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 - 3 Credits

Autumn 2008

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, writing assignments, and examination, students will:
develop introductory 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 legal, ethical and social 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 online for downloading at [https://courses.law.washington.edu/mastroianni/H504ab_Au08/](https://courses.law.washington.edu/mastroianni/H504ab_Au08/)


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:* Class handouts will be posted on the course website. If you miss class, it is your own responsibility to download handouts and get notes from your classmates.

**Course Grade**

Your course grade will be based upon a midterm, final examination, short writing assignment (Reflective Essay, described below), and writing assignment and small group presentation on the subject of direct-to-consumer marketing (Direct-to-Consumer Marketing and Distribution Assignment, described below). The midterm will account for 30% of your grade and the final exam will account for 40% 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 and Direct-to-Consumer Marketing and Distribution Assignment will be graded and each will account for 15% of your course grade. Failure to complete any of the assignments will result in a grade of Incomplete.

**Important instructions for the Midterm and Final Exam:** The midterm will be completed during one scheduled class, **October 29, 2008**, and will cover course content through October 22, 2008. 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 8, 2008, 2:30-4:20pm in Health Sciences, Room T473**. The midterm and the final exam will be based on the course learning objectives. You are encouraged to study with classmates. Both exams will be traditional, closed-book exams. No course related materials are permitted to be used during the exams and no consultation with classmates is permitted during the exams. Violators will be subject to disciplinary action under the University of Washington’s Honor Code.

**Important instructions for the Reflective Essay.** In 4 (minimum) - 5 (maximum) 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—points will be deducted if you do.** 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 a minimum of two of the four criteria identified in the Handout.** Two (2) copies of your essay must be turned in on Wednesday, November 12, 2008 at 1:30 p.m. Please also bring another copy of the essay for your own reference during class. That day, a bioethicist 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.

**Important Instructions for the Direct-to-Consumer (DTC) Marketing and Distribution Assignment.** This assignment is designed to introduce you to advocacy in a key area of public controversy in public health genetics, DTC marketing and distribution of genetic tests. We will assign the role of a key stakeholder to each of you and provide you with some general guidance and background materials. In order to be fully informed to defend your position it is likely that you will need to conduct additional research. In one-page (typed), you will provide a one sentence summary of your position, a series of bullet points of your arguments in support of that position, and a list of sources consulted (your choice of bibliographic style, as long as it is consistent) (“DTC Role Playing Exercise”). In class you will be assigned to a small group in which you will present and defend your position. Please bring **three copies** of your one page document to class on **November 24, 2008**. You will turn in two copies at the **beginning of class** and keep one for yourself for reference and sharing with your group. We will provide you with questions to guide your group discussion. Each student must turn in one-page typed paper reflecting on what was learned during the class exercise no later than **10 a.m. on November 26** by email attachment (“DTC Reflection”). The document should be emailed to the course instructor and TA. 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>Wednesday, October 29, 2008 1:30pm – 2:50pm</td>
<td>30%</td>
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<tr>
<td>Reflective Essay</td>
<td>Wednesday, November 12, 2008, 1:30 p.m.</td>
<td>15%</td>
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<tr>
<td>Direct-to Consumer Marketing and Distribution Assignment</td>
<td>Monday, November 24, 2008, 1:30 p.m. (DTC Role Playing Exercise) Wednesday, November 26, 10:00 a.m. (DTC Reflection)</td>
<td>15%</td>
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<tr>
<td>Final Exam</td>
<td>Monday, December 8, 2008 2:30-4:20 p.m.</td>
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**OUTLINE OF TOPICS COVERED**

1. Introduction to the Course
   a. What is Public Health Genetics?
   b. Introduction to ELSI
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. Public Policy
   b. Ethics: Fundamental Principles and Approaches
   c. Law
d. Research Tools
4. 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
5. Genetic Discrimination
   a. The Genetic Exceptionalism Debate
   b. Insurance
   c. Employment
6. Genetics, Race, and Health Disparities
7. Genetics Research and Therapeutic Applications
   a. Overview – History, Ethics and Law
   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
   a. Direct-to-Consumer Marketing and Distribution of Genetic Tests
   b. Recent 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.

Wednesday, September 24, 2008

<table>
<thead>
<tr>
<th>General Topic:</th>
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<tbody>
<tr>
<td>Course Introduction</td>
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<tr>
<td>- What Is Public Health Genetics?</td>
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<td>- Introduction to ELSI</td>
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<th>Session Objectives:</th>
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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 “public health genetics”</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>- Define the essential public health services and identify the role that genetics plays in provision of these services</td>
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<thead>
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<th>Readings:</th>
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<tr>
<td>Wang, G &amp; Watts, C.  <em>The role of genetics in the provision of essential public health services</em> (2007).</td>
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<tr>
<td>Optional Reading: Reilly PR.  <em>Public concern about genetics</em> (2000).</td>
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**Monday, September 29, 2008**

**General Topic:**
- Historical Perspectives on PHG
  - Eugenics
  - Experiences with Genetic Testing and Screening Programs in the US

**Session Objectives:**
- Define positive eugenics and negative eugenics
- Explain how the science of genetics has been misused in history
- Explain the three alternate definitions of eugenics discussed by Diane Paul, and identify which definition geneticists and other interested parties might likely adopt
- Distinguish between genetic testing and genetic screening
- 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://biotech.law.lsu.edu/research/fed/tfgt/appendix6.htm](http://biotech.law.lsu.edu/research/fed/tfgt/appendix6.htm)

**Additional Assignment:**
Please complete the handout (comparing history and genetic screening for Tay-Sachs and Sickle Cell Diseases) prior to class for in class reference during class discussion.

**Wednesday, October 1, 2008**

**Guest Lecturer:** Prof. Cindy Watts, Dept. of Health Services, SPHCM & Resource Center for Health Policy


**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
- Outline the Genetic Information Nondiscrimination Act and describe what this policy does and does not cover

**Readings:**
- Genomics and Personalized Medicine Act of 2006,
  - [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_bills&docid=f:s3822is.txt.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_bills&docid=f:s3822is.txt.pdf)
  - [http://content.nejm.org/cgi/content/full/358/25/2661](http://content.nejm.org/cgi/content/full/358/25/2661)


### Monday, October 6, 2008

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

**Session Objectives:**
- Define moral dilemma and provide at least one genetics example
- Define and contrast utilitarianism (outcomes) and Kantian (moral rules & duties) 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
- Describe the role of a professional code of ethics
- Explain how the principles of the Public Health Code of Ethics apply to Genomics

**Readings:**
Northwest Association for Biomedical Research. *An Ethics Primer* (2007).
Optional Reading: *Tarasoff v. The Regents of the University of California, 131 Cal. Rptr. 14 (1976).*

### Wednesday, October 8, 2008

**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
- Identify and describe the different sources of liability

**Readings:**
Clayton EW. *Genetics, public health and the law* (2000).
**For non-law students:**
### Monday, October 13, 2008
**Guest Lecturer:** Cheryl Rae Nyberg, Reference Librarian, Gallagher Law Library, UW School of Law

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

**Session Objectives:**
- Identify main sources of law and health policy 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

**Important:** Class will meet in the Legal Research Training Center (LRTC), Room L201, located on L2, UW School of Law, William H. Gates Hall, Gallagher Law Library.

**DIRECTIONS:**

**Readings (for non law students only):**

### Wednesday, October 15, 2008
**Lecturer:** Krysta Shutske

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

**Session Objectives:**
- Define the terms: genetic testing, autosomal dominant; autosomal recessive; penetrance; clinical validity; clinical utility
- Identify the different types of genetic tests and considerations for each test
- Describe and explain the genetic testing classification scheme devised by Burke, Pinsky and Press and then by McPherson and compare the two schemes adequacy in addressing the relevant ELSI issues;
- 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:**
- Scott J (as told to Paige Williams). *Survivor* (2002).
<table>
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<tr>
<th>Date</th>
<th>Lecturer</th>
<th>General Topic</th>
<th>Session Objectives</th>
<th>Readings</th>
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| Monday, October 20, 2008 | Michael Glass, Director, Newborn Screening, Washington State Department of Health | Genetic Testing and Screening - Newborn Screening | - Describe the historical context of newborn screening in the US.  
- Apply the Burke-Pinsky-Press and McPherson Models to Newborn Screening  
- List and describe 3 of Rodney Howell's arguments for expanding newborn screening  
- List and describe 4 recommendations by Botkin et al for proceeding with caution re: expanding newborn screening | Watson MS. [Newborn screening: toward a uniform screening panel and system -- executive summary](2006)  
Botkin JJ et al. [Newborn screening technology: proceed with caution](2006).  
Howell RR. [We need expanded newborn screening](2006).  
Review: [Chapter 246-650 WAC](2006)  
Review: [Chapter 70.83 RCW](2006).  
Optional review: [What is the Office of Newborn Screening?](2006) |
| Wednesday, October 22, 2008 | Updated                         | Genetic Testing and Screening - Oversight of Genetic Testing | - Describe the roles of federal, state and nongovernmental actors in overseeing the use of genetic tests | Burke W, Zimmern RL. [Ensuring the appropriate use of genetic tests](2004).  
Hudson, [Genetic Testing Oversight](2006)  
Review Hudson et al.  
Review Korobkin et al. |
| Monday, October 27, 2008 | Krysta Shutske                  | Genetic Testing and Screening - Reproductive Decision-making | - Identify and describe the societally approved goals and the controversial goals associated with prenatal genetic screening and testing, as presented in the article by | Burke W, Pinsky LE, Press NA. [Categorizing genetic tests to identify their ethical, legal and social implications](2001)  
Optional Reading: [Autosomal dominant handout](2001)  
Optional Reading: [Autosomal recessive handout](2001)  
Optional Reading: Harmon, A. [Facing life with a lethal gene](2007)  
Optional Reading: Cooke P. [A genetic test for Huntington's lets Colin McAllister see his future](1993). |
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
- Define preimplantation genetic diagnosis (PGD) and describe its applications and the ethical and policy challenges surrounding its use

Readings:
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.
Optional Reading: 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

Wednesday, October 29, 2008 - MIDTERM IN CLASS

Monday November 3, 2008
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 and McPherson model
- Describe consequences of linking ethnic identity to genetic disease
- 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).
Geller G et al. Genetic testing for susceptibility to adult-onset cancer: The process
### Wednesday, November 5, 2008

**General Topic:**
Genetic Testing and Screening  
- Genetic Testing in the workplace

**Session Objectives:**
- 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
- Identify primary ethical concerns with workplace genetic screening and testing, applying the Beauchamp and Childress principles
- Describe how the state of science can influence the acceptability of workplace genetic screening
- Identify and describe the current legal limitations on workplace genetic screening derived from GINA, the Bloodsaw case and the BNSF settlement with EEOC

**Readings:**
*Norman–Bloodsaw v. Lawrence Berkeley Laboratory*, 135 F.3d 1260 (9th Cir. 1998).  
Review *Hudson et al.*  
*Optional Reading:* EEOC, Press release, EEOC And BNSF settle genetic testing case under Americans with Disabilities Act (May 8, 2002). Available at: [http://www.eeoc.gov/press/5-8-02.html](http://www.eeoc.gov/press/5-8-02.html)  

### Monday, November 10, 2008

**Lecturer:** Krysta Shutiske

**General Topic**
Genetic Discrimination  
- The Genetic Exceptionalism Debate  
- Health Insurance and Insurance 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 implications of individual genetic testing in terms of human rights issues
- 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
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<th>Date</th>
<th>Topic</th>
<th>Session Objectives</th>
<th>Readings</th>
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| Monday, November 17, 2008 | Genetics Research and Therapeutic Applications                         | - 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  
- Describe ethical and regulatory advances that have been made in human research studies since Jesse Gelsinger's death | National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *The Belmont Report* (1979) (see reading for 10/6/08). DHHS—Basic Policy for the Protection of Human Research Subjects, 45 CFR46. Available at: [http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm) Gelsinger, P & Shamoo, AE. *Eight years after Jesse’s death, are human research...* |
Wednesday November 19, 2008
**Guest Lecturer:** Malia Fullerton, PhD, Medical History and Ethics
(Bio: [http://depts.washington.edu/mhedept/facres/mf_bio.htm](http://depts.washington.edu/mhedept/facres/mf_bio.htm))

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

**Session Objectives:**
- Describe the three main types of health disparities affecting US minority groups
- Explain how the understanding of race as a social construct differs from the understanding of race as a biological construct
- Describe the potential benefits of using racial categories in genetic research
- Describe the potential risks associated with using racial categories in genetic research
- Discuss the significance of the establishment of an NIH Intramural Center for Genomics and Health Disparities

**Readings:**

Monday, November 24, 2008 – **DTC EXERCISE DUE AT 1:30 P.M.**

**General Topic:**
Direct-to-Consumer Marketing and Distribution of Genetic Testing: In Class Role Playing Exercise

**Session Objectives:**
- Research and understand perspectives of advocates and policymakers

**Readings:**
GPPC. *Direct-to-consumer genetic testing: Empowering or endangering the public?* (2008).

Wednesday, November 26, 2008 – **DTC REFLECTION DUE VIA EMAIL BY 10:00 AM**
**NO CLASS MEETING**
**HAPPY THANKSGIVING!**
### Monday, December 1, 2008

**Guest Lecturer:** Whitney Neufeld-Kaiser, MS, CGC, Genetic Counselor, Prenatal Genetics Department, University of Washington Medical Center  
(Bio: [http://depts.washington.edu/pdcweb/counselors.htm#Kaiser](http://depts.washington.edu/pdcweb/counselors.htm#Kaiser))

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<tr>
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<th>Genetic Counseling</th>
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| **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  
- Define 'finding of uncertain significance' and discuss the counseling challenges such results pose |
| **Readings:** | Bennett RL. *Genetic counseling* (2003).  
Bennett RL. *Pedigree Parables* (2000). |

### Wednesday, December 3, 2008

**General Topic:** Gene banks & Use of Stored Tissue Samples in Population-Based Research

| Session Objectives: | - Describe circumstances under which informed consent is required when using DNA samples and discuss the recommendations Caulfield et al. make regarding consent  
- Describe points to consider and recommendations made by Caulfield et al. in participant withdrawal from research.  
- Describe the three 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 and public data release. |

### Monday, December 8, 2008

**2:30-4:20 P.M. FINAL EXAM, Magnuson Health Sciences Building, Room T473**  