International Research Ethics 1

Developed by the faculty of the
Advanced Certificate Program for
Research Ethics in Central and Eastern Europe

Union Graduate College (USA)
Vilnius University (Lithuania)

Course purpose and objectives

The purpose of this course is to provide students with an introduction to the ethics of scientific research, particularly research involving human participants.

By the end of this course, students should be able to: 1) discuss in depth the principles of bioethics; 2) describe how these principles should be applied the ethical design and conduct of research involving human participants; 3) identify, define and analyze ethical issues in the context of novel and potentially problematic areas of scientific research; and 4) identify ethical issues that arise in different contexts and begin to develop appropriate courses of action.

Approach to assignments

The course consists of 10 weeks. Each week students will have assigned readings and/or written assignments, including responses to questions posted on the interactive Discussion Board and analytical papers that will be submitted online.

Assigned materials:

The assigned readings are divided into two sections: 1) required readings, audio and video; and 2) recommended readings, audio and video. All students are expected to read all required readings, which will not exceed an average of 50 pages per week. All students are also expect to watch all assigned video and to listen to all assigned audio. All students are expected to complete the required readings, watch the required audio, and listen to the required video by the start of the week, so that they can fully participate in Discussion Board Forums. All required materials will be available online under “Required Readings, Audio and Video” Section of a week [if a

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publicly available article], via your institutional library [if a copyrighted article], or in one of the assigned text books: 1) Emanuel EJ, et al. (2003) *Ethical and Regulatory Aspects of Clinical Research.* Baltimore, MD: Johns Hopkins University Press, or via UGC Library Databases; and 2) European Commission Directorate-General for Research. (2010) *European Textbook on Ethics in Research.* Luxembourg. Publications Office of the European Union. Available online at http://ec.europa.eu/research/science-society/document_library/pdf_06/textbook-on-ethics-report_en.pdf.

Recommended readings, audio and video contain additional materials for those who would like to go deeper into the topics, but are not required to complete the written assignments or participate fully in the discussion forums. The majority of them will be available online under "Recommended Readings, Audio and Video" Section of a week, via your institutional library, or in one of the assigned text books.

Written assignments:

Students -- individually or in small groups -– will be required to submit brief analyses of key questions or concepts that arise during the course. These analyses are short essays intended to show mastery of the cases, terminology, precepts or principles discussed.

Unless the instructor sets a different deadline, assigned papers should be submitted on the Sunday following the week they were assigned (e.g. an essay assigned for week 2 should be submitted no later than the last Sunday in week 3)

The instructor will return the papers with comments by e-mail and/or the online educational platform. For assignments submitted within a week after the expected deadline, students will receive an automatic 10% grade deduction. Assignments received greater than 7 days after the expected deadline will not be accepted.

Discussion Forums:

The Discussion Forums are the main vehicle for promoting interaction among students. All students are expected to participate fully in each Discussion Forum by answering questions, challenging assumptions, posing new questions, and sharing concerns and insights.

Participation in the Discussion Forums will be assessed and contributes to the overall evaluation of student performance in the course. Discussion Forums will remain active for two weeks (e.g. the Discussion Forums for week 2 will remain active until the last Sunday in week 3). Students are welcome to post additional comments or questions after that time, but such posts will not be not be considered as part of their overall performance in the course.

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Overall Evaluation

In all of the assignments, students will be expected to draw upon not only assigned readings but also outside materials, including the primary literature, existing international and national regulations, and ethical guidance documents, among others.

It is anticipated that each student will need to dedicate 12 to 15 hours per week to course readings and activities, including written assignments and Discussion Forum participation.

In order to receive an “A” grade, a student will need to demonstrate creative thought, independent research and scholarship, and competence in applying ethical theories and models to challenging and novel research problems.

Because of the intensive and interactive nature of this course, students should expect to log onto the online educational system on a daily basis. We do recognize, however, that all students have competing obligations and that unforeseen circumstances do arise. If, for any reason (professional, personal or otherwise), a student cannot participate fully during a given week, they should inform both the Course Coordinator and Instructor immediately so that alternative arrangements can be made.

A total of 1000 points will be awarded during the course, with 100 points assigned for each week. The point value for each Discussion Forum and/or written assignment will be provided in the weekly syllabi and should be used by students to manage their time and effort.

Final letter grades will be determined using the following unweighted scale:

A = 1000-930	B = 869-830
A-minus = 929-900	B-minus = 829-800
B-plus = 899-870	C = 799-750

Any student who scores less than 750 points will receive a failing grade.

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Required Books and Materials

European Commission Directorate-General for Research. European Textbook on Ethics in Research. Luxembourg. Publications Office of the European Union. 2010. Available online at http://ec.europa.eu/research/science-society/document_library/pdf_06/textbook-on-ethics-report_en.pdf. Also available in the "External Resources" section of the course.

Emanuel, E. Crouch, R., Arras, J., Moreno, J. and Grady, C. (eds.). Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary. Baltimore, Maryland. Johns Hopkins University Press. 2003.

Course Readings (online): selected publicly-available articles to be provided free. Copyrighted articles should be accessed through your institutional library.

Supplementary Books and Materials

Supplementary Course Readings (online): selected articles to be provided free. Copyrighted articles should be accessed through your institutional library.

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Preliminary Course Outline

The course outline, required and supplementary readings, and written assignments are subject to modification over the 10 week duration of the course. Students should therefore use this outline in conjunction with the “Week-by-Week” files in the online course.

Week	Topic
Module 1 - Introduction to Human Subjects Research Design and Review	
1	Conceptual and Regulatory Aspects of Human Subjects Research.
2	Structure and Practice of Research Ethics Committees.
3	Research Ethics Capacity Assessment.
Module 2 - Design and Conduct of Clinical Trials	
4	Evidence-Based Medicine.
5	Clinical Trials (1).
6	Clinical Trials (2).
7	Placebo-Controlled Trials.
8	Informed Consent and Therapeutic Misconception.
Module 3 - Vulnerable Subjects and Populations	
9	Vulnerability (1) - Inability to Consent.
10	Vulnerability (2) - Social and Institutional Vulnerability.

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