Course: 410.687.71 Ethical and Legal Aspects of Biotechnology
Instructors: Evan G. DeRenzo, PhD
Jack Schwartz, JD

Time: Mondays, 6:00 pm - 8:45 pm
January 25 to May 3, 2010

Location: Montgomery County Center, [Building and Room to be determined]

Telephone: DeRenzo (301) 279-5734 ; Schwartz (410) 409-4560

Email: DeRenzo: evan@eederenzo.com
Schwartz: jschwartz@law.umd.edu

I. Purpose of Course

The purpose of this course is to provide an introduction, through readings and discussion, to the ethical and legal aspects of biotechnology. The legal component of the course will include selective discussion of pertinent regulatory schemes. This purpose will be achieved through an integrative exploration of the ethical and legal issues raised by various topical areas, including, among others, embryonic stem cell research, the clinical testing and marketing of a stem cell derived therapeutic, reproductive technologies including human cloning, experimentation involving animals, genetically modified food and related environmental issues, and emerging technologies such as neuroenhancement and nanotechnology.

II. Teaching Methods

The teaching methods for this course will be a combination of lecture, seminar format and small group discussions. Students will be expected to have thoroughly prepared for class by having read the assigned material so that class discussions can build on the assigned readings and rigorous and insightful engagement can occur during class. Audio-visual materials will be used adjunctively.
III. Grading: Components and Policies

A) Assigned Papers

1) Each student will write three (3) papers, each of which will be no longer than 4 pages, double-spaced, with 12-point font minimum and normal margins.

2) The first paper, to be submitted on March 1 (class 5), is to be on a topic related to human subject research and must (i) use an ethical matrix or alternative format to analyze an ethical issue raised by the research and (ii) discuss how the regulations of the Food and Drug Administration apply to the aspect of the research that presents the ethical issue.

3) The second paper, to be submitted on March 22 (class 8), is to be on a topic related to experimentation on animals or the use of animals in biotechnology and must (i) use an ethical matrix or alternative format to analyze an ethical issue raised by the topic and (ii) discuss how some aspect of the law, including any applicable regulation, is pertinent to the topic or, if none is, whether new law is needed.

4) The third paper, to be submitted on April 12 (class 11), may be on any topic of the student’s choice that relates to the overall subject matter of the course. The paper should contain both ethical analysis and a discussion of pertinent legal material.

5) Students will submit 2 hard copies in a manila envelope and one electronic copy by the due date. For a good cause like illness, a student may request an extension. To enable the instructors to be blinded during the grading of papers, the envelope and hard copies should be marked with the last 4 digits of the student’s Hopkins ID number ONLY. Do not write your name or other identifying information. The electronic copy may be submitted on a CD or zip drive likewise marked with the last 4 digits of the student’s Hopkins ID number only. Electronic media so marked will be returned with the graded paper. Alternatively, the electronic copy may be submitted to both instructors, by the due date, via email attachment, provided that neither the email account nor the message itself identifies the sender; again, only the 4-digit number that appears on the hard copies should be used. For those using Office 2007, the paper should be saved in “Compatibility Mode,” with a “.doc” extension rather than “.docx”.

6) In researching each paper, the student is to read at least 4 relevant publications from the peer-reviewed scientific or ethics literature or from law journals published under the auspices of a law school or professional society. At least 2 of these publications must have a primary focus in ethics or law. The student may substitute original source legal material (that is, the text of a statute, regulation, or court opinion) for a law journal publication. Each paper will have a reference section citing these publications and any other references used.
B) Examination

There will be a final examination, which will be distributed on April 26 (class 13). This is a take-home exam, to be submitted by the student on May 3, the final class. Students may use any materials they want as reference during the exam, and they are welcome to take as much time reading in preparation for the exam as they like. Students, however, should spend NO MORE THAN 2 HOURS writing the exam. If a student uses reference materials for the writing of the exam, these materials should be specified in end notes. The submission of the exam should follow the same procedures as set forth above for the submission of papers.

The reason students are being asked to provide 2 hard copies of each writing assignment and their exam is because both instructors will be grading these materials separately, with student grades being averaged across instructors' grades. The addition of the electronic copy is to facilitate the use of reading software by one of the instructors, who has a reading disability.

C) Grading Procedures

1) The papers and exam will be graded A, B, C, or F, including plus (+) or minus (-). If a paper is turned in up to 1 week late without prior permission from an instructor for good cause, 1 half-grade will be dropped automatically (e.g., a paper that would have earned an A will receive an A minus, a B minus will drop to a C plus, and so on). If a paper is turned in more than 1 week but no more than 2 weeks late without prior permission from an instructor for good cause, 1 full grade will be dropped automatically. Without prior permission from an instructor for good cause, a paper more than 2 weeks late will not be accepted, and the grade for that paper will be an F. Each paper will contribute a maximum of 20 points to the final grade. The final exam will contribute a maximum of 30 points. Class participation will contribute a maximum of 10 points.

2) Your papers will be handed back with comments where appropriate. For the first paper, you have the option of revising it in light of any comments and resubmitting it. If you choose to do so, submit the revised paper together with a copy of the first version no later than March 8 (class 7). Follow the same procedures as set forth above. At your request, however, the instructors will discuss comments with you. Obviously, this discussion will compromise blind grading, but nevertheless the resubmission should follow the standard procedures. The higher grade will stand. For the second paper, you have the option of revising it in light of any comments and resubmitting it if, but only if, you receive a grade lower than a B. Any resubmitted version of the second paper is due on April 5 (class 10). The higher grade will stand. There are to be no resubmissions of the third paper.

3) Again, please identify all papers, electronic submissions, and manila envelopes only with the last 4 digits of your Johns Hopkins Student ID number.
4) The grading scale is:

- 98 – 100      A+
- 94 – 97        A
- 90 – 93        A-
- 88 – 89        B+
- 84 – 87        B
- 80 – 83        B-
- 70 – 79        C
- 69 and below   F

To help students better understand the instructors’ expectations, we offer the following guidance about how we approach the grading of papers:

**Problem:** Is there a clear statement of the issue or problem that will be discussed in the paper? Does the issue or problem reasonably relate to the concerns of the course? Is the issue or problem manageably limited in scope, or is it too diffuse or expansive? Are facts or examples presented as necessary to clarify the issue or problem? **Maximum possible points: 25.**

**Analysis:** To what extent does the paper address the pertinent ethical, legal, and regulatory issues? Are the descriptions of these issues accurate? Does the paper effectively convey the author’s analysis of the issues? That is, does the paper go beyond mere description or unsupported assertions or opinions and offer adequately justified, well-supported, logical argument? **Maximum possible points: 50.**

**Writing:** Does the paper adhere to the standards of spelling, grammar, and word usage expected of advanced academic writing? Does it conform to the page limit identified in the syllabus? **Maximum possible points: 15.**

**References:** In the text itself, does the paper properly identify sources relied on by the author, through the use of endnotes, footnote, or parenthetical references? Does it conform to the reference requirements identified in the syllabus? **Maximum possible points: 10.**

**IV. Academic Integrity**

The strength of this university depends on academic and personal integrity. In this course, you must be honest and truthful. Students are obliged to refrain from acts that they know or, under the circumstances, have reason to know, will impair the integrity of the university. Ethical violations include cheating on exams, plagiarism, reuse of assignments, improper use of the Internet and electronic devices, unauthorized collaboration, alteration of graded assignments, forgery and falsification, lying, facilitating academic dishonesty, and unfair competition.

Use of professional reference material, either printed or from the Internet, is encouraged, because the topics we cover are dynamic and evolving. It is fully expected, however, that all work represented to be that of the student is original work and reflects the student’s efforts, ideas and
knowledge and that all materials used in the production of the student's work is appropriately referenced.

V. Required Texts and Recommended References

**Required:**


*Note: Additional required reading is noted in the assignments below or, in some cases, will be announced later in the course. Students will not be required to purchase any additional material.

**Recommended References**


VI. Class Schedule

**Class 1, 1/25:** Introduction of students and instructors. General overview of course content and expectation for course requirements. A handout on the US legal system will be distributed; students are encouraged to review this handout as general background for the legal component of future classes. Introduction to the language of ethical analysis. The Mephisto Biotech case study, which presents problems for discussion in several classes, will be distributed.

→→→**Assignment for class 2:** In Mepham, read Chapters 1 and 2. Prepare for discussion of Exercise 2.3, p. 42, as applied to Problem 1 of the Mephisto Biotech case study. Follow exercise directions. Please bring in your completed assignment for your use during discussion. (The assignment will not be collected.)

**Class 2, 2/1:** The philosophical bases for ethical analysis in biotechnology. Understanding the relationship between law and ethics.

→→→**Assignment for class 3:** In Mepham, read Chapter 3 and section 4.7.1, pp. 81-82. Prepare an ethical matrix, of the kind described in Chapter 3, as applied to Problem 1 of the Mephisto Corp. case study. Please bring in your completed assignment for your use during discussion. (The assignment will not be collected.) Also, read Problem 2 of the Mephisto Corp. case study and think about what the corporation’s goals in marketing its product might be.

**Class 3, 2/8:** Approaches for doing ethical analysis in biotechnology. Patent law.


**Class 4, 2/15:** Research with Human Participants: Healthy Volunteers.
Assignment for class 5: Read the following portions of the FDA’s regulations: 21 CFR Part 50, Subpart D. Also, read the chapter entitled “Grimes v. Kennedy Krieger Institute: Revisiting the Ethical Issues,” in National Research Council and Institute of Medicine, Ethical Considerations for Research on Housing-Related Health Hazards Involving Children (2005), available at this link: http://books.nap.edu/openbook.php?record_id=11450&page=41 Finally, read Problem 4 of the Mephisto Biotech case study in preparation for class discussion. Think about how to analyze the ethical issues raised by this research and whether the FDA regulations sufficiently address the ethical concerns. *Reminder: Paper 1 is due at class 5.*

Class 5, 2/22: Research with Human Participants: Children and other Vulnerable Subjects *Paper 1 is due at this class.*

Assignment for class 6: In Mepham, read Chapters 5 and 6.

Class 6, 3/1: Biotechnology and Human Reproduction

Assignment for class 7: Read UNESCO, Human Cloning: Ethical Issues (2004), available at this link: http://unesdoc.unesco.org/images/0013/001359/135928e.pdf Also, read the FDA’s 1998 letter about its jurisdiction over human cloning, available at this link: http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm150508.htm Prepare an ethical matrix for Problem 5 of the Mephisto Biotech case study. Please bring in your completed assignment for your use during discussion. (The assignment will not be collected.)

Class 7, 3/8: Human Cloning for Reproductive Purposes

Assignment for class 8: In Mepham, Chapter 15. Additional readings to be assigned. *Reminder: Paper 2 is due at class 8.*

3/15: No class. Spring break

Class 8, 3/22: Assessing Emerging Technologies: Nanotechnology and Neuroenhancement

*Paper 2 is due at this class.*

Assignment for class 9: In Mepham, read Chapter 8.

Class 9, 3/29: The ethics of animal research

Class 10, 4/5: Animal biotechnology, including xenotransplantation; legal issues concerning the use of animals.

→→→Assignment for class 11: In Mepham read Chapters 12 and 13.

Class 11, 4/12: Biotech and the environment; the Precautionary Principle.

→→→Assignment for class 12: In Mepham, read Chapter 10. Additional material on regulatory issues to be assigned (TBA). Reminder: Paper 3 is due at class 11.

Class 12, 4/19: Genetically modified foods: environmental considerations. Paper 3 is due at this class.

→→→Assignment for class 13: In Mepham, read Chapter 11. Additional material on regulatory issues TBA.

Class 13, 4/16: Genetically modified foods, including the impact of public opinion on regulation

→→→Assignment for class 14: In Mepham, Chapter 14

Final exam distributed, course evaluations to be completed.

Class 14, 5/3: Capstone Class
Final exam due. Class will dismiss at 7:30 pm.