Syllabus

University of Washington

Institute for Public Health Genetics
School of Law
School of Public Health and Community Medicine
School of Medicine

LEGAL, ETHICAL & SOCIAL ISSUES IN PUBLIC HEALTH GENETICS
PHG 512/LAW H504/MHE 514/HSERV 590D - 3 Credits

Autumn 2007

Instructor
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Summary of Course

This core course offered by the Institute for Public Health Genetics provides an introduction to the legal, ethical and social issues arising as genetic knowledge and technologies are developed and made available to individuals and populations. Students will learn to identify and anticipate potential legal, ethical and social concerns that complicate incorporating new genetic advances into public health efforts. The course introduces the analytic tools used to examine public health genetics issues from multidisciplinary perspectives, including ethics, law, social sciences, policy, and economics. It examines the development and uses of genetic information in reproductive and medical decision-making, public health policy, and genetics research, as well as multidisciplinary examinations of privacy and confidentiality and genetic discrimination.

Course Objectives

Through lectures, class discussions, and examination, students will: develop basic skills in legal, ethical, social and policy analysis as it pertains to public health genetics policy and practice; be able to recognize and analyze legal, ethical and social issues arising in the context of public health genetics; become familiar with the diverse literature and research sources regarding ELSI issues in public health genetics, including books, journals, and government reports; and increase the competence with which they make decisions in the area of public health genetics as issues arise in their practice and professional training.

Required Texts

There are two required "texts" for this course:

1. The Course Materials consist of a compilation of medical, scientific, legal, policy and public health journal articles, book excerpts, miscellaneous legal materials, and articles from the popular press. They are available on line for downloading at
https://courses.law.washington.edu/kuszler/H504_Au07/


Since scientific advancements in genetics are occurring and being reported practically every day, from time to time throughout the course we will email news items of potential relevance to the class. Unless specifically identified as *required* reading for the course, these news items are *optional* readings.

**Class Participation**

This course provides an opportunity for students to discuss cutting-edge and controversial issues. Active participation by students is crucial to the success of this class. It is important that students prepare for class, having both read the materials and thought about the issues.

*If you must miss class:* Extra copies of class handouts will either be posted on the course website or can be found in the file cabinet outside of the Institute for Public Health Genetics offices, F363 Health Sciences Building. If you miss class, it is your responsibility to pick up the handouts and get notes from your classmates.

**Course Grade**

Your course grade will be based upon a midterm, final examination, and short writing assignment (Reflective Essay, as described below). The midterm will account for 30% of your grade and the final exam will account for 50% of your grade. Both the midterm and the final exam will be a series of short-answer essay questions. Both exams will be graded anonymously according to the procedures discussed in class. The Reflective Essay will be graded and account for 20% of your course grade. Failure to complete the Reflective Essay will result in a grade of Incomplete.

*Important instructions for the Midterm:* The midterm will be completed during one scheduled class, October 29, 2007, and will cover course content through October 22, 2007. The midterm is a traditional in-class, closed-book exam. No reference materials are permitted for the midterm. Violations will be subject to disciplinary action under the University of Washington’s Honor Code.

*Important instructions for the Final Exam.* The final exam will be completed in a traditional 1-hour-and-50-minute scheduled examination format according to the University Examination Schedule on **December 10, 2007, 2:30-4:20pm**. The exam will be based on the course learning objectives. You are encouraged to study with classmates. However, the final exam will be a traditional in-class, closed-book exam. No materials at all will be permitted in the examination room, and no consultation with classmates is permitted. Violations will be subject to disciplinary action under the University of Washington’s Honor Code. A list of sample questions from a previous course offering will be made available for reference in advance.

*Important instructions for the Reflective Essay.* In 5 pages (double space, 12 point, 1 inch margins, with page numbers, Times New Roman font), reflect on your reading of Mary Shelley’s *Frankenstein*, presenting a personal response to the book following the handout “Narrative Ethics and Frankenstein: What Can We Learn from Stories” provided in
the class readings. Please do not summarize the book. Assume the reader has read the book, and reference a relevant passage only if you must use it for appropriate citation or where it is critical for clarity. The essay is intended to help you put into words some of the thoughts and reactions you may have that may not otherwise emerge from other course readings of the class. **Students are expected to write on each of the 4 criteria identified in the Handout. However, students may choose to emphasize and write in more detail in two of the four areas, but must also include reflections on the other areas. Your essay will be graded on a 10-point scale.** Two (2) copies of your essay must be turned in on Wednesday, November 14, 2007 at 1:30 p.m. That day, a bioethicist and medical historian will lead the class in a discussion using the analytic approach of narrative ethics. Late papers will receive a 1 point deduction for each day (24-hours) late.

Assignments/Examinations and Due Dates are summarized below:

<table>
<thead>
<tr>
<th>ASSIGNMENT/EXAMS</th>
<th>DATE</th>
<th>GRADING WEIGHT</th>
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<tbody>
<tr>
<td>Midterm</td>
<td>Monday, October 29, 2007 1:30pm – 2:50pm</td>
<td>30%</td>
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<tr>
<td>Reflective Essay</td>
<td>Wednesday, November 14, 2007, 1:30 p.m.</td>
<td>20%</td>
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<tr>
<td>Final Exam</td>
<td>Monday, December 10, 2007 2:30-4:20 p.m.</td>
<td>50%</td>
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**COURSE OUTLINE**

1. Introduction to the Course
   a. What is Public Health Genetics
   b. Introduction to ELSI Issue
2. Historical Perspectives on PHG
   a. Eugenics
   b. Experiences with Genetic Testing and Screening Programs in the US
3. Analytic Tools and Research Methods
   a. Ethics: Fundamental Principles and Approaches
   b. Social Issues in the Age of Genetics
   c. Law
   d. Public Policy
4. Genetics, Race, and Health Disparities
5. Genetic Discrimination
   a. The Genetic Exceptionalism Debate
   b. Insurance
   c. Employment
6. Genetic Testing and Screening
   a. Fundamentals of Genetic Testing
   b. Susceptibility Testing
   c. Prenatal Testing, Reproductive Decisionmaking
   d. Carrier Screening
   e. Newborn Screening
   f. Predisposition Testing
   g. Genetic Counseling
7. Genetics Research and Therapeutic Applications
   a. Overview – History, Ethical and Legal Principles
   b. Gene Transfer Research in Humans
   c. Research Using Pedigrees
   d. Use of Stored Tissue Samples in Population Based Research
8. Hot topics in Public Health Genetics - selected by class vote, possibilities include:
   a. Direct-to-Consumer Marketing
   b. New Legislation and National Policies

**COURSE SYLLABUS AND READINGS**

The following syllabus outlines the reading assignments and sets forth a preliminary timetable. It is possible, if not likely, that the timetable and reading assignments will be amended during the course, depending on our pace and new developments. However, this outline should serve as a rough guide as you plan your reading and study schedule. Please note that reading assignments should be completed prior to our coverage of that portion of the outline in class.

<table>
<thead>
<tr>
<th>Wednesday, September 26, 2007</th>
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<tbody>
<tr>
<td><strong>General Topic:</strong></td>
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<tr>
<td>Course Introduction</td>
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<tr>
<td>- What Is Public Health?</td>
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<tr>
<td>- What Is Public Health Genetics?</td>
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<td>- Introduction to ELSI Issues</td>
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<tr>
<td><strong>Session Objectives:</strong></td>
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<tr>
<td>- Understand parameters of public health and the relationship between it and the broader health services landscape</td>
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<td>- Define &quot;public health genetics&quot;</td>
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<td>- Explain what ELSI means</td>
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<td>- Generally characterize the public's concerns with genetics</td>
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<td><strong>Readings:</strong></td>
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<tr>
<td>Excerpt from Institute of Medicine: The Future of the Public's Health in the 21st Century (2002)</td>
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<tr>
<td>Reilly PR. Public concern about genetics (2000).</td>
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<td><strong>For students needing genetics overview or refresher:</strong></td>
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<tr>
<td>Burke W. Genetics primer (2005).</td>
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<tr>
<th>Monday, October 1, 2007</th>
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<tr>
<td><strong>General Topic:</strong></td>
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<tr>
<td>Historical Perspectives on PHG</td>
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<td>- Eugenics</td>
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<tr>
<td>- Experiences with Genetic Testing and Screening Programs in the US</td>
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<tr>
<td><strong>Session Objectives:</strong></td>
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<tr>
<td>- Define positive eugenics and negative eugenics</td>
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<td>- Explain how the science of genetics has been misused in history</td>
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<td>- Explain the three alternate definitions of eugenics discussed by Diane Paul, and identify which definition geneticists and other interested parties might likely adopt</td>
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<tr>
<td>- Distinguish between genetic testing and genetic screening</td>
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</tbody>
</table>
- Contrast and compare the history of development of genetic screening programs for Tay Sachs Disease and Sickle Cell Disease, and explain the implications of these experiences for future screening efforts.

**Readings:**
- Pernick, MS. Eugenics and public health in American history (1997).
- Please review the interactive web site: Cold Spring Harbor Image Archive http://www.eugenicsarchive.org/eugenics/.

### Wednesday, October 3, 2007

**General Topic:**
Analytic Tools and Research Methods
- Ethics: Fundamental Principles and Approaches

**Session Objectives:**
- Define moral dilemma and provide at least one example of a moral dilemma arising in genetics
- Define and contrast utilitarianism and Kantian ethics
- Identify, describe and apply 5 methods to resolve a moral disagreement
- Identify, describe and apply the 4 principles of bioethics developed by Beauchamp and Childress
- Describe the casuist approach and compare it to principlism

**Readings:**

### Monday, October 8, 2007

**General Topic:**
Analytic Tools and Research Methods
- Law
- Sources of Law

**Session Objectives:**
- Describe the relationship between law and morality
- Describe the roles and relationships among the federal constitution, state constitutions, federal and state statutes and regulations, and federal and state common law
- Define and explain the role of precedent and *stare decisis* in the US legal system

**Readings:**
- Clayton EW. Genetics, public health and the law (2000).
- Excerpt from: Burnham, Introduction to the Law and Legal System of the
### Wednesday, October 10, 2007
**Guest Lecturer:** Prof. Cindy Watts, Dept. of Health Services, SPHCM & Resource Center for Health Policy (confirmed)

**General Topic:**
- Analytic Tools and Research Methods
- Public Policy

**Session Objectives:**
- Examine the role of government in market societies
- Explore an economic model of policy formation
- Outline the tools available to government
- Present a framework for policy development

**Readings:**
- Kaufert PA. Health policy and the new genetics (2000).

**Optional Reading:** Wilfond BS, Thomson EJ. Models of public health genetic policy development (2000).

### Monday, October 15, 2007
**Guest Lecturer:** Mary Whisner and Kelly Aldrich, Reference Librarians, Gallagher Law Library, UW School of Law (confirmed)

**General Topic:**
- Analytic Tools and Research Methods
- Law and Health Policy Research

**Session Objectives:**
- Health Policy Research
- Legal Research
- Identify the components of a legal citation
- Identify print and online resources for locating each of the four main sources of law (constitutions, statutes, regulations, and common law)
- Identify print and online resources for the conduct of secondary legal research

**Readings:**
- Important: Class will meet in the Computer Lab, UW School of Law, William H. Gates Hall, Gallagher Law Library, Legal Research Training Center (LRTC), Located on L2.

**For Reference:** Ferguson M. Genetics privacy and nondiscrimination legislation: a research guide (unpublished) (Mar. 10, 2002).

### Wednesday, October 17, 2007
**Guest Lecturers:** Malia Fullerton, PhD, Medical History and Ethics and Joon-Ho Yu, MPH, PhD (cand.)

**General Topic:**
- Genetics, Race and Health Disparities

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Session Objectives:
- Describe the difference between health disparities and health differences
- Describe the historical basis of race in science and what is at stake in today's "stormy" dialogues about race and genetics
- Describe three hypotheses involving race in the etiology of disease and health or social disparities
- Critically evaluate the context and rationale that promote genetic explanations of health disparities and its implications
- Understand, and critically evaluate, the distinction made by geneticists between socially constructed race and genetic ancestry

Readings:

Monday, October 22, 2007

General Topic:
Genetic Discrimination
- The Genetic Exceptionalism Debate
- Health Insurance and Discrimination

Session Objectives:
- Define genetic discrimination
- Define the insurance terms adverse selection, experience rating, and underwriting in the context of concerns about genetic discrimination in insurance
- Describe the relevant federal laws that address genetic discrimination by health insurers and their applications to individual and group plans, and their limitations in applicability
- Describe the circumstances under which state laws concerning genetic discrimination apply to individual and group plans
- Define genetic exceptionalism, explain the pros and cons of genetic exceptionalism, and explain its potential impact on medical practice and health policy

Readings:
Billings PR. Genetic nondiscrimination (2005).
Rothstein MA. Genetic exceptionalism & legislative pragmatism (2005).

Wednesday, October 24, 2007

General Topic:
Genetic Testing and Screening
- Fundamentals
- Predisposition Testing

Session Objectives:
- Define the terms: autosomal dominant; autosomal recessive; penetrance;
clinical validity; clinical utility
- Describe and explain the genetic testing classification scheme devised by Burke, Pinsky and Press designed to elicit relevant ELSI issues;
- Describe the objectives of non directive genetic counseling and the conditions under which directive and nondirective counseling is warranted
- Describe Huntington’s Disease and how it is inherited, why people choose to be tested or not to be tested, and the primary ethical and social issues that arise in genetic testing

| Readings: |
| Fact Sheet on Huntington's Disease. |
| Scott J (as told to Paige Williams). Survivor (2002). |
| Burke W, Pinsky LE, Press NA. Categorizing genetic tests to identify their ethical, legal and social implications (2001) |

Optional Reading: Autosomal dominant handout
Optional Reading: Autosomal recessive handout

Monday, October 29, 2007 -- Midterm in Class

Wednesday, October 31 2007 - Public Health Genetics 10th Anniversary Symposium

Monday, November 5, 2007

General Topic:
Genetic Testing and Screening
- Susceptibility Testing

Session Objectives:
- Identify the general medical and social implications of positive, false positive, negative and false negative tests
- Define the term "unpatient", as described by Jonsen, Durfy, Burke and Motulsky, and its implications for the health care system and individuals
- Describe and discuss the challenges of fitting BRCA1/2 testing in the Burke, Pinsky and Press model
- Identify and describe the contextual themes identified by Rothenberg regarding genetic testing generally and testing in the Ashkenazi Jewish community for breast cancer susceptibility
- Distinguish the process model of informed consent from the event model of informed consent, and describe the implications of BRCA1/2 testing for the informed consent process

Readings:
Jonsen AF et al. The advent of the “unpatients” (1996).
Lerman C, Shields A. Genetic testing for cancer susceptibility: The promise and the pitfalls (2004).
Rothenberg K. Breast cancer, the genetic "quick fix," and the Jewish community: ethical, legal, and social challenges (1997). Please read first
4 pages for general understanding, the rest is optional.
Harmon A. Cancer free at 33, but weighing a mastectomy. N.Y. Times, Sept. 16, 2007; The story of a "previvor" (video), N.Y. Times (article and video are optional).

**Wednesday, November 7, 2007**

**General Topic:**
Genetic Testing and Screening
- Prenatal Testing and Reproductive Decision-making

**Session Objectives:**
- Identify and describe the societally approved goals and the controversial goals associated with prenatal genetic screening and testing, as presented in the article by Nancy Press
- Define, compare and contrast the medical definition of chronic illness and disability and the social definition of chronic illness and disability
- Describe how the social definition of chronic illness and disability may or may not be reconciled with reproductive choice and how the definitions impact genetic counseling, medical practice and policy
- Describe the role of socioeconomic class and culture in decisions to choose prenatal testing
- Describe generally the assumptions of medicine, science, public health, and consumers about the use and access to prenatal testing and the follow up use of selective abortion

**Readings:**
Powell CM. The current state of prenatal genetic testing in the United States (2000).
Press N. Assessing the expressive character of prenatal testing: the choices made or the choices made available (2000).
Rapp R. Women’s responses to prenatal diagnosis: a sociocultural perspective on diversity (1994).
Patricia A. Bauer. The Abortion Debate No One Wants to Have Prenatal testing is making your right to abort a disabled child more like "your duty" to abort a disabled child. washingtonpost.com, October 18, 2005.
Hoffman J. Where risk and choice and hope converge, a guiding voice. N.Y. Times, Sept. 18, 2007; In the trenches: The genetic counselor. (slideshow) N.Y. Times (article & slide show are optional)

**Wednesday, November 14, 2007 - Reflective Essay due at 1:30 p.m.**
**Guest Lecturer: Prof. Kelly Fryer-Edwards, Dept. of Medical History and Ethics, UW School of Medicine (confirmed)**

**General Topic:**
Mary Shelly’s *Frankenstein*: Narrative Ethics & Historical Perspectives

**Session Objectives:**
- Apply a narrative ethics framework

**Readings:**
Mary Shelly’s *Frankenstein* (unabridged version)
Reading guidance for *Frankenstein*

**Monday, November 16, 2007, noon (tentative)**

**General Topic:**
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<th>Monday, November 19, 2007</th>
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<tr>
<td><strong>General Topic:</strong></td>
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<tr>
<td>Genetic Testing and Screening</td>
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<tr>
<td>- Newborn Screening</td>
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<td><strong>Session Objectives:</strong></td>
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<tr>
<td>- Describe the historical context of newborn screening in the US.</td>
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<td>- Apply the Burke-Pinsky-Press Model to Newborn Screening</td>
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<td>- List and describe 3 of Rodney Howell’s arguments for expanding newborn screening</td>
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<td>- List and describe 4 recommendations by Botkin et al for proceeding with caution re: expanding newborn screening</td>
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<tr>
<td><strong>Readings:</strong></td>
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<tr>
<td>Howell RR. We need expanded newborn screening (2006).</td>
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<tr>
<td>Review: Chapter 246-650 WAC</td>
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<td>Review: Chapter 70.83 RCW</td>
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<tr>
<td>Optional review: What is the Office of Newborn Screening?</td>
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<td><strong>General Topic:</strong></td>
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<td>Genetic Testing and Screening</td>
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<tr>
<td>- Genetic Testing in the Workplace</td>
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<td><strong>Session Objectives:</strong></td>
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<tr>
<td>- Define the purpose of workplace genetic screening and testing and the justifications in favor of workplace screening from the perspective of workers, employers, and society</td>
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<td>- Identify primary ethical concerns with workplace genetic screening and testing, applying the Beauchamp and Childress principles</td>
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<td>- Describe how the state of science can influence the acceptability of workplace genetic screening</td>
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<td>- Identify and describe the current legal limitations on workplace genetic screening derived from the Bloodsaw case and the BNSF settlement with EEOC</td>
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<tr>
<td><strong>Readings:</strong></td>
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<tr>
<td>Norman-Bloodsaw v. Lawrence Berkeley Laboratory, 135 F.3d 1260 (9th Cir. 1998).</td>
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<tr>
<td>EEOC, Press release, EEOC And BNSF settle genetic testing case under Americans with Disabilities Act (May 8, 2002). Available at: <a href="http://www.eeoc.gov/press/5-8-02.html">http://www.eeoc.gov/press/5-8-02.html</a></td>
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<tr>
<td><strong>General Topic:</strong></td>
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<tr>
<td>Genetic Testing and Screening</td>
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## Session Objectives:
- Describe the roles of federal, state and nongovernmental actors in overseeing the use of genetic tests and their introduction to physicians and consumers
- Conducting ethics and policy analysis using case study (carrier screening)
- Case study analysis

### Readings:
Burke W, Zimmern RL. Ensuring the appropriate use of genetic tests (2004).
Hudson, Genetic Testing Oversight (2006)
DNA policy issue brief
http://www.dnapolicy.org/policy.issue.php?action=detail&issuebrief_id=33#
Case Study: Cystic Fibrosis Carrier Screening (please read in its entirety and think about **before** class meeting)

**Wednesday, November 28, 2007**

**Guest Lecturer: Whitney Neufeld-Kaiser, MS, CGC, Genetic Counselor, Prenatal Genetics Department, University of Washington Medical Center (confirmed)**

**General Topic:** Genetic Counseling

### Session Objectives:
- Describe the components of genetic counseling
- Understand what training is required to provide genetic counseling
- Identify and describe three healthcare settings in which genetic counseling is likely to occur
- Define nondirectiveness and describe how it applies to genetic counseling
- Describe the current status of licensure for genetic counselors

### Readings:
Bennett RL. Genetic counseling (2003).
Bennett RL. Pedigree Parables (2000).
Kessler S. Psychological Aspects of Genetic Counseling (1997).

**Monday, December 3, 2007**

**General Topic:** Genetics Research and Therapeutic Application
- Overview: History, Ethical and Legal Principles
- Gene Transfer Research in Humans

### Session Objectives:
- Identify and define the three ethical principles from The Belmont Report applicable to research conducted on humans and describe the specific applications of each principle to research
- Explain how the Belmont principles correspond to federal regulations
- Describe the conditions under which the federal regulations known as the Common Rule apply to research
- Describe the role of the IRB in the review of human subjects research
- Describe the administrative sanctions and legal recourse for noncompliance with the federal regulations
- Explain why some people believe that the term “gene therapy” is inaccurate or misleading
- Describe the purported ethical deficiencies in the clinical trial that Jesse Gelsinger participated in and describe the trial’s ramifications for gene transfer research and the conduct of clinical trials generally

Readings:
Smith L, Byers JF. Gene therapy in the post Gelsinger era (2002).
Gelsinger P. Jesse's Intent.

Wednesday, December 5, 2007
General Topic: Genebanks & Use of Stored Tissue Samples in Population-Based Research

Session Objectives:
- Describe circumstances under which informed consent is required when using DNA samples
- Describe the two legal decisions on commercialization of DNA samples and their implications for ownership and informed consent processes
- Describe points to consider in disclosing genetic results to research subjects.

Readings:
Optional: Arnason V. Coding and consent: Moral challenges of the database project in Iceland (2004).
Optional: NHLBI Working Group on Reporting Genetic Results in Research Studies Meeting Summary, Bethesda, MD (2004)

Monday, December 10, 2007, 2:30-4:20 p.m. Final Exam
http://www.washington.edu/students/reg/A2007exam.html