Overview and 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.

Responsibilities:

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. Explain a scientific research protocol in language that promotes laypeople’s understanding sufficient to provide 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.)
Course Requirements:

- **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 explicit reference to the concepts from the course and citations to relevant literature from the textbook—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 10, 2011 via CourseWeb.)*

- In addition to the writing assignment, which is required for all students, there will be a **role-playing exercise for informed consent conversations on May 3, 2011 from 1pm – 5pm in Parkvale 305.** 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 Grading Scale”) will be adjusted accordingly in determining their final grade.

Attendance Policy:

- Students are expected to sign-in to each class (computer provided in suite lobby). If a problem is encountered with the sign-in system, please contact the course instructor(s) as well as Lauren Talotta (talottals@upmc.edu) immediately.

Course Grading Scale:

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

For students **NOT ENROLLED** in the ICRE Grant Writing Course:

- Ethical critique of research protocol: 75 points
- Participation in class discussion: 20 points
- Observation of the role-play: 5 points

For students **ENROLLED** in the ICRE Grant Writing Course:

- Ethical critique of research protocol: 60 points
- Participation in class discussion: 20 points
- Participation in the role-play: 20 points

Required Textbook(s):

Supplemental Textbook(s):

- 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.

Website resources:

- http://courseweb.pitt.edu/

Academic Integrity:

Students in this course will be expected to comply with the University of Pittsburgh’s Policy on Academic Integrity (http://www.provost.pitt.edu/info/ai1.html). Any student suspected of violating this obligation for any reason during the semester will be required to participate in the procedural process, initiated at the instructor level, as outlined in the University Guidelines on Academic Integrity. This may include, but is not limited to, the confiscation of the examination of any individual suspected of violating University Policy. Furthermore, no student may bring any unauthorized materials to an exam, including dictionaries and programmable calculators.

Course Schedule

Date: March 8, 2011
Session 1: Topic(s) Historical and social context
Instructor(s): David Barnard, PhD, JD and Valerie Satkoske, PhD

At the conclusion of this lecture, the student will be able to:

1. Appreciate the historical antecedents to contemporary regulation of clinical research.
2. Identify potential value conflicts in the conduct of medical experimentation with human beings.
3. Describe the impact of societal expectations, processional reward systems, and power dynamics on the ethical conduct of clinical research.
4. Apply social and historical perspectives to case examples.

Required Reading(s):

1. Chapter 6: Arras, JD. “The Jewish Chronic Disease Hospital Case”
2. Chapter 8: Jones, JH. “The Tuskegee Syphilis Experiment”

Recommended Reading(s):

1. Chapter 2: Weindling, PJ. “The Nazi Medical Experiments”
2. Chapter 10: Steinbrook, R. “The Gelsinger Case”
At the conclusion of this lecture, the student will be able to:

1. List eight principles for ethical clinical research.
2. Describe practical benchmarks that help ensure fulfillment of each principle in the conduct of a research protocol.
3. Define “conflict of interest,” “fraud,” “fabrication,” and “falsification” in the research context.
4. Analyze policies that have been proposed to eliminate or manage conflicts of interest in research.
5. Describe the ethical aspects of authorship and publication.
6. Apply the standards of research integrity to case examples.

Required Reading(s):

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

At the conclusion of this lecture, the student will be able to:

1. List the range of ethical issues that are raised by Randomized Controlled Trials (RCT).
2. Define "clinical equipoise" and explain its importance to the decision to initiate or terminate an RCT.
3. State ethical arguments in favor of and against the use of placebos in an RCT when an active treatment is available for the condition under study.
4. State the conditions, if any, under which it is ethically permissible to employ deception in the design or execution of research with human subjects.
5. Analyze the tensions between individuals' privacy interests and the communal benefits of biomedical research.

Required Reading(s):

1. Chapter 24: Joffe, S & Truog, RD. “Equipoise and Randomization”
2. Chapter 25: Miller, FG. “The Ethics of Placebo-Controlled Trials”

Recommended Reading(s):

2. Chapter 61: Hodge, JG & Gostin, LO. “Confidentiality”
At the conclusion of this lecture, the student will be able to:

1. Analyze the concept of "vulnerability" as it relates to potential subjects of clinical research.
2. Describe criteria for the ethical inclusion of people with impaired decision making capacity or children in clinical research.
3. Define "decision making capacity" in clinical and research settings.
4. Describe the ethical concerns raised by research with fetuses and human embryos.

Required Reading(s):

1. Chapter 41: Rosenstein, DL & Miller, FG. “Research Involving Those at Risk for Impaired Decision-Making Capacity”
2. Chapter 42: Fleischman, AR & Collogan, LK. “Research With Children”

Recommended Reading(s):

1. Chapter 46: Green, RM. “Research With Fetuses, Embryos, and Stem Cells”

Date: April 19, 2011
Session 5: Topic(s) Risk-benefit assessment and subject recruitment
Instructor(s): David Barnard, PhD, JD and Valerie Satkoske, PhD

At the conclusion of this lecture, the student will be able to:

1. Distinguish among clinical benefits, societal benefits and inclusion benefits in the context of participation as a subject in clinical research.
2. Analyze the potential for investigators to exaggerate the benefits (relative to the risks) of participating in early-phase clinical trials.
3. Describe the difficulties investigators and IRB members have in implementing the "minimal risk" standard in pediatric research.
4. Describe and apply the empirically-based comparative risk analysis method of characterizing the level of risk interventions and studies involving children.
5. Describe and apply criteria of appropriate advertisements seeking participants for research studies.

Required Reading(s):

3. Chapter 37: Miller, FG. “Recruiting Research Participants”
At the conclusion of this lecture, the student will be able to:

1. Identify the ethical foundations of informed consent.
2. List three necessary conditions for valid informed consent to participate in a biomedical research study.
3. List the elements of informed consent to participate in a biomedical research study.
4. Define the therapeutic misconception and explain why it is a common occurrence in enrolling subjects in randomized clinical trials.
5. Distinguish between consent as the signing of a form and consent as the result of a process of dialogue between investigator and subject.
6. Describe the criteria applied by the IRB to the ethical evaluation of research protocols.

Required Reading(s):

1. Chapter 58: Appelbaum, P and Lidz, CW. “The Therapeutic Misconception”

Recommended Reading(s):

1. Chapter 56: Brock, DW. “Philosophical Justifications of Informed Consent in Research”
2. Chapter 52: Speers, MA. “Evaluating the Effectiveness of Institutional Review Boards”

At the conclusion of this lecture, the student will be able to:

1. Demonstrate communication skills adequate to obtain a potential research subject’s meaningful informed consent.

Required Reading(s):

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.