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


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

Readings and resources will be posted on Blackboard.

Optional:


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](http://course-management.northwestern.edu/tipsheets.html).

### July 5, 2011  
(Week 1)  

**READINGS** In preparation for class

| (also Emanuel text, p. 29.) |
| (also Emanuel text, pp. 30-2.) |
| (also Emanuel text, pp. 33-8.) |
| (also Emanuel text, pp. 43-4.) |

**Ethical Issues in Clinical Research**

**INTRODUCTION TO THE COURSE**

Course Requirements:
- Case reviews
- Class Participation
- Take home exam
- Readings

Case Assignments for the remaining weeks

**LECTURE**

Protection of Human Participants and the rise of Institutional Review Boards

**DISCUSSION**

See cases at right.

**CASES**

(except as noted all cases are taken from Murphy’s *Case studies in biomedical research ethics*)

Innovative Care or Research (Investigational Use)? (handout)

Surgical Innovation and Research, p 25
**July 12, 2011**  
*(Week 2)*

**READING In preparation for class**


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,

**Fair Subject Selection**

**LECTURE**

Recruiting, Retaining and Paying Subjects

**CASES**

- Involvement of Poor and Wealthy Subjects, p. 123
- Payment of Physicians for Enrolling Research Subjects, handout
- Payment of Research Subjects (handout)
- The Tuskegee Syphilis Study, p. 21-22

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**Informed Consent**

**LECTURES**

Informed Consent: More than a form but what's in the form matters

**CASES**

Freezing and Storing of Ovarian Tissue (handout)

Disclosure of Study Results (handout)

Research using stored biological samples (handout)

Yellow Fever Experiments, p. 71-72

**HOMEWORK**

Homework Assignment will be distributed in class and due on August 2.

**July 19, 2011**  
*(week 3)*

**READINGS In preparation for class**

The ICH Harmonised Tripartite Guideline—Guideline for Good Clinical Practice (ICH-GCP Guideline), Section 4.8. Informed Consent of Trial Subjects,

Common Rule 46.116 General Requirements for Informed Consent and 46.117 Documentation of Informed Consent


### July 26, 2011 (week 4)

**READINGS** In preparation for class


Moreno MA, Fost NC, Christakis DA. Research ethics in the MySpace era. Pediatrics 2008; 121:157-161

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**Waivers of Informed Consent and Waivers of Written Informed Consent**

**LECTURE**

May I Be Excused? Getting a Waiver

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**CASES**

Retrospective and Prospective Studies of Fertility Clinic Patients, (handout)

Cystic Fibrosis Study, (handout)

Emergency Research Incorporating a Waiver of Informed Consent (handout)

A Study of Public Behavior (handout)

Obedience to Authority, p 75-76.
### 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.
August 8, 2011  
(week 6)

READINGS In preparation for class

Freedman B.  Equipoise and the ethics of clinical research.  

Green L.  Cholesterol-Lowering Therapy for Primary Prevention: Still Much We Don't Know  
Arch Intern Med 2010;170 1007-1008

Macklin R.  The ethical problems with sham surgery in clinical research.  

Bavdekar SB, Thatte UM.  Compensation for research-related injury.  

Emmanuel EJ, Miller FG.  The ethics of placebo-controlled trials – a middle ground.  
N Engl J Med 2001;345(12):915 - 918

Clinical Trials

LECTURE

Issues specific to Clinical Trials

COURSE EVALUATION (ON LINE)

CASES

Sham Surgical Procedures, p 33.
Compensation for Research Related Injuries, handout
Propylactic Prevention of Psychosis, handout
Losing Equipoise, handout
Access to Unapproved drugs, p. 28-29

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 mmoran@northwestern.edu or placed in the electronic drop box via Blackboard.