[All required weekly readings must be done before the seminar meets for the week in question. (e.g., the readings for January 31st should be done before the first meeting of the seminar, etc.]

**Textbooks**


**Weekly Assignment:** After our first seminar all students should come to our weekly seminar prepared to discuss the issues under consideration in the weekly readings, the controversies involved and a tentative view on the desirable role of public policy in the area under discussion.

**Required Reading**

**January 31st Meeting:**

**A Brief Introduction/Overview of Normative Ethics and the Subject Matter of Bioethics**

In this first of our seminar meetings I will be doing more lecturing than in our remaining seminars. In future seminars I expect to share this sort of “leadership” with other members of the seminar.

In the first segment of this week’s seminar I will outline the overall scope of the bioethics/public policy issues that will be dealt with in this seminar. This will include the briefest introduction to the development of various approaches to setting ethical norms,
a brief review of the major public policy tools available to address issues in bioethics and the relationship of bioethics to the law [particularly the U.S. Constitution] and to religion. Some common themes that will continue to arise in the seminar will be identified.

In the second segment of this week’s seminar we will begin to focus on the material in this week’s required readings. Our objective in this segment (which will continue into next week’s session) is to gain an initial acquaintance with the nature and the kinds of questions raised by normative ethics and some of the proposed frameworks that have been developed for considering answers to these questions (Kuhse and Singer, Rachels, Childress, Boyle, and Hare). Particular attention will be devoted to distinguishing moral views based on consequences vs. duties vs. rights. The Gutmann and Thompson and the Warren readings focus on two specific issues that will come up again and again throughout the seminar namely: the problem faced by public policy makers in dealing with morally contested issues in a pluralistic democracy (Gutmann and Thompson) and the issue of Moral Status (Warren).


Since a great many contemporary bioethical issues arise from developments on the scientific frontier and resulting challenges for public policy in the second meeting of this seminar we will consider, in brief, an overview of the history of science and technology policy in the U.S. Since the U.S. government finances a great deal of both biomedical research and the provision of medical care public policy cannot escape its own moral responsibilities with respect to many bioethical issues.

**February 7th Meeting:**

**Introduction (continued): Science Policy, Medical Ethics, “Concerns”**

This week’s seminar will begin with a review of the material covered in segment two of our first meeting. In addition there will be three segments of new material. One will deal with the development of science policy in the U.S. since the involvement of the federal government in biomedical research and health care delivery is an important source of public policy disagreements in the arena of bioethics. A second segment is aimed at an initial understanding of both the history and nature of: medical ethics or the nature of the mutual obligations of physicians (and other care givers) and patients to each other. This is, perhaps, the oldest branch of what is now known as bioethics. Moreover, medical ethics is intimately connected to a relatively more recent issue in bioethics namely: the treatment of human subjects participating in medical experiments. A third segment will deal with some “concerns” regarding scientific and technological progress (i.e. How do we understand our simultaneous embrace of new technology and our continuing sense of unease regarding its meaning for our lives.)

**Science Policy**


Medical Ethics

“Ancient” Approaches:

“AMA Code of Ethics (1847)” (see Course Pack).


"The Hippocratic Oath" [see Course Pack].

Contemporary Approaches:

AMA “Fundamental Elements of the Patient-Physician Relationship”, a concise summary of the key principles (see Course Pack).

Emanuel, E. and Emanuel, L., “Four Models of the Physician-Patient Relationship”, in Ethical Issues in Modern Medicine, Steinbock,


Concerns Regarding Scientific and Technological Progress


February 14th Meeting:

Scientific Medicine and the Protection of Human Subjects

This is an issue that is primarily associated with the rise of scientific medicine and the increasing desire to carry out experiments using human subjects beginning in the 19th century and continuing to the present day. There are earlier examples of circumstances where the investigation of the human body and/or specific diseases raised the issue of the investigator’s ethical obligations to human subjects, but our focus will be on developments since the rise of modern scientific medicine. We will also discuss a series of examples where human subjects were seriously abused and the impact of these events on the articulation and development of attitudes related to the protection of human subjects.


“The Nuremberg Code” (see Course Pack).


**February 21st Meeting:**

**Federal and International Regulations Regarding Human Subjects**

Our primary focus in this session will be on the nature and development of the specific U.S. regulations regarding the protection of human subjects. In this respect it is particularly important to review The Belmont Report and the United States “Code of Federal Regulations (CFR), Title 45 Part 46”. With respect to “CFR 45-46” the reading is hardly exciting or “gripping”, but it is critical to understand how difficult it is to translate ideas into regulations. Keep your focus on the challenge of protecting human subjects through voluntary informed consent and independent review of the risks, protections,
and benefits of research protocols that employ human subjects. We will also take up
the challenges of obtaining voluntary informed consent in more unusual settings (i.e.
with vulnerable populations, with third party consent and when working in other
countries). In the case of international research we will review various international
documents such as the Nuremberg declaration, various UN declarations, the
Declaration[s] of Helsinki, and the CIOMS reports dealing with the protection of human
subjects. With respect to policy our attention should focus on whether or not
contemporary oversight mechanisms should be enhanced.


Emanuel, E.J., Wendler, D., & Grady, C. “What Makes Clinical
Research Ethical?” Journal of the American Medical Association
283 (2000); pp. 2701-2711.

Foddy, Bennet, “A Duty to Deceive; Placebos in Clinical Practice”,
The American Journal of Bioethics, December 2009, Volume 9,
Number 12, pp. 4-12.

Brendel, D.H., and Miller, F.G., “A Plea for Pragmatism in Clinical
Research Ethics”, American Journal of Bioethics, April 2008, Vol. 8,
Number 4, pp. 24-31.

Elliot, Carl, “Making a Killing”, in Mother Jones Vol. 35, no. 5
[September/October 2010], pp 55-63

Levine, Robert J., “International Codes and Guidelines for Research
Ethics: A Critical Appraisal”, The Ethics of Research Involving
Human Subjects: Facing the 21st Century, ed. Vanderpool, Harold
Y., Frederick, MD: University Publishing Group, Inc., 1996, pp. 235-
259.

Miller, Franklin G. and Colloca, Luanda, “The Legitimacy of Placebo
Treatments in Clinical Practice: Evidence and Ethics” The American
Journal of Bioethics, December 2009, Volume 9, Number 12, pp 39-
47.

National Bioethics Advisory Commission Report, “Research
Involving People with Mental Disorders...”, Vol. I., Bethesda,
Maryland, August 2001.

Shamoo, Adil E, Schwartz, Jack, “Universal and Uniform Protections
of Human Subjects in Research,” The American Journal of
Bioethics, December 2007, Volume 7, Number 12, pp. 7-9.
United States “Code of Federal Regulations, Title 45 Part 46” (see Course Pack).


**February 28th Meeting:**

**The Moral Status of the Human Embryo and the Issue of Abortion**

This session will focus on aspects of what is in the U.S. the most politically polarizing and controversial issue within bioethics namely the moral status of the fertilized human ova and its implication for such issues as abortion, embryonic stem cell research, and reproductive or therapeutic cloning. This session will focus on the general issues of how one might think about the moral status of the human embryo and the implications this holds for public policy on the issue of abortion. In this session we will also review both the ‘facts’ regarding the changing incidence of abortion, both where it is legal and illegal and some of the key arguments in the pro-life/pro-choice approaches. We will deal with these issues as they impact attitudes toward cloning and embryonic stem cell research at a later date.

**The Moral Status of the Human Embryo.**

A significant portion of contemporary bioethical controversies concern the moral status we assign, or should assign to the fertilized human ova and the resulting
“early stage” embryo. This issue is significant in a large number of contexts including abortion, reproductive or therapeutic cloning, assisted reproductive technologies (e.g. IVF), and embryonic stem cell research. The issue of moral status also arises in the debate regarding the appropriate use of non-human animals which we will discuss in a subsequent seminar.


Abortion.

The issue of Abortion is one of the most polarizing issues in America and one on which thoughtful persons have strong disagreements. Our task is to try to develop a clear understanding of the arguments behind the different views.


March 7th Meeting:

The Status of Non-Human Animals. Experimentation with Animals, Animal Rights etc.

There has been a long history of debate over the appropriate relationship of the human species to non-human animals. For some this reduces to a discussion of what the moral status of non-human animals is, but historically there has never been complete agreement on this issue. For others a large number of additional matters arise including the concern that if we mistreat non-human animals we will eventually mistreat humans as well, and the view that God’s world includes many forms of life all of which deserve thoughtful consideration. This session will focus on some of the principal approaches to these issues.


March 21st Meeting:

Eugenics, and Assisted Reproductive Technologies (ART)

Human societies have always been fascinated by familial relationships and the apparent inheritance of various traits from one’s parent or other family members. It is
only in the last century or so, however, that a scientific understanding of the genetic mechanisms governing aspects of this inheritance has been developed. While the full role of genes in determining various characteristics remains hotly debated, it seems quite clear that in most cases a large variety of genetic and environmental and cultural factors work together in some symbiotic manner. Nevertheless there are some traits that seem to be dominated by genetic factors and many more whose probability of expression (i.e. its presence in a specific phenotype) are impacted by genetic factors. Moreover in the last decade or so the possibility of altering one’s genetic inheritance via genetic engineering either on somatic or germ line cells has raised a number of controversial bioethical issues. In this session we will consider how these matters relate to the Eugenics movement.

Eugenics as a concept may have begun more or less innocently enough, as an idea that it might be a good idea to do something to improve the “quality” of the gene pool bequeathed to the next generation. In the late 19th century and until very recently this meant adopting certain social practices that “encouraged” the “right” people to reproduce and “others” to cease doing so. Quite aside from the misuse or mistaken use of science the movement had a tendency, one way or another, to became quite a coercive one eventually “culminating”, for example, in forced sterilization, or even more ominous in the Nazi eugenics program of the 1930s and 1940s. Nevertheless, continued progress on the biomedical frontier keeps bringing this issue back for the consideration of individuals as well as public policy. Contemporary discussions focus on the use of our new knowledge to eliminate disease, but this has proved difficult to separate fully from various eugenic concepts. On the U.S. legal front since the Supreme Court case of *Buck v. Bell*, involuntary sterilizations either as punishments for specific crimes or as a “public health” measure, have not withstood legal scrutiny.

The development of ART has provided a large number of intentional parents to overcome various fertility problems and enjoy the fulfillment of raising a family where the children have some biological relationship to at least one of the parents. It has also raised a number of new issues regarding our understanding of the meaning of family, the regulation of medical practice, and the role of public policy and the law with respect to defining the legal frameworks within which family rights and responsibilities are articulated.

Part I. Eugenics


Part II. Assisted Reproductive Technologies


March 28th Meeting:

**Further Issues in Genetics, Behavioral Genetics**

The development of genetic science has opened up a truly vast array of issues in bioethics in the following areas: genetic testing and reproduction, genetic screening, genetic counseling, gene therapy, parentage and family law, forensic testing, behavioral genetics, the regulation of genetic research, patenting of genes, and the use of genetic information. A relatively new interest within the “enhancement/privacy/safety” area is neuroethics which deals with the ethical issues arising because of the implications of new and prospective technologies able both to monitor brain function and to alter the brain with specific and selective chemicals. We will be able to deal with only a subset of these issues in this seminar, and will probably not have time to deal with neuroethics at any length. This session we will focus on the issue of enhancement and how this differs, if at all, from traditional “treatment” and the difference, if any, between medical and behavioral genetics.

**Part I. Further Issues in Genetics, Enhancement, Therapy, and Reproduction.** As a group we will discuss whether there should be any limit either to the human capacity to create and/or master the world we inhabit, or to the level of responsibility we take for the future. In particular we will focus on whether public policy or professional norms should limit in any way the use of new biomedical modalities to provide enhancement potentials to individual human beings, the implications of these issues for the formation of human identity, and how one might differentiate between enhancement and therapy.


Part II. Behavioral Genetics


April 4th Meeting:

**Issues Surrounding Human Reproductive Cloning and Stem Cell Research: Some Case Examples Concerning the Formation of Public Policy and the Role of Advisory Commissions**

Since the early 1970s the U.S. has appointed a number of advisory commissions to help address the role of public policy and/or professional norms regarding a sequence of bioethical issues. However, unlike the situation in many other countries, there has not been any standing committee in this arena. Indeed, from the early 1980s until the mid 1990s no such committee and/or commission existed in the U.S. In 1996, however, President Clinton appointed the National Bioethics Advisory Commission (NBAC), and among the issues it dealt with were reproductive cloning (subsequent to the Dolly experiment) and human embryonic stem cell research (subsequent to the ability to isolate human embryonic cells, and culture such stem cell lines). More recently President Bush appointed the Presidents Council on Bioethics (PCOB) which has issued a number of reports which address a variety of issues including: embryonic stem cell research, reproduction, and ART.


April 11th Meeting:

Death and Dying, Euthanasia and Suicide

The moral status of suicide has a long history and attitudes towards suicide are heavily influenced by the surrounding culture and its attitudes towards life and death. These cultural attitudes range from outright opposition to any form of suicide or euthanasia, to its glorification under certain circumstances and for the most part public policies in this respect reflected these cultural attitudes and norms. It has long been recognized that a person who “dies” loses their human agency and efficacy, and as a result enters into a new moral category in the sense that their rights and obligations are now either greatly diminished or non-existent. As a result it is both morally and practically important to determine when death has occurred. Modern technology has made this a challenging matter. Moreover there is the associated matter of attitudes towards refusing treatment and physician-assisted suicide (PAS) and the role of public policy in these respects. As regards these latter matters you might want to keep in mind the fact that it is estimated that about 70% of those that die in the hospital do so after someone’s decision to refuse, withhold, or withdraw treatment.

Death and Dying


**Suicide: Ethical Considerations**


**April 18th Meeting:**

**Distributive Justice and Access to Biotechnologies**

Every society has specific attitudes towards assigning tasks and benefits with respect to the distribution of work effort on the one hand and material rewards on the
other. An important question is whether the status quo meets our sense of social justice and the role of public policy in insuring that over time we achieve a just distribution of effort and rewards. In the context of this overall issue we will focus on the distribution of health care services. In this context we will also want to consider the relationship between health and human rights. An important issue here is whether universal access to health care services eliminates health disparities. If time allows we may review the ethical dimensions of the new Prescription Drug Benefit recently enacted as a supplement to Medicare.


April 25th Meeting:

**Genetically Modified Food [Segment 1] and Medical Ethics in a Time of “Crisis” (Segment 2)**

The application of contemporary scientific developments to the production of food, as with other applications, presents both risks and benefits. The potential benefits include improving nutritional content, improving agricultural efficiency, and decreasing the allergic potential of certain foodstuffs. The risks include any unknown health and environmental risks. In addition there are those who believe it is unethical to “fool with mother nature”. It is an excellent example of the need to properly “manage” the introduction of new technologies. In any case there is now considerable world wide controversy regarding the application of biotechnology to agriculture despite the fact that farmers have been genetically modifying their crops in the “old fashioned way” for millennia. Without a specialist using advanced technology we could not recognize the “ancestor” rice or corn plant that is now common. Nevertheless we should focus on the current controversy and try to understand and evaluate the nature of the disagreements. Interestingly the issue seems “hotter” in Europe than in the U.S.

The second issue this week is whether or not medical ethics need to be at least partially set aside in a time of real crisis such as in wartime, or at a “time of terror”, or in the midst of a public health crisis of one type or another. This set of issues has become more salient in the public’s mind because of recent events such as the SARS “epidemic” and the “involvement” of physicians in legally authorized executions, or in the
“no-mans” land of the treatment of both POWs and “enemy combatants”. If time allows we will also spend some time discussing the issues that surround just and unjust wars.

Segment 1


Segment 2


Additional Sources

January 31st Meeting:


- President’s Council on Bioethics, December 2003, Being Human: Readings from the President’s Council on Bioethics.


**February 7th Meeting:**

**Ancient Approaches**

• Bloche, Mr. Gregg MD, JD, and Marks, Jonathan H., MA, BCL, “When Doctors Go to War”, The New England Journal of Medicine, Volume 352:3-6; January 6, 2005, Number 1.


• Essay on Herophilus and Vivisection of Human Subjects.

• Essay on Premodern Human Subject Research.


**Contemporary Approaches**

• AHA, “A Patient’s Bill of Rights (1992)” [see Course Pack].


**Concerns Regarding Scientific and Technological Progress**


**February 14th Meeting:**


February 21st Meeting:


• CIOMS, “International Ethical Guidelines for Biomedical Research Involving Human Subjects” [see Course Pack].

• Evans, Donald and Evans, Martyn, A Decent Proposal, New York: John Wiley & Sons, 1996, pp. 33-49.


• United States, “21 CFR 50. Protection of Human Subjects” [see Course Pack].


• World Medical Association, “The Declaration of Helsinki (2002)” [see Course Pack].

**February 28th Meeting:**


• *Roe v. Wade* (1973), The US Supreme Court Decision.


**March 7th Meeting:**


• Maehle, A.H., and Trohler, U., “Animal Experimentation from Antiquity to the End of the 18th Century”.


**March 21st Meeting:**

**Eugenics**


- Buck v. Bell, U.S. Supreme Court [1927] upholding the rights of States, under certain circumstances to carry out involuntary sterilizations. Since 1974 Virginia no longer has an involuntary sterilization statute.


**Assisted Reproductive Technologies**


• Davis v. Davis (1992). Tennessee Supreme Court decision on the ownership of frozen embryos.

• Johnson v. Calvert (1993). Supreme Court of California. (Is the surrogate mother the natural mother?)


March 28th Meeting:

Further Issues in Genetics, Enhancement, Therapy, and Reproduction


• President’s Council on Bioethics, October, 2003, Beyond Therapy: Biotechnology and the Pursuit of Happiness.


Behavioral Genetics


April 4th Meeting:


April 11th Meeting:

Death and Dying


### Suicide: Ethical Considerations


• *Washington v. Glucksberg and Vacco v. Quill* (1997). The U.S. Supreme Court recognized the power of each State to regulate Physician Assisted Suicide [PAS], but denied the Constitutional right to PAS.

**April 18th Meeting:**

**Other Sources**


• London, Alex John, “Another Voice, What is Social and Global Justice to Bioethics or Bioethics to Social and Global Justice”,
The Hastings Center Report, Volume 36, No. 4, July-August, 2006, pg. 3.

- Unequal Treatment, Institute of Medicine, Washington D.C. 2002, pp. 1-23 (Summary).


April 25th Meeting:

Segment 2
