Text
- Andrew Siegel, “Kantian Ethics, Exploitation and Multinational Clinical Trials,” Course Text

Week 11: March 21

- John Arras, “Another Voice,” *Hastings Center Report* 34/3 (2004)
- Alex John London, “Justice and the Human Development Approach to International Research,” *Hastings Center Report* 35/1 (2005)

Week 12: March 28

- Thomas Pogge, “Testing our Drugs on the Poor Abroad,” Course Text
- Thomas Pogge, “Human Rights and Global Health: A Research Program,” *Metaphilosophy* 36/1-2 (2005)

Week 13: April 4 - Course Conclusion and Wrap-up Discussion

Department of Philosophy and Carleton University Policies

Assignments:

Unless specifically told otherwise by their instructors, students:

- must not use a plastic or cardboard cover or paper clips
- must staple the paper (there is a stapler on the essay box)
- must include the following in the lower right corner of the cover sheet:
 - student name
 - student number
 - course number and section
 - instructor's name
- The Philosophy Department does not accept assignments by FAX. You may send them by courier, if necessary.
- No assignments will be accepted after the last day for handing in term work – see dates in next column.
- Assignments handed in through the essay box (just inside the glass doors, Paterson Hall, Floor 3A) must be dropped into the box by **4:15** on a regular business day in order to be date-stamped with that day's date. Assignments handed in after 4:15 or on a non-business day will be stamped as having been handed in on the next business day.
- Students are required to keep copies of their assignments. If your paper is lost at any point, you will be considered not to have submitted it if you cannot produce a copy immediately on request.

Deferrals for Term Work:

If you miss a final examination and/or fail to submit a final assignment by the due date because of circumstances beyond your control, you may apply for a deferral of examination/assignment. For deferred examinations, you must apply within 5 working days after the scheduled date of your exam. To apply for deferral of a final assignment, you must apply within 5 working days of the last scheduled day of classes. Visit the Registrar's Office for more information.

Plagiarism:

It is the responsibility of each student to understand the meaning of 'plagiarism' as defined in the Undergraduate or Graduate Calendars, and to avoid both committing plagiarism and aiding or abetting plagiarism by other students. (Undergraduate Calendar Academic Regulations, section 14.3, or <http://www4.carleton.ca/calendars//ugrad/current/regulations/academicuniv14.html#14.3>)

Academic Accommodation:

You may need special arrangements to meet your academic obligations during the term. For an accommodation request the processes are as follows:

Pregnancy obligation: write to me with any requests for academic accommodation during the first two weeks of class, or as soon as possible after the need for accommodation is known to exist. For more details visit the Equity Services website <http://www2.carleton.ca/equity/accommodation/>

Religious obligation: write to me with any requests for academic accommodation during the first two weeks of class, or as soon as possible after the need for accommodation is known to exist. For more details visit the Equity Services website <http://www2.carleton.ca/equity/accommodation/>

Students with disabilities requiring academic accommodations in this course must register with the Paul Menton Centre for Students with Disabilities (PMC) for a formal evaluation of disability-related needs. Documented disabilities could include but are not limited to mobility/physical impairments, specific Learning Disabilities (LD),

psychiatric/psychological disabilities, sensory disabilities, Attention Deficit Hyperactivity Disorder (ADHD), and chronic medical conditions. Registered PMC students are required to contact the PMC, 613-520-6608, every term to ensure that I receive your Letter of Accommodation, no later than two weeks before the first assignment is due or the first in-class test/midterm requiring accommodations. If you only require accommodations for your formally scheduled exam(s) in this course, please submit your request for accommodations to PMC by the deadlines published on the PMC website: <http://www2.carleton.ca/pmc/new-and-current-students/dates-and-deadlines/>

Important Dates:

Sept. 8	Classes start (after Orientation events).
Sept. 21	Last day for registration and course changes in Fall term and two-term courses.
Sept. 30	Last day for entire fee adjustment when withdrawing from fall term or two-term courses.
Oct. 7	University Day – no classes.
Oct. 10	Thanksgiving Day – university closed.
Nov. 21	Last day for tests or examinations in courses below 4000 level before the Final Examination period.
Dec. 5	Last day of classes, Fall term. Last day for handing in term assignments, subject to any earlier course deadline.
Dec. 5	Last day to withdraw from Fall term courses (academic purposes only).
Dec. 8-21	Final examinations for Fall courses, mid-terms for Fall/Winter courses.
Jan. 4	Winter term classes begin.
Jan. 17	Last day for registration and course changes in Winter term classes.
Jan. 31	Last day for entire fee adjustment when withdrawing from winter courses or winter portion of two-term courses.
Feb. 20	Family Day – university closed
Feb. 20-24	Winter Break, classes suspended.
Mar. 22	Last day for tests or examinations in courses below 4000 level before the Final Examination period.
Apr. 5	Last day of Fall/Winter and Winter term classes. Last day for handing in term assignments, subject to any earlier course deadline.
Apr. 5	Last day to withdraw from Fall/Winter and Winter term courses (academic purposes only).
Apr. 6	Good Friday – university closed.
Apr. 11-24	Final Examinations.

Addresses:

Department of Philosophy:	3A46 Paterson Hall www.carleton.ca/philosophy 520-2110
Registrar's Office:	300 Tory www.carleton.ca/registrar 520-3500
Student Academic Success Centre:	302 Tory www.carleton.ca/sasc 520-7850
Paul Menton Centre:	500 University Centre www.carleton.ca/pmc 520-6608
Writing Tutorial Service:	4 th Floor, Library www.carleton.ca/wts 520-6632
MacOdrum Library	http://www.library.carleton.ca/ 520-2735