

## Syllabus

### Ethical Issues in Clinical Research PUB HLTH 441 Summer quarter, 2011

Time: Tuesday, 3:30- 6:00 p.m., July 5- August 9  
McGaw 2-403

Course Directors: Maureen Moran, MPH  
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Office Hours: By appointment

#### I. Course Description

Debate and discussion of ethical issues surrounding clinical research studies, including conflicts of interest, social accountability, risk benefit analyses, vulnerable populations, recruiting strategies, and equipoise.

#### II. Course Objectives:

Through the course sessions and homework assignments, students will 1) actively participate in class discussion, 2) show respect for different points of view within the context of class discussion, 3) identify ethical issues in clinical research proposals and offer alternative protocols and procedures to eliminate those that are unethical, 4) demonstrate the ability to write and to edit critically, 5) describe the characteristics of vulnerable groups, identify protocols involving vulnerable groups and determine the means by which their rights as research participants are to be protected.

**III. Grading Policies:** Written homework assignment: 20%,  
Class participation: 20%, Class discussion assignment 20%, Final Exam (take home):  
40%

#### **IV. Course Materials**

Murphy TF. Case studies in biomedical research ethics. Cambridge, Massachusetts: The MIT Press, 2004.

Additional cases will be distributed in class and posted on Blackboard.

Readings and resources will be posted on Blackboard.

Optional:

Skloot R. The immortal life of Henrietta Lacks. New York: Crown Publishers, 2010.

Emanuel EJ, Crouch RA, Arras JD, Moreno JD, Grady C, editors. Ethical and regulatory aspects of clinical research Readings and Commentary. Baltimore and London: The Johns Hopkins University Press, 2003.

#### **V. Course Workload**

Weekly class attendance and participation in discussion, weekly preparation of cases, writing assignment, written take-home examination due not later than August 16 at 6 p.m.

#### **VI. Course Evaluation**

The MPH Program administers web-based course evaluations to students for each course near the end of the quarter. Your completion of both the Unit (course) and Faculty evaluations is required; failure to complete the evaluations will result in an incomplete grade until the evaluations are submitted. You will be sent the web link and instructions via e-mail later in the quarter. You will have several weeks to complete the evaluations before grades are submitted. Your evaluation of the course and faculty is anonymous; your identity can not be linked with your responses.

#### **VII. Academic Integrity**

Academic integrity at Northwestern University is based on a respect for individual achievement that lies at the heart of academic culture. Every faculty member and student, both graduate and undergraduate, belongs to a community of scholars where academic integrity is a fundamental commitment. The Programs in Public Health abides by the standards of academic conduct, procedures, and sanctions as set forth by The Graduate School at Northwestern University. Students are responsible for knowledge of the information provided by The Graduate School on their Web page at <http://www.tgs.northwestern.edu/studentsvcs/ethics/>.

Additionally, faculty reserve the right to use the “Safe Assignment: Plagiarism Detection Tool” that is part of the Course Management System. Info about this tool is found at <http://course-management.northwestern.edu/tipsheets.html>.

<p><b>July 5, 2011 (Week 1)</b></p> <p><b>READINGS In preparation for class</b></p> <p>Nuremberg Code <a href="http://ohsr.od.nih.gov/guidelines/nuremberg.html">http://ohsr.od.nih.gov/guidelines/nuremberg.html</a> (also Emanuel text, p. 29.)</p> <p>Declaration of Helsinki <a href="http://ohsr.od.nih.gov/guidelines/helsinki.html">http://ohsr.od.nih.gov/guidelines/helsinki.html</a> (also Emanuel text, pp. 30-2.)</p> <p>Belmont Report <a href="http://ohsr.od.nih.gov/guidelines/belmont.html">http://ohsr.od.nih.gov/guidelines/belmont.html</a> (also Emanuel text, pp. 33-8.)</p> <p>Common Rule Sections 46.107-109 <a href="http://ohsr.od.nih.gov/guidelines/45cfr46.html">http://ohsr.od.nih.gov/guidelines/45cfr46.html</a> (also Emanuel text, pp. 43-4.)</p>	<p><b>Ethical Issues in Clinical Research</b></p> <p><b>INTRODUCTION TO THE COURSE</b></p> <p>Course Requirements: Case reviews Class Participation Take home exam Readings</p> <p>Case Assignments for the remaining weeks</p> <p><b>LECTURE</b> Protection of Human Participants and the rise of Institutional Review Boards</p> <p><b>DISCUSSION</b> See cases at right.</p>	<p><b>CASES</b> (except as noted all cases are taken from Murphy’s <i>Case studies in biomedical research ethics</i>)</p> <p>Innovative Care or Research (Investigational Use)? (handout)</p> <p>Surgical Innovation and Research, p 25</p>
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<p><b>July 12, 2011 (Week 2)</b></p> <p><b>READING In preparation for class</b></p> <p>International Ethical Guidelines for Biomedical Research Involving Human Subjects. Guideline 12: Equitable distribution of burdens and benefits in the selection of groups of subjects in research.</p> <p>Dickert N, Grady C. What's the price of a research subject? Approaches to payment for research participation, N Engl J Med 1999;341:198-203.</p> <p>Wendler D, Krohmal B, Emanuel EJ, Grady C. for the ESPRIT Group. Why patients continue to participate in clinical research Arch Intern Med 2008;168 (12): 1294-9,</p>	<p><b>Fair Subject Selection</b></p> <p><b>LECTURE</b></p> <p>Recruiting, Retaining and Paying Subjects</p>	<p><b>CASES</b></p> <p>Involvement of Poor and Wealthy Subjects, p. 123</p> <p>Payment of Physicians for Enrolling Research Subjects, handout</p> <p>Consent and Assumption of Risk in Genetic Therapy, p. 237-8.</p> <p>Payment of Research Subjects (handout)</p> <p>The Tuskegee Syphilis Study, p. 21-22</p> <p style="text-align: center;">▽▽▽▽▽▽▽▽▽▽</p>
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<p><b>July 19, 2011 (week 3)</b></p> <p><b>READINGS In preparation for class</b></p> <p>The ICH Harmonised Tripartite Guideline—Guideline for Good Clinical Practice (ICH-GCP Guideline), Section 4.8. Informed Consent of Trial Subjects,</p> <p>Common Rule 46.116 General Requirements for Informed Consent and 46.117 Documentation of Informed Consent</p> <p>Hochhauser M. “Therapeutic Misconception” and “Recruiting Doublespeak” in the Informed Consent Process. IRB: Ethics and Human Research 2002; 24 (1):11-16.</p> <p>American Society of Human Genetics. Statement on informed consent for genetic research Am J Hum Genet 1996; 59:471-474.</p>	<p><b>Informed Consent</b></p> <p><b>LECTURES</b></p> <p>Informed Consent: More than a form but what’s in the form matters</p>	<p><b>CASES</b></p> <p>Freezing and Storing of Ovarian Tissue (handout)</p> <p>Disclosure of Study Results (handout)</p> <p>Research using stored biological samples (handout)</p> <p>Yellow Fever Experiments, p. 71-72</p> <p><b>HOMEWORK</b></p> <p>Homework Assignment will be distributed in class and due on August 2.</p>
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<p><b>July 26, 2011 (week 4)</b></p> <p><b>READINGS In preparation for class</b></p> <p>Applebaum PS, Roth LH, Lidz CW, Benson P, Winslade W. False hopes and best data. Consent to research and the therapeutic misconception. Hastings Center Report 1997;17(2):20-24</p> <p>International Ethical Guidelines for Biomedical Research Involving Human Subjects. Guideline 19: Right of injured subjects to treatment and compensation.</p> <p>Moreno MA, Fost NC, Christakis DA. . Research ethics in the MySpace era. Pediatrics 2008; 121:157-161</p>	<p><b>Waivers of Informed Consent and Waivers of Written Informed Consent</b></p> <p><b>LECTURE</b></p> <p>May I Be Excused? Getting a Waiver</p>	<p><b>CASES</b></p> <p>Retrospective and Prospective Studies of Fertility Clinic Patients, (handout)</p> <p>Cystic Fibrosis Study, (handout)</p> <p>Emergency Research Incorporating a Waiver of Informed Consent (handout)</p> <p>A Study of Public Behavior (handout)</p> <p>Obedience to Authority, p 75-76.</p>
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**August 2, 2011  
(week 5)**

**READINGS In preparation  
for class**

The Common Rule Subparts  
B, C and D.

Oberman M, Frader J. Dying  
children and medical research:  
access to clinical trials as  
benefit and burden. *Am J Law  
& Med* 2003;29:301-17.

Goldkind SF, Sahin L,  
Gallauresi B. Enrolling  
pregnant women in research –  
lessons from the H1N1  
influenza pandemic. *N Engl J  
Med* 2010;362(24):2241-2243.

**Children and Other Vulnerable  
Population**

**LECTURE**

Regulations Involving Vulnerable  
Populations

**CASES**

Children and Lead Dust, p.  
49 in place of Study  
Questions consider the  
following:

How is minimal risk  
defined? Did the Kennedy-  
Kreiger study meet the  
definition of minimal risk?  
Minimal risk and minimizing  
risk are different. Was the  
risk to children minimized?  
What more could have  
been done to minimize risk  
to children?

Evaluating a Program to  
Prevent Recurrence of  
Domestic Violence  
(handout)

When is it justifiable to do  
research with children?  
(handout)

Placebos in Research with  
Children, p 214-15.

Malaria Experiments in  
Prisoners, p 102-103.

**Homework Due Today**

Take home exam will be  
distributed in class. See  
page 8 for more  
information.

<p><b>August 8, 2011 (week 6)</b></p> <p><b>READINGS In preparation for class</b></p> <p>Freedman B. Equipoise and the ethics of clinical research. N Engl J Med 1987;317:141-45.</p> <p>Green L. Cholesterol-Lowering Therapy for Primary Prevention: Still Much We Don't Know Arch Intern Med 2010;170 1007-1008</p> <p>Macklin R. The ethical problems with sham surgery in clinical research. N Engl J Med 1999; 341: 992-6.</p> <p>Bavdekar SB, Thatte UM. Compensation for research-related injury. J Postgrad Med 2009;55:87-8</p> <p>Emmanuel EJ, Miller FG. The ethics of placebo-controlled trials – a middle ground. N Engl J Med 2001;345(12):915 - 918</p>	<p><b>Clinical Trials</b></p> <p><b>LECTURE</b></p> <p>Issues specific to Clinical Trials</p> <p><b>COURSE EVALUATION (ON LINE)</b></p>	<p><b>CASES</b></p> <p>Sham Surgical Procedures, p 33.</p> <p>Compensation for Research Related Injuries, handout</p> <p>Prophylactic Prevention of Psychosis, handout</p> <p>Losing Equipoise, handout</p> <p>Access to Unapproved drugs, p. 28-29</p>
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The take-home final exam will be distributed in class on August 2 and is due not later than August 16, 2011 at 6 p.m. It may be delivered to Ms. Moran, Department of Preventive Medicine, 680 N Lake Shore Drive Suite 1400, Chicago IL 60611 (note that the office closes at 5 pm) or it may be sent by electronic mail to [m-moran@northwestern.edu](mailto:m-moran@northwestern.edu) or placed in the electronic drop box via Blackboard.