

**INSTITUTE FOR CLINICAL RESEARCH EDUCATION**

**CLRES 2050: ETHICS AND REGULATION OF CLINICAL RESEARCH**

**Tuesday, 1:00 p.m. to 3:00\* p.m., March 3 – April 28, 2009**

*\*Class meets from 1:00 p.m. to 5:00 p.m. on April 28.*

**Instructor:**

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**Teaching Assistant:**

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**Course objectives:**

This course aims to enhance students' ability to think about the ethical dimensions of research, especially research involving human subjects, and to participate thoughtfully and knowledgeably in the ethical design and review of research protocols. Our objectives can be expressed in terms of the following knowledge, attitudes, and skills.

**Knowledge:**

By the end of the course, students should be able to:

1. Describe the historical context for today's heightened scrutiny of clinical research.
2. Identify and explain the basic concepts, values, and potential ethical conflicts associated with the conduct of human subjects research.
3. Define the elements of scientific misconduct.

**Attitudes:**

By the end of the course, students should be able to:

1. Demonstrate a commitment to integrity in the conduct of scientific research.
2. Demonstrate a commitment to advocate for the rights and welfare of human research subjects.

## **Skills:**

By the end of the course, students should be able to:

1. Analyze a research protocol from the ethical point of view according to criteria developed by federal regulatory agencies and local Institutional Review Boards.
2. Write a consent form for a research protocol that is clear and understandable to laypersons, and sufficiently informative to promote subjects' meaningful informed consent.
3. Demonstrate communication skills adequate to obtain a potential research subject's meaningful informed consent. (*This Learning Objective applies only to students enrolled in the ICRE Grant Writing Course.*)

## **Required Textbook:**

Ezekiel Emanuel, et al, eds. *The Oxford Textbook of Clinical Research Ethics*. New York: Oxford University Press, 2008.

Unless otherwise noted, all reading assignments for the course are from the textbook, and are identified by chapter number, author, and title in the class schedule below.

## **Required work:**

Class meetings will be devoted to discussion of assigned readings and cases designed to illustrate, amplify, and apply the material in the readings. In addition to active participation in class, all students will complete two written assignments:

1. **An ethical critique of a research protocol.** The instructor, in cooperation with members and staff of the University of Pittsburgh Institutional Review Board, will select the protocol for this assignment. Students will write a critique of 5 to 7 double-spaced typed pages, identifying ethical issues raised by the protocol and accompanying consent form, and explaining with reference to the concepts and readings from the course the significance of those issues for the ethical conduct of research. The essay should conclude with the student's recommendation to the IRB whether the protocol should be approved as is, modified to meet ethical concerns, or rejected. (**Critique due May 5, 2009 via CourseWeb.**)
2. **A consent form.** For this assignment, too, the instructor will select a research protocol in cooperation with members and staff from the IRB. Students will receive the protocol but *not* the accompanying consent form. The assignment will be to write a consent form for the protocol that is clear and understandable to laypersons, and sufficiently informative to promote subjects' meaningful informed consent. While there is no set length for the consent form (which will depend in part on the complexity of the protocol), the form should probably not exceed 3 single-spaced typed pages. (**Consent form due May 5, 2009 via CourseWeb.**)

In addition to the two writing assignments, which are required for all students, there will be a **role-playing exercise for informed consent conversations** in class on **April 28, 2009**. Participation in the role-play is required for all students, in either the live or on-line versions of the course, **who are also enrolled in the ICRE Grant Writing Course**. These students will use the research project they are developing for the ICRE Grant Writing Course as the basis for an informed consent conversation with a trained actor who will be simulating a potential subject for the student's research. After the role-play, students will receive feedback on their communication skills from the actor and from fellow students who will observe the role-play.

Students who are not enrolled in the ICRE Grant Writing Course, or who for any other reason do not have a research protocol of their own for which they can role-play a conversation with a prospective research subject, are required to attend this class session as observers. Their point totals (see "Course Grade") will be adjusted accordingly in determining their final grade.

### **Course Grade:**

The final grade for the course will be based on the following point values for the required assignments:

Ethical critique of research protocol:	40 points (all students)
Consent form:	40 points (all students)
Participation in the role-play:	20 points (students in ICRE Grant Writing Course)

### **Class Schedule:**

#### **Week 1 (March 3, 2009)**

Historical and social context

#### *Reading:*

Chapter 2: Weindling, PJ. "The Nazi Medical Experiments"  
Chapter 6: Arras, JD. "The Jewish Chronic Disease Hospital Case"  
Chapter 8: Jones, JH. "The Tuskegee Syphilis Experiment"  
Chapter 10: Steinbrook, R. "The Gelsinger Case"

#### **Week 2 (March 10, 2009)**

Ethical frameworks and standards of conduct

#### *Reading:*

Chapter 11: Emanuel, E, et al. "An Ethical Framework for Biomedical Research"

Chapter 69: Emanuel, E & Thompson, DF. “The Concept of Conflicts of Interest”  
Chapter 72: Resnick, DB. “Fraud, Fabrication, and Falsification”  
Chapter 73: Rennie, D. “The Obligation to Publish and Disseminate Results”

### **Week 3 (March 17, 2009)**

Research design

*Reading:*

Chapter 24: Joffe, S & Truog, RD. “Equipose and Randomization”  
Chapter 25: Miller, FG. “The Ethics of Placebo-Controlled Trials”  
Chapter 30: Wendler, D & Miller, FG. “Deception in Clinical Research”  
Chapter 61: Hodge, JG & Gostin, LO. “Confidentiality”

\*\*\*\*\* **BREAK** \*\*\*\*\*

### **Week 4 (April 7, 2009)**

Vulnerable populations and special concerns

*Reading:*

Chapter 41: Rosenstein, DL & Miller, FG. “Research Involving Those at Risk for Impaired Decision-Making Capacity”  
Chapter 42: Fleischman, AR & Collogan, LK. “Research With Children”  
Chapter 46: Green, RM. “Research With Fetuses, Embryos, and Stem Cells”

### **Week 5 (April 14, 2009)**

Risk-benefit assessment and subject recruitment

*Reading:*

Chapter 48: King, NMP & Churchill, LR. “Assessing and Comparing Potential Benefits and Risks of Harm”  
Chapter 49: Varma, S & Wendler, D. “Risk-Benefit Assessment in Pediatric Research”  
Chapter 37: Miller, FG. “Recruiting Research Participants”

### **Week 6 (April 21, 2009)**

*Guests: members and staff of the University of Pittsburgh IRB*  
Informed consent and protocol review

*Reading:*

Chapter 56: Brock, DW. "Philosophical Justifications of Informed Consent in Research"  
Chapter 58: Appelbaum, P and Lidz, CW. "The Therapeutic Misconception"  
Chapter 60: Wendler, D. "The Assent Requirement in Pediatric Research"  
Chapter 52: Speers, MA. "Evaluating the Effectiveness of Institutional Review Boards"

**Week 7 (April 28, 2009)**

*NOTE: This class will meet from 1:00 p.m. to 5:00 p.m.*

Role-playing informed consent conversations

*Reading:*

There is no reading assignment for this week. Students who will participate in the role-play should review their research protocol and prepare to present it to a simulated prospective subject in a conversation designed to promote the subject's meaningful informed consent (or refusal) to participate in the protocol.