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Office Hours: By Appointment

**Summary of Course**

This seminar course deals with issues arising from the interface and relationship between law and medicine. During the Winter term, the seminar will concentrate on three areas of controversy in medicine and health care, spending three weeks on each area of concentration. This year all of the areas that we will be considering involve legal, ethical and policy issues in medical research. During the first three week segment, we will focus on clinical research studies using human subjects, the use and misuse of human subjects, and the issues arising as a result of the exclusion of women from participation in clinical trials. The second three week segment will consider issues arising from the use of animals in research, including the question of whether animals have rights and how they should be protected. The third three week segment will consider scientific misconduct and research fraud, an issue which has become particularly prominent over the last several years. First, we will consider the increasing confusion in law and medicine regarding the use of human organs, tissues and cells. During the Winter term and first half of the Spring term, each student will be researching and preparing a presentation on a similarly controversial topic of their choice. The last several weeks of spring term will be devoted to student presentations of their research and class discussion of these topics.

**Required Texts**

The Course Materials include several recent cases, articles, excerpts from texts, and legislative/regulatory materials. They are organized into three sets - one dedicated to each of the three areas of concentration. Set I is available for purchase at RAMS Copy Center, 4144 University Way N.E. (phone 632-6630). The Cost is 14.85 plus tax. Sets II and III will be available later in the term.

**Class Participation**

In a seminar course of this type, active participation by all of the parties is integral. While I will moderate and focus the seminar as necessary, I anticipate that the subject material will generate spontaneous and vigorous discussion. It will be imperative that you are prepared for the class, having read the materials and thought about the issues.
Course Grade

Your course grade will be based upon a research paper and presentation of same to the class. Although the topic may be one of your choice, it must be approved by the professor. You must submit a prospectus describing your research topic on or before January 20, 1998. You must submit a first draft of your paper no later than April 15; I will meet with you to discuss your draft, potential revisions and plans for completion in during April. During the last several weeks of the Spring term, students will be presenting their papers and research to the class; Date of presentation will be on the basis of lottery drawing on the first day of class. The final version of your research paper is due on June 5, 1998.

Course Syllabus

January 6, 1998

Introduction: This class session will be devoted to an overview of the course and its requirements.

January 13, 20, and 27

I. Medical Research: Use and Misuse of Human Subjects

Reading Assignment:


Robert J. Levine, Ethics and Regulation of Clinical Research, Chapter One: Basic Concepts and Definitions (2d ed. 1986)


The Nuremberg Code
Declarations of Helsinki, Recommendations Guiding Doctors in Clinical Research, Declarations I-IV.

The Belmont Report

Robert J. Levine, Ethics and Regulation of Clinical Research, Chapter Four: Selection of Subjects (2d ed. 1986)

Robert J. Levine, Ethics and Regulation of Clinical Research, Chapter Eight: Randomized Clinical Trials (2d ed. 1986)


Kenneth J. Rothman & Karin B. Michels, The Continuing Unethical Use of Placebo Controls, 331 N.E.J.M. 394 (Aug. 11, 1994); The Use of Placebo Controls (Correspondence), 332 N.E.J.M. 60 (Jan 5, 1995).


Rebecca Voelker, Debating Dual AIDS Guidelines, 278 JAMA 613 (1997).


February 3, 10, and 17

II. Animals & the Research Enterprise

February 3, 1998 - Reading Assignment:


Eugene Linden, Can Animals Think, Time, March 22, 1993, at 54


Andrew A. Skolnick, Yerkes Primate Studies Yielding Clinical Fruit, Results Useful in Ophthalmology, Behavioral Science, 272 JAMA 909 (1994)

February 10, 1998 - Reading Assignment:

Dennis L. Breo, Animal Rights vs Research? A Question of the Nation’s Scientific Literacy, 264 JAMA 2564 (1990)

Lewin et al. v. United States Surgical Corp., 575 A.2d 262 (Ct. App. 1990)

Andrew A. Skolnick, Terrorists Strike Again as Us Congress Considers Bills to Outlaw Attacks on Animal Research Centers. 267 JAMA 2577 (1992)

PAWS v. University of Washington, 125 Wash. 2d 243 (1994)

February 17, 1998 - Reading Assignment:


Paul Cotton, Animals and Science Benefit from 'Replace, Reduce, Refine' Effort, 270 JAMA 2905 (1993)

Reduced Use of Laboratory Animal in Research Institute, 349 Lancet 1557 (1997)

Monkeys Spoil Paradise in Keys - Hundreds of research Animal Devastate Islands and Vegetation, Florida Today, Sept. 28, 1997 at 12B.

February 24, March 3, and March 10

III. Scientific Misconduct & Research Fraud: Ethical Questions and Legal Consequences

March 30 - April 24

Student Research, Preparation of First Draft and First Draft Conference

April 28 - May 26

Student Presentations