

Course Syllabus and Calendar

PHRM 7230 Ethical Issues in Research Call Number 49-452

Spring 2010

This course syllabus is a general plan for the course; deviations announced to the class by the instructor may be necessary.

Instructor information:

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Course Support (including technical support):

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Course Description:

This course provides an introduction to bioethical principles used to make decisions when confronted with ethical issues involving research in animals and human subjects, fraud, scientific misconduct, and conflicts of interest. The goal is to develop a framework for decision making to predict and solve ethical dilemmas within the pharmaceutical, biotechnology and medical device fields. Students will be introduced to fundamental bioethical review systems, including the theory of peer review and moral and ethical responsibilities of leadership.

Prerequisites: Permission of Department

Course Materials and Recommended Reading:

There is no required text book for this course. Readings will come from a bibliography list and many of these will be available from the internet or library. A variety of materials and methods will be employed in providing the information for PHRM 7230. These may include audio tapes, lectures, power point presentations, reading materials and interactive web exercises.

Policies and Academic Honesty:

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All academic work must meet the standards contained in *A Culture of Honesty*. Each student is responsible to inform themselves about those standards before performing any academic work. A Culture of Honesty is the University of Georgia's policy and procedures for handling cases of suspected dishonesty and can be found online at www.uga.edu/ovpi. UGA Student Honor Code states "I will be academically honest in all of my academic work and will not tolerate academic dishonesty of others."

IMPORTANT for ALL CLASSES:

As Regulatory Affairs or Clinical Trials professionals and as UGA Graduate Students, our program expects that each assignment is submitted as though you were submitting this task to your Board of Directors, FDA or other managing body. With this in mind, when you submit a research paper or written assignment, be sure that you follow the assignment directions; use your computer’s spell checking feature to assure that there are no misspellings; and you proof-read your document for typographical errors. Finally, be sure that you cite your references for those ideas and quotes that are not your own.

Netiquette:

In this course, and all the courses in the program, you will be required to interact with students and faculty electronically, either through email or eLC Discussion Boards or Chat Rooms. Therefore, we ask that you follow these simple guidelines of network etiquette.

- 1) Please always be respectful of classmates opinions and ideas. If you disagree on a topic, do so respectfully and with tact. These discussions are monitored by faculty and often your grade will depend on your participation and the quality and content of your posting. Should you be disrespectful, this may impact your grade.
- 2) Do not post anything off-topic in the designated discussion, email or chat topic areas. At no point are you to use our email distribution lists or eLC programs for soliciting.
- 3) Take care when using humor or sarcasm in emails, discussions and chats. Humor and sarcasm are often hard to convey electronically. It is safest to avoid using it; but if you chose to add humor, consider using the little smileys icons.

Grading Formula:

100-point scale	Grade
100-94	A
93-90	A-
89-88	B+
87-84	B
83-80	B-
79-78	C+
77-74	C
73-70	C-
69<	D
59<	F

Online and Class participation – 60%

Final Paper – 40%

Chat Sessions:

Please be aware that we will have live chat sessions during the course of the semester. You will need to allow yourself time for these sessions as you plan for this course. The sessions will take place either on a Monday, Tuesday, or Wednesday, from 9:00 pm- 10:00 pm. These days and times are subject to change. It is at the instructor discretion as to when these chat sessions will take place.

Objectives for course participants are to:

- 1. Understand historical, legal, and cultural contexts of ethical decision-making relevant to conducting research with human subjects.

2. Identify important ethical concepts in conducting research and be capable of appropriately applying the concepts to research.
3. Learn strategies for addressing and minimizing ethical conflicts in conducting research.
4. Understand the importance and function of the Institutional Review Board (IRB) process and gain experience in carrying out IRB reviews.
5. Understand historical, legal, and cultural contexts of ethical decision-making relevant to conducting research in animals.
6. Identify ethical issues that arise in drug development and clinical testing of pharmaceuticals, biotechnology products and medical devices.
7. Identify important issues involving conflicts of interest and develop strategies to resolve identified conflicts.
8. Examine issues of scientific integrity and processes used to resolve reported cases of misconduct.

Course Calendar: This course calendar is a general plan for the course; deviations announced to the class by the instructor may be necessary.

Note: Generally, a new topic will begin with each Saturday session.

Week of:	Topic: Spring Semester 2010 Ethics in Research
January 9	Orientation and Guidance Documents
January 9	Guidance Documents for Ethical Conduct of Clinical Trials
January 16	Guidance Documents for Ethical Conduct of Clinical Trials
January 23	IRBs and Clinical Research
January 30	Paper Topic Due
January 30	Ethical Challenges of Clinical Research in Special Populations
February 6	Ethical Challenges of Clinical Research in Special Populations
February 13	Ethical Use of Animals in Research
February 20	Conflicts of Interest
February 27	Stem Cells and Cloning Issues
March 8-12	Spring Break
March 13	Academic Detailing/Labeling/Drug Promotion
March 20	Academic Detailing/Labeling/Drug Promotion
March 23	Withdrawal Deadline
March 27	Direct-to-Consumer Advertising
April 3	Off Label Prescribing and Communication
April 10	Authorship and Ghost Writing
April 17	Seattle Paper
May 1	Final Paper

Paper is due May 1