

These materials were developed for a course in International Bioethics offered in late 2011 as part of the Advanced Certificate Program for Research Ethics in Central and Eastern Europe, a collaborative project between Union Graduate College and Vilnius University. They are free for use, distribution and modification with proper attribution.

## **International Bioethics**

**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 historical and theoretical foundations of global bioethics. Topics will include: the history and development of key international institutions and regulatory documents, pivotal policies, theoretical frameworks informing international bioethics and research ethics, and case studies of specific areas in international bioethics.

By the end of this course, students should be able to: 1) describe the history and development of key international institutions and regulatory documents; and 2) explain and employ the basic concepts, policies and theoretical frameworks of international bioethics and research ethics to case studies.

This course is designed to help students: 1) develop and refine their skills in the theory and practice of bioethical review and practice; 2) develop and refine their ability to analyze individual cases and to make informed and reasoned judgments; and 3) improve their research and writing through independent examination of key ethical theories, policies and regulations.

### **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

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read all required readings, which will not exceed an average of 40 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 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](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 a brief analyses of key questions or concepts that arise during the course. These analyses are short essays (two to four pages; max. 1200 words) intended to show student mastery of the cases, terminology, precepts or principles discussed. There will be four written assignments during the course, in weeks 2, 5, 8, and 10.

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.

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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 considered as part of their overall performance in the course.

## **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](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.

<b>Week</b>	<b>Topic</b>
1	Why Do People Differ in Moral Judgments?
2	Ethical Theories and Their Application to Bioethical Disputes.
3	The Failure of Medical Ethics, Whistleblowers and the Birth of Bioethics.
4	Foundations of International Bioethics. Dignity and Human Rights Discourse.
5	Basic Concepts and Principles of International Research Ethics.
6	Respect for Persons, Autonomy and Informed Consent.
7	Duty of Care in Research and Clinical Equipoise.
8	Balancing Risks and Benefits in Research.
9	Justice and Solidarity in Research.
10	International Research and Benefit Sharing.

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