UNIVERSITY OF TORONTO
DEPARTMENT OF PHILOSOPHY

PHL 381 - Fall 1991
HUMAN VALUES: EXPERIMENTATION ON HUMAN SUBJECTS
Thursdays 2-4 pm
Course Director: Eric M. Meslin, Ph.D

OFFICE AND TELEPHONE NUMBER

Philosophy Department
Room 1025, 215 Huron Street
978-6790
Office Hours: Thursdays 12:00 - 2:00

I. COURSE OBJECTIVES

> *"To conserve health and to cure disease: medicine is still pursuing a scientific solution to this problem, which has confronted me from the first."*
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> *"So, among the experiments that may be tried on man, those that can only harm are forbidden, those that are innocent are permissible, and those that may do good are obligatory."*
>
> - Claude Bernard, An Introduction to the Study of Experimental Medicine (1865)

These words by the French physiologist, Claude Bernard, illustrate the nature of many of the historical ethical problems arising from the use of human beings in medical research: on the one hand, medical research has a laudatory goal, to promote health and to cure disease. Yet at the same time these goals cannot be accomplished without at some point involving human beings as experimental subjects.

This course is designed to investigate in some detail several ethical issues that arise in the context of research involving human subjects bearing in mind these twin demands. Complicating this situation is the fact that the ethical issues are not limited to research participants: several issues are routinely faced by those who design, report on and publish research.

The primary objective of the course is to examine these issues from a philosophic point of view; that is to say, we will be interested not only in identifying the ethical issues themselves, but critically discussing their relevance and importance to medical research.

To identify, appreciate and evaluate these issues requires a method or paradigm. We will use the research protocol--the research plan that researchers use to guide their investigation--as a

paradigm, in order to examine the ethical issues as they arise chronologically during the course of a research study.

II. COURSE OVERVIEW

The course if divided into three (3) sections as follows:

A. Ethical Issues in the Justification and Conduct of Clinical Research

1. Justification of Research
2. Research Design
3. Placebos and Investigational Drugs

B. Ethical Issues in the Protection of Human Subjects

1. Informed Consent
2. Assessing Harms and Benefits
3. Privacy and Confidentiality
4. Research Ethics Committees

C. Scientific Fraud and Misconduct

1. Fraud and Misconduct: Cases and Issues
2. Responses to Fraud and Misconduct

III. COURSE MATERIALS

A. TEXTS

1. Robert J. Levine, *Ethics and Regulation of Clinical Research.* 2nd ed. New Haven: Yale University Press, 1986. [Levine]

2. Robert M. Veatch, *The Patient As Partner.* Bloomington, Indiana: Indiana University Press, 1987. [Veatch]

3. Committee on the Conduct of Science, National Academy of Sciences, *On Being a Scientist,* Washington, DC: National Academy Press, 1989.

B. ARTICLES AND HANDOUTS

Throughout the course several additional handouts will be provided.

C. CHANGES IN SYLLABUS

It is possible that changes in the readings may occur. This is possible in a field like bioethics, where new developments occasionally render some article less relevant. In the event of a change, you will be given as much advance warning as possible. It is for this reason that handouts will be available the week prior to their assignment. It is also possible that due to class size, the format for class presentations (see IV. B. below) will change. If the need arises you will be notified.

IV. COURSE REQUIREMENTS

The course is designed to encourage discussion. Some of the issues raised will be controversial, and it is unlikely that you will not eventually have some opinion on each of them. While it is not expected that you will have worked out a philosophic argument for each of the issues we discuss in this course, it is expected that you will be able to understand the nature of the ethical issues themselves and be able to argue about them both verbally and in your writing.

There are four (4) course requirements.

A. **Issue Paper (25%).** Each student will submit a 1250 word (5 page) paper that evaluates an article from the syllabus. This is not a research paper. Students will be expected to identify the ethical issues raised by one of the assigned readings, and to take a position on this issue. **DUE IN CLASS: OCTOBER 10, 1991.**

B. **Class Presentation (25%).** You will prepare for and conduct a mock research ethics review of a research study that will be provided to you. This will be a small group project (4-5 students per group depending on class size). More information will be available in class.
DATES FOR THESE PRESENTATIONS WILL BE NOVEMBER 21 & 28.

C. **Term Paper (40%).** Each student will submit a 2500 word (10 page) term paper that presents a philosophic argument about a topic or issue raised in the lectures or readings. Topics not directly related to lectures or readings may be pursued with the permission of the course director.
DUE ON CLASS DECEMBER 5, 1991.

D. **Class Participation (10%).** It is expected that you will attend all classes and have read course materials prior to the lecture for which they were assigned. Discussion by the entire class will be a regular feature of the course, so far as possible.

V. STYLE AND FORMAT OF WRITTEN WORK

All written work will be **typed** (either by typewriter or personal computer), **double-spaced**, and will conform to usual standards for academic papers in philosophy regarding bibliography, citations, etc. See for example, Kate L. Turabian, A Manual for Writers of Term Papers, Theses and Dissertations, Chicago. University of Chicago Press, 1973. Exceptions to this policy are permitted only with approval of the course director.

VI. PENALTIES FOR LATE WORK

Papers are due in class on the dates indicated. The only exception from this policy is medical, for which a medical note is required. Late papers will be accepted, but will be assessed a one-half (1/2) letter grade deduction for each late day. **Late papers must be handed in to the Philosophy Department secretary** (9th Floor, 215 Huron Street), and entered into the log book. If you expect that an assignment will be late, please inform me as soon as possible.

VII. OTHER EVENTS

A. Guest Speakers

October 3	Dr. Neal Shear, Head, Clinical Pharmacology, Sunnybrook Health Science Centre
November 7	Ms. Susan Pilon, Executive Officer, Office of Research Administration, University of Toronto

B. Site Visit

All students are invited to observe the Sunnybrook Health Science Centre's Research Ethics Committee (REC), of which I am the current chair. This is an opportunity to observe a committee in action. It is optional, and no grades will be assigned for attending (nor will they be detracted for choosing not to attend). The visit is scheduled for Wednesday, November 6. More details to follow. Space is limited to the first 10 students who indicate an interest.

LECTURE SCHEDULE AND COURSE READINGS
PHL 381F, FALL 1991
Eric M. Meslin, Ph.D.

A. ETHICAL ISSUES IN THE DESIGN AND CONDUCT OF CLINICAL RESEARCH

September 12 (#1): COURSE INTRODUCTION: WHAT IS CLINICAL RESEARCH AND WHAT ARE THE ETHICAL ISSUES?

FILM: "Evolving Concern"

September 19 (#2): THE JUSTIFICATION OF MEDICAL RESEARCH

(1) Veatch, pp. 2-35.
(2) Hans Jonas, "Philosophical Reflections on Experimenting with Human Subjects" In: Paul A. Freund (ed.) *Experimentation With Human Subjects*. New York: George Braziller, Inc. 1969, reprinted in: Tom L. Beauchamp and LeRoy Walters (eds.) *Contemporary Issues in Bioethics* 3rd ed. Belmont, CA: Wadsworth, 1989, pp. 432-440.

September 26 (#3): RANDOMIZED CLINICAL TRIALS

(1) Veatch, pp. 66-76.
(2) Levine, pp. 185-212.
(3) Samuel Hellman and Deborah Hellman, "Of Mice But Not Men: Problems of the Randomized Clinical Trial," [Sounding Board] *New England Journal of Medicine* 324 (1991): 1585-1589
(4) Eugene Passamani, "Clinical Trials--Are They Ethical?" *New England Journal of Medicine* 324 (1991): 1589-1592.

October 3 (#4): ETHICAL ISSUES IN DRUG RESEARCH: INVESTIGATIONAL NEW DRUGS AND THE USE OF PLACEBOS

(1) Levine, pp. 202-207, 229-230.
(2) Veatch, pp. 178-182.

GUEST: Dr. Neal Shear

October 10 (#5): RECRUITMENT OF RESEARCH PARTICIPANTS

(1) Levine, pp. 67-93.
(2) Veatch, pp. 130-135.
(3) David A. Salisbury and Martin T. Schecter "AIDS trials, civil liberties and the social control of therapy: should we embrace new drugs with open arms?" *Canadian Medical Association Journal* 142 (1990): 1057-1062.

NOTE: SHORT PAPER DUE

B. ETHICAL ISSUES IN THE PROTECTION OF HUMAN SUBJECTS

October 17 (#6): INFORMED CONSENT

FILM: "The Belmont Report"

(1) Veatch, pp. 36-65
(2) Levine, pp. 95-130

October 24 (#7): ASSESSING HARMS AND BENEFITS

(1) Levine, pp. 37-65.
(2) Edward Pochin, "Risks and Medical Ethics" *Journal of Medical Ethics* 8 (1982): 180-184.
(3) Peter C. Williams, "Success in Spite of Failure: Why IRB's Falter in Reviewing Risks and Benefits"*IRB: A Review of Human Subjects Research* 6 (May/June 1984): 1-4.

October 31 (#8): PRIVACY AND CONFIDENTIALITY

(1) Levine, pp. 168-183.
(2) Veatch, pp. 168-176.

November 7 (#9): RESEARCH ETHICS REVIEW

(1) Veatch, pp. 108-127.

(2) Levine, pp. 322-328.
(3) MRC Guidelines, pp. 45-50.

GUEST: Ms. Susan Pilon, Office of Research Administration, University of Toronto

November 14 (#10): NO CLASS

November 21 (#11): CLASS PRESENTATIONS: MOCK RESEARCH ETHICS REVIEW

November 28 (#12): CLASS PRESENTATIONS: MOCK RESEARCH ETHICS REVIEW

C. SCIENTIFIC FRAUD AND MISCONDUCT

December 5 (#13): FRAUD AND MISCONDUCT

(1) Levine, pp. 19-35.
(2) Committee on the Conduct of Science, National Academy of Sciences, *On Being a Scientist*, Washington, DC: National Academy Press, 1989.
(3) Selected Guidelines from Canadian Universities

NOTE: TERM PAPER DUE IN CLASS