Syllabus

PUB HLTH 441
Ethical Issues in Clinical Research – 0.5 Units
Spring 2015

Day and Time: Wednesday, 4:30-6:00 pm
   April 1 – June 3, 2015
Location: McGaw 2-403

Course Directors:
    Maureen Moran, MPH
    Assistant Professor of Preventive Medicine
    m-moran@northwestern.edu
    (312) 503-0500
    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. Learning 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. Texts and readings

Required Texts
None.

Blackboard™
The syllabus, cases and selected readings will be posted on the course’s Blackboard™ site, available at https://courses.northwestern.edu/webapps/login if you are registered for the course.
Optional Reading
This book touches on many ethical issues including informed consent, understandable “lay language” and the issues surrounding commercialization of products that result from human subjects research.

Includes the Nuremberg Code, Declaration of Helsinki, Belmont Report, Common Rule (45 CFR 46), International Ethical Guidelines for Biomedical Research Involving Human Subjects as well as many journal articles for those who prefer a hard copy of the key documents used in the course.

IV. Class assignments, homework and exam

Weekly class attendance and participation in case discussion, weekly reading assignments, leading of at least 1 class discussion including a written commentary on the case being discussed, Informed Consent Document homework assignment, take home examination. Optional: attendance at an IRB meeting (Mondays, 11:30 am - 1 pm, Chicago Campus).

V. Student Evaluation

Students will be evaluated based on

• Written homework assignment: 20%
  Students will prepare an informed consent document that meets federal regulations and Northwestern University guidelines. Grading is based on how well the student incorporates lay language and includes the required elements.
• Class participation: 20%
  Students are expected to fully prepare for each class session by reading all assigned materials. Students will be graded on class participation in case discussions including critical thinking, posing thoughtful questions, responses to questions, communication skills, and respect for other points of view.
• Class discussion assignment 20%
  Each student will take responsibility for serving as leader of at least one discussion and for serving as reader of at least one case. The leader will also submit a 1-2 page summary relating the case to the week’s assigned readings or other scholarly material not less than 24 hours before the class session.
• Final Exam (take home): 40%
  Four short essays requiring synthesis of material covered in class and assigned readings. The take-home final exam will be distributed in class on April 8th. It will be available on Blackboard™, and is due not later than June 10th at 6:00 p.m. Do NOT discuss the exam with other students; you are expected to work alone on the take-home exam. The final exam should be sent by electronic mail to m-moran@northwestern.edu.
**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 cannot be linked with your responses.

**Academic Integrity**
Every Northwestern faculty member and student belongs to a community of scholars where academic integrity is a fundamental commitment. The Program in Public Health abides by the standards of academic conduct, procedures, and sanctions as set forth by The Graduate School at Northwestern University. Students and faculty are responsible for knowledge of the information provided by The Graduate School on their Web page at http://www.tgs.northwestern.edu/academics/academic-services/integrity/index.html

Academic misconduct includes, but is not limited to
1. Receiving or giving unauthorized aid on examinations or homework
2. Plagiarism
3. Fabrication
4. Falsification or manipulation of academic records
5. Aiding or abetting any of the above

The PPH follows The Graduate School’s procedure for evaluating alleged academic misconduct, as outlined on the TGS website. http://www.tgs.northwestern.edu/academics/academic-services/integrity/dishonesty/index.html

Faculty reserve the right to use the “Safe Assignment: Plagiarism Detection Tool” that is part of the Course Management System to evaluate student assignments. Information about this tool can be found at http://www.it.northwestern.edu/education/course-management/support/assessments/safeassignment.html
<table>
<thead>
<tr>
<th>April 1, 2015</th>
<th>Ethical Issues in Clinical Research</th>
<th>CASES</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Week 1)</td>
<td>INTRODUCTION TO THE COURSE</td>
<td>Innovative Care or Research (Investigational Use)?</td>
</tr>
<tr>
<td>READINGs In preparation for class</td>
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<tr>
<td>Nuremberg Code</td>
<td>Course Requirements:</td>
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<tr>
<td><a href="http://history.nih.gov/research/downloads/nuremberg.pdf">http://history.nih.gov/research/downloads/nuremberg.pdf</a></td>
<td>Case reviews</td>
<td></td>
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<tr>
<td>(also Emanuel text, p. 29.)</td>
<td>Class Participation</td>
<td></td>
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<tr>
<td>Declaration of Helsinki</td>
<td>Take home exam</td>
<td></td>
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<tr>
<td>(also Emanuel text, pp. 30-2.)</td>
<td></td>
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<tr>
<td>Belmont Report</td>
<td>Case Assignments for the remaining weeks</td>
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<tr>
<td><a href="http://www.fda.gov/ohrms/dockets/ac/05/briefing/2005-4178b_09_02_Belmont%20Report.pdf">http://www.fda.gov/ohrms/dockets/ac/05/briefing/2005-4178b_09_02_Belmont%20Report.pdf</a></td>
<td>Optional IRB meeting attendance</td>
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<tr>
<td>(also Emanuel text, pp. 33-8.)</td>
<td></td>
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<tr>
<td>Common Rule Sections 46.107-109, available online at:</td>
<td></td>
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<tr>
<td><a href="http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html">http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html</a></td>
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<tr>
<td>(also Emanuel text, pp. 43-44)</td>
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April 8, 2015 (Week 2)

READING In preparation for class


Fair Subject Selection

LECTURE
Recruiting, Retaining and Paying Subjects

DISCUSSION
See cases at right.

CASES
Payment of Research Subjects
Payment of Physicians for Enrolling Research Subjects,

Final Exam will be distributed in class and available on Blackboard. You may find it useful to think about the essay questions each week and record your thoughts accordingly.
### Informed Consent Document

#### LECTURE

Anatomy of a Consent Form

#### DISCUSSION

See cases at right.

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### CASES

Freezing and Storing of Ovarian Tissue

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**Homework assignment will be distributed in class today and posted on Blackboard™**

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**April 15, 2015**  
*(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

### April 22, 2015 (Week 4)

**READINGS In preparation for class**


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### Obtaining Informed Consent

**LECTURE**

Informed Consent: It’s not just a form

**DISCUSSION**

See cases at right.

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### CASES

- Recruiting Healthy Subjects for Yellow Fever Research
- A Clinical Trial of Fetal Surgery
<table>
<thead>
<tr>
<th>Reading</th>
<th>Lecture</th>
<th>Discussion</th>
<th>Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common Rule 46.116 General Requirements for Informed Consent (c) and (d)</td>
<td>Waivers of Informed Consent and Waivers of Written Informed Consent</td>
<td>May I Be Excused? Getting a Waiver</td>
<td>Cystic Fibrosis Screening and Early Treatment</td>
</tr>
<tr>
<td>Common Rule 46.117 Documentation of Informed Consent (c)</td>
<td></td>
<td>See cases at right.</td>
<td>Research Using Stored Biologic Samples</td>
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</table>
May 6, 2015  
(Week 6)

**READINGS** In preparation for class


<table>
<thead>
<tr>
<th>Privacy, Confidentiality and HIPAA</th>
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</thead>
<tbody>
<tr>
<td>LECTURE</td>
</tr>
<tr>
<td>Respecting and Protecting Subjects’ Privacy</td>
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</table>

**DISCUSSION**
See cases at right.

**CASES**

Communicating With and About Subjects

Prospective and Retrospective Studies of Fertility Clinic Patients
<table>
<thead>
<tr>
<th>May 13, 2015 (Week 7)</th>
<th>Research With Children</th>
<th>CASES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>READINGS</strong> In preparation for class</td>
<td><strong>LECTURE</strong></td>
<td><strong>When is it justifiable to do research with children?</strong></td>
</tr>
<tr>
<td>The Common Rule Subpart D.</td>
<td>Research Protection of Children</td>
<td>Environmental lead exposure study</td>
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</table>
May 20, 2015  
(Week 8)

**READINGS** In preparation for class

- The Common Rule Subparts B, C

**Vulnerable Populations**

**LECTURE**

Protection of Vulnerable Adult Subjects: Prisoners and Pregnant Women

**DISCUSSION**

See cases at right.

**CASES**

- Applying Subparts C and D in Genetic Research
- Prophylactic Prevention of Psychosis
May 27, 2015  
(Week 9)

**READINGS**  
In preparation for class


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**Subject’s Rights**

**LECTURE**

Comments on “When Brain Scans Bear Bad News”

**DISCUSSION**

See cases at right.

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**CASES**

Compensation for Research Related Injuries

Disclosure of Study Results

TAKE HOME EXAM DISTRIBUTED AND AVAILABLE ON BLACKBOARD
June 3, 2015  
(Week 10)

**READINGS In preparation for class**


<table>
<thead>
<tr>
<th><strong>Clinical Trials</strong></th>
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<tbody>
<tr>
<td><strong>LECTURE</strong></td>
</tr>
<tr>
<td>Issues specific to Clinical Trials</td>
</tr>
<tr>
<td><strong>DISCUSSION</strong></td>
</tr>
<tr>
<td>See cases at right.</td>
</tr>
<tr>
<td><strong>COURSE EVALUATION (ONLINE)</strong>. See page 3 of the syllabus for more information</td>
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<tr>
<th><strong>CASES</strong></th>
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<tbody>
<tr>
<td>Losing equipoise</td>
</tr>
<tr>
<td>Sham surgery in multiple sclerosis (MS)</td>
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