I. General Topics in Biomedical Research

Session 1: Introduction to the Course (August 30)

Session 2: Definitions and Categories of Research; the Freedom of Scientific Inquiry (September 6)

Session 3: Research with DNA, Cells, Tissues, and Primitive Organisms (September 13)

Session 4: Research with Vertebrate, Non-Human Animals (September 20)

Session 5: Research with Human Subjects I (September 27)

Session 6: Research with Human Subjects II (October 4)

Session 7: Research with Human Groups: Social Science Research (October 11)

Session 8: Social Responsibilities of Biomedical Scientists; Commercial Aspects of Biomedical Research (October 18)

II. Special Topics in Human Research

Session 9: Randomized Clinical Trials I (October 25)

Session 10: Randomized Clinical Trials II (November 1)

Session 11: Research Involving Human Gene Therapy I (November 8)

Session 12: Research Involving Human Gene Therapy II (November 15)

Session 13: Research Involving Early Human Embryos (November 29)

Session 14: Institutional Review Boards (December 6)
TEXTBOOKS


READINGS

Session 2: Definitions and Categories of Research; the Freedom of Scientific Inquiry (September 6)


Session 3: Research with DNA, Cells, Tissues, and Primitive Organisms (September 13)


Session 4: Research with Vertebrate, Non-Human Animals (September 20)


Session 5: Research with Human Subjects I (September 27)


Session 6: Research with Human Subjects II (October 4)


Royal College of Nursing, "Ethics Related to Research in Nursing", B-W, pp. 513-516.
Session 7: Research with Human Groups: Social Science Research (October 11)


Session 8: Social Responsibilities of Biomedical Scientists; Commercial Aspects of Biomedical Research (October 18)


Session 9: Randomized Clinical Trials I (October 25)


Charles Fried, "Informed Consent and Medical Experimentation," B-W, pp. 541-546.


Session 10: Randomized Clinical Trials II (November 1)


Session 11: Research Involving Human Gene Therapy I (November 8)

President's Commission, Splicing Life, entire report (115 pages).

Session 12: Research Involving Human Gene Therapy II (November 15)


Session 13: Research Involving Early Human Embryos (November 29)


Session 14: Institutional Review Boards (December 6)


RESERVE SHELF

Readings not included in the textbooks or distributed in class are available on the reserve shelf in the Ethics Library of the Kennedy Institute (D.C. Transit Building, 3520 Prospect Street, Room 302). The library is open from 9:00 AM to 5:00 PM on weekdays.

COURSE REQUIREMENTS

1. Completion of assigned readings.

2. Participation in seminar discussion.

3. Preparation of a hypothetical human research protocol, including a consent form. The protocol and consent form together should not exceed ten double-spaced pages. The case may be discussed by seminar members or by the members of the Georgetown University Research Committee. Due dates for research protocols will vary.

4. Preparation of a brief bibliographical essay on three to five readings on a particular ethical issue or problem in biomedical research. The essay may discuss readings assigned in this course, but should include discussion of at least two unassigned readings that you judge to be important. The essay should be critical and analytical. It should not exceed eight double-spaced pages. The due date for the bibliographical essay is Thursday, October 25.

5. Participation in a discussion with members of the Georgetown University Research Committee on Thursday, November 8, from 1:00 PM to 2:00 PM, your schedule permitting.

6. Preparation of a term paper fifteen to twenty double-spaced pages in length. The paper may analyze an issue or the viewpoint of a particular individual or group. Issues or authors selected for analysis in term papers need not be those formally covered in the course, but should be related to biomedical research. Whatever topic is chosen, the paper should not be merely a summary or exposition of issues or views; rather, it should be a critical and analytical paper that asks questions like the following:

   What are the author’s presuppositions, and are they explicitly acknowledged?

   On what aspects of the issue is there controversy and why?

   How can the arguments of the author or the controversial aspects of the issue be related to general ethical principles or to normative theories of ethics?

The due date for term papers is Thursday, December 13.
COMPONENTS OF FINAL GRADE

1. Completion of assigned readings, as reflected in class discussion and final term paper (20%).

2. Research protocol (20%).

3. Bibliographical essay (20%).

4. Term paper (40%).