

University of Washington

**Institute for Public Health Genetics
School of Law
School of Public Health
School of Medicine**

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

Autumn 2010

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, policy, 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, policy 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 and policy. 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, case studies, class discussions, writing assignments, and examination, students will: develop introductory skills in legal, ethical and policy analysis as they pertain to public health genetics practice and policy; be able to recognize and analyze legal, ethical, policy and social issues arising in the context of public health genetics; become familiar with the diverse literature and research sources regarding legal, ethical, policy 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

The Course Materials for this course 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. The vast majority are linked and available for downloading via the Syllabus webpage at:

https://courses.law.washington.edu/mastroianni/H504abc_Au10/syllabus.aspx.

You will need to log in with your UWNet ID when prompted. The remainder of the course readings must be purchased in a bound course pack at the University Bookstore at 4326 University Way N.E. ("the Ave").

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—we will do our best to remember to label them "FYI ONLY."

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 obtain notes from your classmates.

Course Grade

Your course grade will be based upon a take-home midterm, take-home final examination, and two case study assignments. The take-home midterm will account for 25% of your grade and the final exam will account for 35% of your grade. The midterm and the final exam will be essay style. Both exams will be graded anonymously according to procedures discussed in class. Each of the case study assignments will be worth 20% of your grade. All exams and assignments are subject to the University of Washington's Student Conduct Code and/or the University of Washington School of Law's Honor Code, including sanctions and disciplinary actions [<http://www.washington.edu/students/handbook/conduct.html>]; <http://www.law.washington.edu/students/academics/HonorCode.aspx>]

Important instructions for the Take-Home Midterm: The Take-Home Midterm will be distributed at the end of class on October 25, 2010 and is **due no later than 4:30 pm on October 29, 2010**. The midterm will cover course content through October 25, 2010. You may use any relevant course materials (i.e., lecture notes, powerpoints, course readings, handouts) in the preparation of your midterm examination. Use of outside sources is not permitted. You are encouraged to study with classmates prior to midterm distribution but no consultation with classmates regarding course content or the midterm is permitted once the midterm is distributed. Please follow the submission directions provided on the midterm.

Important instructions for the Take-Home Final Exam: The Take-Home Final Exam will be distributed at the end of class on December 8, 2010 and is **due no later than 4:30 pm on Monday, December 13, 2010**. The final exam will be cumulative. You may use any relevant course materials (i.e., lecture notes, powerpoints, course readings, handouts) and any materials that you have played a substantial role in preparing in responding to the questions of your final examination. Use of outside sources is not permitted. You are encouraged to study with classmates prior to final exam distribution but no consultation

with classmates regarding course content or the final exam is permitted once the final exam is distributed. Please follow the submission directions provided on the final exam.

Important Instructions for Newborn Screening Case Study Assignment #1. This assignment is designed to further your skills at identifying policy issues, conducting stakeholder analyses, and sorting through policy options. You will write a short (3-4 pages) paper in which you identify a policy problem associated with newborn screening (expressed in the form “what is the problem, for whom, and with what consequences”), identify the stakeholders who care about this issue and their interest(s) in it, describe 2-3 policy options that might address this problem, and identify 2 advantages and 2 disadvantages associated with each option. (As with the DTC assignment, these advantages and disadvantages can include support or opposition of powerful stakeholder groups). More details on submission requirements will be provided in class. This paper is due **November 8, 2010 at 9:30 a.m.** Late papers will receive a 2 point deduction for each day (24-hours) late.

Important Instructions for the Case Study Assignment #2: Direct-to-Consumer (DTC) Genetic Tests. This assignment is designed to introduce you to advocacy and policy development in a key area of public controversy in public health genetics, DTC genetic testing. It is a two part assignment. Late papers will receive a 2 point deduction for each day (24-hours) late.

- In Part A, we will assign a 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 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 **four (4) copies** of your one-page document to class on **November 22, 2010**. You will turn in two copies at **1:30 p.m** (beginning of class) and keep one for yourself for reference and one for sharing with your group. We will provide you with questions to guide your group discussion.
- In Part B, you will analyze a policy action relevant to the position you took in Part 1. In 2-3 pages, you will identify at least 4 stakeholder groups that will be affected by the policy action and describe their interests GENERALLY, NOT JUST WITH REGARD TO DTC. You will also describe the policy action you have chosen and at least 2 advantages of it and 2 disadvantages. (Note: An advantage can be the support of a powerful interest group; a disadvantage can be the opposition of a powerful interest group.) Be prepared to discuss your paper in class. This paper is due **November 29, 1:30 p.m.**

Assignments/Examinations and Due Dates are summarized below:

ASSIGNMENT/EXAMS	DATE	GRADING WEIGHT
Take-Home Midterm	Distributed: Monday, October 25, 2010, 2:50 PM Due: Friday, October 29, 2010, 4:30 PM	25%
Case Study #1: Newborn Screening	Monday, November 8, 2010, 9:30 AM	20%
Case Study #2: Direct-to Consumer Genetic Tests	Monday, November 22, 2010, 1:30 PM (DTC Role Playing Exercise) Wednesday, December 1, 2010, 1:30 PM (DTC Policy Analysis)	20%

Take-Home Final Exam	Distributed: Wednesday, December 8, 2010, 2:50 PM Due: Monday, December 13, 2010, 4:30 PM	35%
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Disability-related Needs

To request academic accommodations due to a disability, please contact Disability Resources for Students (DRS), 448 Schmitz, (206) 543-8924 (V), (206) 543-8925 (TTY). If you have a letter from DRS, please present the letter to me so we can discuss the accommodations you might need in this class.

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 29, 2010	
OVERVIEW – WHAT IS PUBLIC HEALTH GENETICS?	
Professor Mastroianni	
	<u>General Topic:</u> Course Introduction Overview: What Is Public Health Genetics? Introduction to “ELSI” Application: Bring your genes to Cal
	<u>Session Objectives:</u> - Define “public health genetics” and the relationship between public health and genetics - Explain what ELSI means
	<ul style="list-style-type: none"> a. <u>Readings:</u> <ul style="list-style-type: none"> i. Holtzman NA. What Role for Public Health in Genetics and Vice Versa. Public Health Genomics [formerly Community Genetics], 2006, 9(1):8–20 (13 pages) (in Course Pack) ii. Wang G, Watts C. The role of genetics in the provision of essential public health services. American Journal of Public Health, April 2007, 97(4):620-625 (6 pages) b. <u>Readings continued: Bring your genes to Cal:</u> <ul style="list-style-type: none"> i. Lewin T: College Bound, DNA Swab in Hand NYtimes May 18, 2010 ii. Council for Responsible Genetics Press Release iii. UC Berkeley Statement c. <u>Optional Readings:</u> <ul style="list-style-type: none"> i. NPR interview with dean of biological sciences at Cal ii. Stanford to pursue a similar program for medical students, partnering with 23andMe and Navigenics

		<p>d. <u>Additional Resources (Optional):</u></p> <ul style="list-style-type: none"> i. 10 year HGP anniversary. Compares 1997 to 2007. ii. What's Next in the HGP: Includes links to the HapMap and the ENCODE project. iii. The Cancer Genome Atlas iv. About the HapMap <p><u>For students needing genetics overview or refresher:</u> Burke W. Genetics primer. National Association of Women Judges, Genome Justice, September 2005, 1-14 (14 pages)</p>
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Monday, October 4, 2010 – HEALTH CARE PROVIDER DUTY TO WARN AT-RISK RELATIVES: INTRODUCTION TO ETHICS
Professor Mastroianni

		<p><u>General Topic:</u></p> <ul style="list-style-type: none"> - Ethics - Fundamental Principles and Approaches
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		<p><u>Session Objectives:</u></p> <ul style="list-style-type: none"> - 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 - Briefly describe the framework for public health ethics proposed by Childress et al.
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		<p>a. <u>Readings:</u></p> <ul style="list-style-type: none"> i. Northwest Association for Biomedical Research. An Ethics Primer. 2008 (skip 24-26), 11 pages, http://www.nwabr.org/education/pdfs/PRIMER/PrimerPieces/Outcomes.pdf ii. Excerpt from: Beauchamp TL et al. Contemporary Issues in Bioethics (7th ed. 2008) 4-7 (4 pages) iii. Childress JF. Public Health Ethics: Mapping the terrain: Journal of Law, Medicine & Ethics, 2002, 30(2):170-178 (9 pages) iv. American Society of Human Genetics Social Issues Subcommittee on Familial Disclosure. ASHG Statement: Professional Disclosure of Familial Genetic Information. American Journal of Human Genetics, 1998, 62(2):474-483 (10 pages) v. Tarasoff v. The Regents of the University of California, 131 Cal. Rptr. 14 (1976) <p>b. <u>Additional Ethics Resources (OPTIONAL):</u></p> <ul style="list-style-type: none"> i. Beauchamp DE, Steinbock B. Introduction: Ethical Theory and Public Health in New Ethics for the Public's Health (1999), 3-23 (21 pages) (on Course Reserve at Gallagher Law Library). ii. Coughlin SS. Case Analysis and Moral Reasoning Ch. 1 in Case Studies in Public Health Ethics (1st. ed. 1997), 1-18 (18 pages) (on Course Reserve at Gallagher Law Library) iii. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report (1979): http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm
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Wednesday, October 6, 2010 - HEALTH CARE PROVIDER DUTY TO WARN AT-RISK RELATIVES: INTRODUCTION TO LEGAL APPROACHES
Professor Mastroianni

General Topic:

- Introduction to 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
- Define genetic exceptionalism, explain the pros and cons of genetic exceptionalism, and explain its potential impact on medical practice and health policy

a. Readings:

- i. **Read for background understanding and reference:** Clayton EW. Genetics, public health and the law, Ch. 25 in Genetics and Public Health in the 21st Century: Using Genetic Information to Improve Health and Prevent Disease (Khoury MJ, Burke W, Thomson EJ eds., 2000), 489-503 (15 pages) (in Course Pack)
- ii. Review Tarasoff v. The Regents of the University of California, 131 Cal. Rptr. 14 (1976)
- iii. Safer v. Pack, 677 A.2d 1188 (NJ. 1996)
- iv. Pate v. Threlkel, 661 So.2d 278 (Fla. 1995)
- v. Rothstein MA. Genetic Exceptionalism & Legislative Pragmatism. The Hastings Center Report, 2005, 35(4):27-47 (21 pages)

b. **For non-law students:**

- i. Excerpt from: Wing KR, Gilbert B. Chs. 1 & 2 in The Law and the Public's Health (6th ed., Health Administration Press, 2003), 1-17, 19-28 (27 pages) (in Course Pack)
- ii. Excerpt from: Burnham W. Legal Methodology. Ch. II.A in Introduction to the Law and Legal System of the United States (3th ed. 2002), 37-41 (5 pages)

Monday, October 11, 2010 – EUGENICS & HISTORICAL PERSPECTIVES ON PHG
Professor Mastroianni

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

	<p>a. <u>Readings:</u></p> <ul style="list-style-type: none"> i. Paul DB. Is Human Genetics Disguised Eugenics? In <i>Genes and Human Self-Knowledge: Historical and Philosophical Reflections on Modern Genetics</i> (Weir RF, Lawrence S, Fales E eds., 1994), 67-83 (17 pages) (in Course Pack) ii. Pernick, MS. Eugenics and public health in American history. <i>American Journal of Public Health</i>, 1997, 87(11):1767-1772 (6 pages) iii. Markel H. Scientific advances and social risks: historical perspectives of genetic screening programs for Sickle Cell Disease, Tay-Sachs Disease, neural tube defects and Down Syndrome, 1970-1997 (1997): http://biotech.law.lsu.edu/research/fed/tfgt/appendix6.htm iv. Please review the interactive web site: Cold Spring Harbor Image Archive http://www.eugenicsarchive.org/eugenics/
<p>Wednesday, October 13, 2010 – Introduction to Policy Guest Speaker: Catharine Riley, MPH, PhD candidate, Health Services Consultant: Office of Newborn Screening, Washington State Department of Health</p>	
	<p><u>General Topic:</u></p> <ul style="list-style-type: none"> -Public Policy -Policy Framework
	<p><u>Session Objectives:</u></p> <ul style="list-style-type: none"> - Outline the tools available to government - Provide an overview of public health policy - Present a framework for policy development - Outline the Genetic Information Nondiscrimination Act and describe what this policy does and does not cover
	<p>a. <u>Readings:</u></p> <p>Katz A, Thompson J. The role of public policy in health care market change. <i>Health Affairs</i>, 1996, 15(2): 77-91 (15 pages)</p> <p>Hudson K. Prohibiting Genetic Discrimination. <i>New England Journal of Medicine</i>, 2007, 356(20):2021-2023 (3 pages)</p> <p>Gerston L. The Context of Public Policy. Ch. 1 in <i>Public Policy Making: Process and Principles</i> (2d ed. 2004), 3-21 (19 pages)</p> <p><u>Optional Reading:</u></p> <p>Wilfond BS, Thomson EJ. Models of public health genetic policy development Ch. 4 in <i>Genetics and Public Health in the 21st Century: Using Genetic Information to Improve Health and Prevent Disease</i> (Khoury MJ, Burke W, Thomson EJ eds., 2000), 61-81 (21 pages) (in Course Pack)</p>
<p>Monday, October 18, 2010 – GENETIC DISCRIMINATION & HEALTH INSURANCE Guest speaker: Professor Sallie Sanford, University of Washington Professor Sanford's Bio</p>	
	<p><u>General Topic:</u></p> <ul style="list-style-type: none"> - Health Insurance and Insurance Discrimination
	<p><u>Session Objectives:</u></p> <ul style="list-style-type: none"> - Define the insurance terms adverse selection, experience rating, and underwriting in the context of concerns about genetic discrimination in insurance - Describe the circumstances under which state laws concerning genetic discrimination apply to individual and group plans - Describe GINA's protections against health insurance discrimination

		<p>a. <u>Readings:</u> These are potential readings. Final readings to be decided by guest speaker.</p> <ul style="list-style-type: none"> i. Carol Ostrom, Rate Hikes for health policies cause pain, The Seattle Times, Sept. 7, 2010. ii. "Summary of Coverage Provisions in the Patient Protection and Affordable Care Act," Kaiser Family Foundation, April 28, 2010. iii. "How Private Health Coverage Works: A Primer (2008 Update)" Kaiser Family Foundation, April 2008. iv. <u>Please identify sections of GINA that apply to insurance and come to class prepared to discuss:</u> <ul style="list-style-type: none"> 1. GINA Legislation
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Wednesday, October 20, 2010 – GENETIC DISCRIMINATION & EMPLOYMENT
Professor Mastroianni

		<p><u>General Topic:</u> - Genetic Discrimination</p>
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		<p><u>Session Objectives:</u></p> <ul style="list-style-type: none"> - Define genetic discrimination - 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 some of the current legal limitations on workplace genetic screening derived from GINA, the Bloodsaw case and the BNSF settlement with EEOC
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		<p>a. <u>Readings:</u></p> <ul style="list-style-type: none"> i. Greely HT. Banning Genetic Discrimination. New England Journal of Medicine, 2005, 353(9):865-867 (3 pages) ii. Billings PR. Genetic nondiscrimination. Nature Genetics, 2005, 37(6):559-560 (2 pages) iii. Brandt-Rauf PW, Brandt-Rauf SI. Genetic Testing in the Workplace: Ethical, Legal, and Social Implications. Annual Review of Public Health, 2004, 25:139–53 (15 pages) iv. Norman–<u>Bloodsaw</u> v. Lawrence Berkeley Laboratory, 135 F.3d 1260 (9th Cir. 1998) v. 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 <p>b. <u>Please identify sections of GINA that apply to employment and come to class prepared to discuss:</u></p> <ul style="list-style-type: none"> i. GINA Legislation <p>c. <u>For Reference:</u></p> <ul style="list-style-type: none"> i. Notice Concerning The Americans With Disabilities Act (ADA) Amendments Act Of 2008, http://www.eeoc.gov/ada/amendments_notice.html ii. ADA Amendments Act of 2008, http://www.access-board.gov/about/laws/ada-amendments.htm <p>d. <u>Optional Reading:</u> American College of Occupational and Environmental Medicine: Position Statement Genetic Screening in the Workplace, http://www.acoem.org/guidelines.aspx?id=6986</p>
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Monday, October 25, 2010 – class rescheduled to Tuesday, November 2, 2010
William H. Gates Hall, Room 118, from 1:30-2:50 PM
MIDTERM posted to Assignments webpage at 2:50PM
Submit by 4:30 PM, Friday Oct. 29 on Catalyst Collect-It Dropbox

Wednesday, October 27, 2010 – GENETIC COUNSELING: A PRACTITIONER'S PERSPECTIVE
Guest Speaker: Ms. Corrie O. Smith, M.S., C.G.C., Certified Genetic Counselor, University of Washington, Genetic Medicine and Neurology
 Ms. Smith's Bio

General Topic:
 - Genetic Counseling

Session Objectives:
 - Understand what training is required to provide genetic counseling
 - Define nondirectiveness and describe how it applies to genetic counseling
 - Describe the current status of licensure for genetic counselors

- a. Readings: Note: These readings may be changed by the guest speaker
- i. Bennett RL Genetic Counseling, in Principles of Molecular Medicine (Runge MS, Patterson C eds., Humana Press 2006) 46-52 (7 pages) (in Course Pack)
 - ii. Bennett RL. Pedigree Parables. Clinical Genetics, 2000, 58(4): 241–249 (9 pages)

Monday, November 1, 2010 –NEWBORN SCREENING
Guest lecturer: Ms. Catharine Riley MPH, PhD candidate, Health Services
Consultant: Office of Newborn Screening, Washington State Department of Health

General Topic:
 -Genetic Testing and Screening
 -Newborn Screening

Session Objectives:
Session Objectives:
 - Describe the historical context of newborn screening in the US
 - List and describe 3 arguments Rodney Howell makes regarding the need to expand newborn screening
 - List and describe 4 recommendations put forth by Botkin et al re: how to "proceed with caution" when expanding newborn screening

- a. Readings:
- i. Watson MS et al. Newborn Screening: Toward A Uniform Screening Panel And System -- Executive Summary, Pediatrics, 2006, 117(5):S296-S307 (12 pages)
 - ii. Botkin JR et al. Newborn Screening Technology: Proceed With Caution. Pediatrics, 2006, 117(5): 1793-1799 (7 pages).
 - iii. Howell RR. We Need Expanded Newborn Screening. Pediatrics , 2006, 117(5): 1800-1805 (6 pages)
 - iv. Review: Chapter 246-650 WAC
 - v. Review: Chapter 70.83 RCW
- b. Optional:
- i. Review: What is the Office of Newborn Screening?, <http://www.doh.wa.gov/ehsphl/phl/newborn/default.htm>

Tuesday, November 2, 2010 – INTRODUCTION TO CLINICAL APPLICATIONS
William H. Gates Hall, Room 118, from 1:30-2:50 PM
Professor Mastroianni

General Topic:

- Overview of Genetic Testing
- Clinical Utility
- Application: Testing for Huntington's Disease

Session Objectives:

- Apply the Burke-Pinsky-Press Model to Newborn Screening
- Define the terms: genetic testing, autosomal dominant; autosomal recessive; penetrance; clinical validity; clinical utility
- 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

a. Readings:

- i. Burke W, Zimmern RL. Ensuring the appropriate use of genetic tests. *Nature Reviews*, 2004, 5(12):955-959 (5 pages)
- ii. McPherson E. Genetic Diagnosis and Testing in Clinical Practice. *Clinical Medicine & Research* 2006, 4(2):123-129 (7 pages)
- iii. Burke W, Pinsky LE, Press NA. Categorizing Genetic Tests to Identify Their Ethical, Legal, and Social Implications, *American Journal of Medical Genetics*, 2001, 106(3):233-240 (8 pages)

b. HD example:

- i. Fact Sheet on Huntington's Disease.
- ii. Gargiulo M et al. Long-term outcome of presymptomatic testing in Huntington disease. *European Journal of Human Genetics*, 2009, 17(2): 165–171 (7 pages)

c. Optional Readings:

- i. Autosomal dominant handout
- ii. Autosomal recessive handout
- iii. Harmon A. Facing Life With a Lethal Gene, *New York Times*, Mar. 18, 2007, A-1
- iv. Scott J (as told to Paige Williams). *Lives; Survivor*, *New York Times Magazine*, July 14, 2002, <http://www.nytimes.com/2002/07/14/magazine/lives-survivor.html>
- v. Cooke P, Wilson M. Sentenced to live. *Health*, 1993, 7(4):80 (7 pages)

Wednesday, November 3, 2010 – NEWBORN SCREENING & POLICY
Guest Speakers: Ms. Catharine Riley , MPH, PhD candidate, Health Services, Consultant, Office of Newborn Screening, Washington State Department of Health; Professor Ray Nicola, Director, Community Oriented Public Health Practice program, Health Services, Senior Consultant, Centers for Disease Control & Prevention; and Professor Mastroianni
 Prof. Nicola's bio

- General Topic:
- Newborn Screening Policy—Case Study Discussion

- Session Objectives:
- Provide an overview of newborn screening policy
 - Explore stakeholder analysis
 - Apply framework to NBS

- a. Readings:
- i. Letters to the Editor. Every Child is Priceless: Debating Effective Newborn Screening Policy, Hastings Center Report, 2009, 39(1): 4-8 (5 pages)
 - ii. Hubbard HP. Policy Issues Related to Expanded Newborn Screening: A Review of Three Genetic/Metabolic Disorders. Policy, Politics & Nursing Practice, 2007, 8(3): 201-209 (9 pages)

Monday, November 8, 2010 – APPLYING THE BPP MODEL; PRENATAL TESTING
Professor Mastroianni

NBS assignment due: submit by 9:30 AM on Catalyst Collect-It Dropbox

- General Topic:
- BPP Model Applications: predisposition testing (hereditary Breast Cancer)
 - Prenatal Testing

- Session Objectives:
- Apply the BPP model to hereditary Breast Cancer
 - 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

- a. Readings:
- i. Press N. Assessing the expressive character of prenatal testing: the choices made or the choices made available in Prenatal Testing and Disability Rights (Parens E, Asch A eds., 2000), 214-233 (20 pages) (in Course Pack)
 - ii. Asch A. Prenatal Diagnosis and Selective Abortion: A Challenge to Practice and Policy. American Journal of Public Health, 1999, 89(11): 1649-1657 (9 pages)
 - iii. Bauer PE. The Abortion Debate No One Wants to Have, Washingtonpost.com, Oct. 18, 2005.

Wednesday, November 10, 2010 – GENETIC RESEARCH: ETHICS AND REGULATORY ENVIRONMENT
Professor Mastroianni

General Topic:

- Overview of ethics and regulatory environment
- Exploration of hot topics in genetics research

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
- Describe the conditions under which the federal regulations known as the Common Rule apply to genetic 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
- "Hot topics" in genetics research

a. Readings:

- i. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report (1979) (see reading for 2nd class), <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>
- ii. DHHS—Basic Policy for the Protection of Human Research Subjects, 45 CFR46. Available at: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm> (2007).
- iii. Policy Guidance - Office for Human Research Protections (OHRP), HHS, <http://www.hhs.gov/ohrp/humansubjects/guidance/gina.html>
- iv. Dressler LG. Disclosure of Research Results from Cancer Genomic Studies: State of the Science. *Clinical Cancer Research*, 2009, 15(13): 4270-4276 (7 pages)
- v. Cho MK. Understanding Incidental Findings in the context of genetics and genomics. *J Law Med Ethics*. 2008 Summer; 36(2): 280-5, 212 (6 pages)
- vi. Attached are the two pieces on returning individual genetic results to research participants that utilize ethical frameworks:
 - Ravitsky & Wilfond (2006). *Disclosing Individual Genetic Results to Research Participants*.
<http://www.informaworld.com.offcampus.lib.washington.edu/smpp/finterface-db=all-content=a762495719-fulltext=713240930>
 - Response to above: Meltzer (2006). *Undesirable Implications of Disclosing Individual Genetic Results*.
<http://www.informaworld.com.offcampus.lib.washington.edu/smpp/finterface-db=all-content=a762495725-fulltext=713240930>
- vii. Recent story on Dr. Frances Oldham Kelsey, who is largely responsible for the relatively limited impact of thalidomide in the US relative to Europe: <http://www.nytimes.com/2010/09/14/health/14kelsey.html>
- viii. Another important (and fascinating) case in the history of research ethics -- Henrietta Lacks:
http://entertainment.timesonline.co.uk/tol/arts_and_entertainment/books/non-fiction/article7143286.ece (this is a review of Rebecca Skloot's recent book *The Immortal Life of Henrietta Lacks*)

Monday, November 15, 2010 – ETHICAL ISSUES IN WHOLE GENOME AND EXOME SEQUENCING

**Guest Lecturer: Professor Holly Tabor, PhD, Pediatrics, Division of Bioethics
UW School of Medicine & Treuman Katz Center for Pediatric Bioethics.**

Professor Tabor's Bio

General Topic:

- Ethical issues in whole genome and exome sequencing

Session Objectives

a. Readings:

- SB. Exome sequencing identifies the cause of mendelian disorder. Nature Genetics, 2010, 42(1):30-35 (6 pages)
- LG. Exome sequencing makes medical genomics a reality. Nature Genetics, 2010, 42(1):13-14 (2 pages)

Wednesday, November 17, 2010 – GENETIC TESTING IN CHILDREN

Guest Speaker: Benjamin Wilfond, MD, Director, Treuman Katz Center for Pediatric Bioethics, Seattle Children's Research Institute and Professor of Pediatrics, University of Washington School of Medicine

Dr. Wilfond's Bio

General Topic: Genetic Testing in Children

a. Readings:

- Wade et al. Effects of genetic risk information on children's psychosocial wellbeing: A systematic review of the literature, Genetics in Medicine, 2010, 12(6):317-226
- Wilfond B & Ross L. From Genetics to Genomics: Ethics, Policy, and Parental Decision-making, Journal of Pediatric Psychology, 2009, 34(6):639-647
- Denny CC, et al. All in the Family: Disclosure of "Unwanted" Information to an Adolescent to Benefit a Relative, American Journal of Medical Genetics Part A, 2008, 146A:2719-2724
- ASGH/ACMG REPORT, Points to Consider: Ethical, Legal, and Psychosocial Implications of Genetic Testing in Children and Adolescents, American Journal of Human Genetics, 1995, 57:1233-1241

Monday, November 22, 2010 – DTC GENETIC TESTING IN CLASS ROLE-PLAYING EXERCISE: ADVOCACY

Professor Mastroianni

DTC Part A assignment due: submit by 1:30 PM on Catalyst Collect-It Dropbox AND bring 4 copies to class

General Topic:

- Direct-to-consumer genetic testing

Session Objectives:

- Describe the roles of federal, state and nongovernmental actors in overseeing the use of genetic tests
- Case study small group discussion

b. Readings:

- Executive Summary of the Secretary's Advisory Committee on Genetic Testing Report : U.S. System of Oversight of Genetic Testing: A Response to the Charge of the Secretary of Health and Human Services

		<p>(2008) (pages 1-12 only) http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS_oversight_report.pdf</p> <ul style="list-style-type: none"> ii. Kuehn, BM. Risks and Benefits of Direct-To-Consumer Genetic Testing Remain Unclear. <i>Journal of the American Medical Association</i>, 2008, 300(13): 1503-1505 (3 pages) iii. Genetics & Public Policy Center. Direct-to-consumer Genetic Testing: Empowering or Endangering the Public?, May 30, 2008, http://www.dnapolicy.org/policy.issue.php?action=detail&issuebrief_id=32 iv. Hogarth S, Javitt G, Melzer D. <u>The Current Landscape for Direct-to-Consumer Genetic Testing: Legal, Ethical, and Policy Issues</u>. <i>Annual Review of Genomics & Human Genetics</i> 2008, 9:161-182 (22 pages) v. Locate and Review Websites for the following companies: 23andMe, DeCode, Navigenics <p>c. <u>Optional Readings:</u></p> <ul style="list-style-type: none"> i. Javitt G. Which way for genetic-test regulation? Assign regulation appropriate to the level of risk. <i>Nature</i>. 2010, 466(7308):817-818. (2 pages) ii. Patch C. Genetic Horoscopes: is it all in the genes? Points for regulatory control of direct-to-consumer genetic testing. <i>European Journal of Human Genetics</i>, 2009, 17(7): 857-859 (3 pages)
<p>Wednesday, November 24, 2010: NO CLASS – HAPPY THANKSGIVING!</p>		
<p>Monday, November 29, 2010 – DTC GENETIC TESTING IN CLASS ROLE-PLAYING EXERCISE: POLICY DEVELOPMENT Professor Mastroianni</p>		
		<p><u>General Topic:</u> Policy framework and stakeholder analysis</p> <p><u>Session Objectives:</u> Apply Policy Framework to Direct to Consumer Genetic Testing</p>
		<p>a. <u>Readings:</u></p> <ul style="list-style-type: none"> i. Institute of Medicine Report: The Value of Genetic and Genomic Technologies, Workshop Summary (2010), Ch. 4, 25-35 (11 pages) ii. European Geneticists Take a Strong Stand on Direct-to-Consumer Gene Test: http://www.biopoliticaltimes.org/article.php?id=5361 iii. <u>(For reference):</u> statement full text: European Society of Human Genetics, Statement of the ESHG on direct-to-consumer genetic testing for health-related purposes, <i>European Journal of Human Genetics</i> (2010), 1–3 (3 pages) https://www.eshg.org/fileadmin/www.eshg.org/documents/PPPC/2010-ejhg2010129a.pdf

Wednesday, December 1, 2010 – BIOSAMPLES AND GENETIC RESEARCH: THE HAVASUPAI CASE

Professor Mastroianni

DTC Part B assignment due: submit by 1:30 PM on Catalyst Collect-It Dropbox

General Topic:
TBD

Session Objectives:

- Identify the relevant facts and identify, describe, and analyze the ethical, legal and policy issues arising in the Havasupai genetics project
- Compare and contrast the three legal cases related to ownership and control of DNA samples in research (*Moore, Greenberg, & Catalona*)
- Identify and describe the legal and ethical requirements for informed consent in human subjects research

a. Readings:

- i. Mello MM & Wolf LE. The Havasupai Indian Tribe Case — Lessons for Research Involving Stored Biologic Samples, 2010, New England Journal of Medicine, 363:204-207 (4 pages)
- ii. Bommersbach J: Arizona's Broken Arrow Phoenix Magazine. 2008 Nov; 134
- iii. Harmon A, Indian Tribe Wins Fight to Limit Research of Its DNA, New York Times, Apr. 21, 2010, A-1
- iv. Havasupai tribe of Havasupai Reservation v. Arizona Board of Regents Court of Appeals of Arizona, Division 1, Department D. Nov. 28, 2008.
- v. Glantz L. Rules for donations to tissue banks – what's next? New England Journal of Medicine, 2008, 358(3):298-303 (6 pages)

b. Optional Readings:

- i. Moore v. Regents of the Univ. of California, 793 P.2d 479 (Cal. 1990), cert. denied, 499 U.S. 936 (1991); full opinion: http://www.eejlaw.com/materials/Moore_v_Regents_T08.pdf
- ii. Greenberg v. Miami Children's Hosp., 264 F. Supp. 2d 1064 (2003).
- iii. Washington University v. Catalona, 400 F.3d 667 (8th Cir. 2007)

Monday, December 6, 2010 – NO CLASS

NO CLASS MEETING

Wednesday, December 8, 2010

Sum up and Review
TAKE HOME FINAL HANDED OUT
Professor Mastroianni

General Topic:
Pedigree Research

Session Objective:

Describe the kind of information that a pedigree can reveal, the potential harms that can arise from revealing this information to family members and others through publication, alternative strategies to protect privacy and confidentiality

a. Readings:

- i. Bennett RL. Pedigree Parables. Clinical Genetics, 2000, 58(4): 241–249 (9 pages)
- ii. Austin, MA. "Ethical Issues in Human Genome Epidemiology: A Case Study Based on The Japanese American Family Study in Seattle, Washington" Am J Epidemiol. 2002 Apr 1; 155(7):585-92. Read the following sections:
 - Abstract & Introduction
 - "Japanese American family study"
 - "Protecting privacy and confidentiality of family members"
 - "Publication of pedigrees"
 - "Summary and Conclusions" (optional)

Monday, Dec. 13, 2010

Take-home Final due: submit by 4:30 PM on Catalyst Collect-It Dropbox