

**UNIVERSITY OF WASHINGTON
SCHOOL OF LAW
INSTITUTE FOR PUBLIC HEALTH GENETICS**

**Genetics and the Law
LAW H520 / PHG 523 (3 Credits)
Fall, 2014**

GENERAL INFORMATION AND COURSE SYLLABUS

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Course Description

This course explores legal, policy and ethical consequences of genetic technologies and information. The overarching context for the course is to address the response of the law and the legal system to advances in genetic information and technologies and posit what the response should be in the future. For those who have taken in PHG 512/LAW H504/BH 514/HSERV 590D (Legal, Ethical and Social Issues in Public Health Genetics), the course extends the discussion by examining in greater depth the legal consequences of genetic technologies and information. This course is offered to students from diverse disciplines that may or may not have a genetics, public health or law background. We will therefore begin with an overview of genetic science, the recent explosion of knowledge about the human genome, and an introduction to law. We will explore the legal implications of medical mistakes in genetic testing; genetics and reproductive decision-making; genetics and parenting; and genetics and research. The course examines the concepts of privacy and confidentiality and their applications to genetic information. We consider genetic information and its use in the workplace, and its role in access to insurance and health care coverage. We also explore the use of DNA in the courtroom, forensics, and genetic evidence in the criminal context. We will look at the movement of genetics from bench science to the marketplace, including a brief consideration of intellectual property and direct-to-consumer marketing.

This course will be taught and conducted in a seminar style. We will be engaged in our exploration of the topics covered through shared learning. Each member of the class will participate in and contribute to the learning that occurs. Collaborative learning will be reflected in the way that the course is structured and your work is evaluated.

Course Materials

The text for the course is Andrews, Mehlman and Rothstein, *Genetics: Ethics, Law and Policy* 3rd ed. (West 2010) (hereafter "AMR"). The text is available at the University Bookstore or may be purchased or rented from various online retailers. In addition, copies are available "on reserve" at Gallagher Law Library. Additional course readings will be provided via the course website on CANVAS (accessible via link below), and will include the 2013 AMR supplement, articles, cases and news

items: https://courses.law.washington.edu/MastroianniA/H520aabc_Au13/

For students seeking additional background reading on law and legal systems, a general introductory text, *Introduction to the Law and Legal System of the United States* (3th ed. 2002), is available on reserve in the Gallagher Law Library. The law library also has excellent resources in this area, which can be found at

<http://lib.law.washington.edu/ref/basic.html>. (See also the Recommended References and Reading on Law page on CANVAS.) The loan period for items from Course Reserves is 4 hours; you cannot renew a book on loan from Course Reserves.

Course Grade

The course grade will be based upon: (1) one 1850-2500 word Research Memorandum (in legal memo form) examining a topic of interest in law and genetics, (2) Eight (8) Blog Postings, and (3) Class Participation and Attendance. Out of fairness to all students in the course, a two-point deduction will be made for each 24 hours (or portion thereof) a written submission is late. See point distributions and weighting in summary table below. Grading Note: This course is not subject to the law school's mandatory grading curve.

(1) The Research Memorandum

Please ensure that you read the formatting requirements delineated below carefully. Additional guidance will be provided during the first two weeks of class. Examples of Legal Research Memos are provided on the Recommended References and Reading on Law page on CANVAS. In order to provide you with some feedback on your writing during the course, the writing process has been divided into three parts as outlined below. The course includes a legal research training session for law students and non-law students as well as a brief introduction to legal memo writing for non-law students. Please see the instructor for any additional questions.

(a) Prospectus. Students must select a legal topic or question of interest in the area of law and genetics. Although the topic may be of the student's choice, it must be approved by the instructor. The specific topic may not be one that the student has written on before for any class or publication. Students should talk to the instructor for clarification if questions arise concerning this requirement. The prospectus should be approximately one page and should describe the research topic in sufficient detail so that the instructor can provide feedback or guidance. The prospectus should include a list of research sources the student plans to consult and may include a preliminary bibliography. There is no required style or formatting for this submission. The Prospectus is due via its Assignments link on CANVAS by no later **than 12:00 PM (Noon) on Wednesday, October 15**. The instructor will provide feedback, including topic approval (or disapproval) via email or in person. This submission will constitute 5% of your grade.

(b) **OPTIONAL Draft Submission**. A draft of the memo, in a condition as close to final as reasonably possible, may be submitted to the instructor via its Assignments link on CANVAS by no later **than 12:00 PM (Noon) on Friday, November 21**. Drafts must be double-spaced, with one-inch (1") margins all around, and 12-point Times New Roman font (or equivalent). Students should use footnote formatting (rather than endnotes). The instructor will be providing feedback on the draft via email or in a scheduled one-on-one instructor-student meeting. This submission is optional and ungraded. No late submissions are accepted (i.e., the instructor will not provide written comments and guidance on late submissions), although students may make appointments after the draft submission deadline with the instructor to discuss memo topics, research and approaches.

(c) Final Memo. The final version of the Research Memo will constitute 35% of your grade. The format should be standard legal memo form. Resources on legal memo writing are available on the Recommended References and Reading on Law page on CANVAS. The minimum number of words required is 1850, and the maximum number of words permitted is 2500, not including footnotes. Papers must be double-spaced, with one-inch margins, page numbers, and in 12-point Times New Roman or similar font. All papers from law students must use the appropriate Bluebook citation format. All papers from non-law students must select one standard reference format (MLA, APA, Chicago, AMA, Bluebook) and use it consistently throughout the paper. Points will be deducted for failure to follow any of the style requirements. The final version of your paper is due via its Assignment link on

CANVAS by no later **than 12:00 PM (Noon) on Wednesday, December 10**. Early submissions are always welcome.

Note on Writing Quality. High-quality writing is the standard for graduate education. Thus, I expect that you will have proofread all of your submissions for spelling and grammatical errors before turning them in. I will pay attention to style as well as content. In general, you will lose points for sloppiness and gain points for eloquence. If you know you have trouble in these areas, please let me know so I can take that into consideration as I grade your papers. Your best strategy is to have someone else review and proof your papers. For guidance, please refer to *The Elements of Style*, by William Strunk, Jr., (<http://www.bartleby.com/141/>) and *Style: Ten Lessons in Clarity & Grace* (7th ed.), by Joseph M. Williams. Both are excellent references for organizing and improving your writing in any discipline. In addition, there is a free consultation service available through the UW's Odegaard Writing and Research Center (<http://depts.washington.edu/owrc/>). Please consult their website for policies, contact information and hours.

(2) Blog Postings

The instructor will post a series of questions for class meetings on the Course Blog (Discussions page on CANVAS). Each student is required to post in response to the student's choice of 8 blogging assignments available on the Course Blog. The purpose of the posts is to foster discussion and questions before class so that we can make the best use of our class time together. Unless specifically directed otherwise on the Course Blog, students are required to (a) submit responses to each question posted by the instructor, and (b) respond to at least two (2) comments posted by classmates (two comments total, not per question). **Responses to Questions (a, above) are due no later than 10AM on the day before class meetings, and Peer Comments (b, above) are due by 7PM on the day before class meetings.** Please plan your schedules accordingly. Responses and questions posted on the Course Blog will be used to organize and guide in-class discussions. I plan to post the questions in advance, so you are welcome to submit your responses early. The eight blog postings comprise 40% of your course grade. **IMPORTANT: ONCE YOU POST TO A COURSE BLOG YOU ARE COMMITTED TO POSTING FOR THE WHOLE ASSIGNMENT. PARTIALLY COMPLETED ASSIGNMENTS WILL BE TREATED AS A FULL RESPONSE FOR GRADING PURPOSES.** Please contact the instructor if you have any questions.

(3) Class Attendance & Participation

Active participation by **all** students is crucial to the success of this class. It is very important that you come prepared for class, having read the assigned materials and thought about the issues. Only two excused absences will be allowed during the course out of fairness to other students. You must notify me in advance (by email, phone/voice mail, or in person); you will lose points for unexcused absences. Class Attendance and Participation will constitute 20% of your grade.

Our class will consist of law students, public health students and other graduate students from the University. Your learning will be greatly enhanced by the interaction among students from different backgrounds and disciplines. I urge you to share notes, outlines, and insights with your classmates as your learning will benefit from interdisciplinary dialogue. The class will be podcasted and podcasts will be accessible on the course website. The quality of the podcast is not guaranteed.

Important Note on Late Submissions. Due dates are firm, and will not be extended except in extenuating circumstances. In the interest of fairness to other students, a two-point deduction will be made each 24-hour period any assignment is late. This applies to both the legal memo assignment and to the 8 blog postings. If you have extenuating circumstances that will require renegotiating deadlines, please give me as much warning as possible. You must have prior approval to avoid late penalties. Early submissions are always welcome.

ASSIGNMENT	GRADE VALUE	DUE DATE
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		Points [total 400]	Percentage [total 100]	
Class Attendance & Participation		80	20	Each class
Eight (8) Blog Postings		160	40	By 10:00 AM day before class meeting (dates noted on syllabus) via Discussions page on CANVAS Peer Comments due by 7:00 PM day before class (dates noted on syllabus) via Discussions page on CANVAS
Research Paper	One Page Prospectus	20	5	By 12:00 PM (Noon), October 14, via its Assignments link on CANVAS
	OPTIONAL Draft Memo Submission	0	0	By 12:00 PM (Noon), November 21, via its Assignments link on CANVAS No late submissions accepted
	Final Memo	140	35	By 12:00 PM (Noon), December 10, via its Assignments link on CANVAS

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 that we can discuss appropriate accommodations.

OUTLINE OF THE COURSE AND READING ASSIGNMENTS – AUTUMN, 2014

The following syllabus outlines the course, reading assignments and sets forth a preliminary timetable. It is possible that the timetable and reading assignments will be amended during the course. I will alert you to any changes and post them on the course website. "AMR" refers to chapters and pages in the assigned textbook; and "AMR Supp" refers to the pages in the supplement to the textbook and will be available on the course website. All other readings will be available via the course website.

Because this course is offered in the School of Law as well as other schools throughout the University, which operate on a different calendar for the School of Law, the first day of class will follow the UW calendar. Therefore our first day of class will be Wednesday, September 25.

SEPTEMBER 24 Blog Posting due Introductions

Course Introduction [PPT

Assignment due no later than 7:00 PM, September 24

Find a magazine or newspaper article about a new genetic technology or discovery; on the Discussions page on CANVAS provide a link to the article, and write one paragraph about the technology and another paragraph speculating on the legal issues it raises. Be prepared to discuss in class. Please note that this assignment is graded credit/no credit and is not included in the grading for the required 8 blog postings.

Reading Assignment:

AMR 90-93; 484-487

SKIM: Institute of Medicine, Implications of Genomics for Public Health: Workshop Summary (2005) Free PDF available at <http://www.nap.edu/openbook.php?isbn=0309096073>

SEPTEMBER 30

Introduction to Law and Legal Approaches for Non-Lawyers [PPT]

Introduction for Non-Lawyers to Legal Writing: The Legal Memo and Bluebook Style

Students with training in the law are not required to attend this class. Law Students will automatically be excused from this class. Non-law students must email the instructor before the class meeting indicating that s/he will not be attending the class because s/he has a working knowledge of law and legal approaches.

Reading Assignment:

AMR 450-457

Case Briefs:

<http://lawschool.westlaw.com/shared/marketinfodisplay.asp?code=sg&id=3&mainpage=23>

- Read the two cases. Be prepared to walk through the elements of a Case Brief for each.
- Become familiar with the Recommended References and Reading on Law so that you can refer to and use them throughout the course.
- Lexis/Nexis Law School 101: Case

citation http://wiki.lexisnexis.com/academic/index.php?title=Law_School_101:_Case_Citations

Handout: Flowchart Showing Elements of a Good Case Brief [PDF] 

OCTOBER 2

Scientific Overview: Introduction to Genetics for Non-Genetics Students [PPT]

Students with training in genetics are not required to attend this class. No participation points will be deducted if the student emails the instructor before the class meeting indicating that s/he will not be attending the class because s/he has a working knowledge of genetics.

Reading Assignment:

AMR Chapter 2: Scientific Overview

AMR Supp at 2 

OCTOBER 7

Genetic Services and Liability [PPT]

Reading Assignment:

AMR 305-310 (genetic testing technology); 450-469 (duties of health care professionals)
Washington Statutes:

Rev. Code Wash. §§ 7.70.030, <http://apps.leg.wa.gov/rcw/default.aspx?cite=7.70.030>,

7.70.040 <http://apps.leg.wa.gov/rcw/default.aspx?cite=7.70.040>,

7.70.050 <http://apps.leg.wa.gov/rcw/default.aspx?cite=7.70.050>,

7.70.060 <http://apps.leg.wa.gov/rcw/default.aspx?cite=7.70.060>

OCTOBER 9

Library Research Session

1:30 - 2:50 PM (full class time) -- attendance by NON-LAW STUDENTS

2:10 - 2:50 PM (partial class time) -- attendance by LAW STUDENTS

Guest Lecturers: TBD, Gallagher Law Library

Please review the following Reference Guides prior to class meeting:

Research/Writing Guides: <https://lib.law.washington.edu/content/guides/writing2>

<http://lib.law.washington.edu/ref/writing.html>

Genetics/Health Research Guides <https://lib.law.washington.edu/content/guides/genlaw>

<https://lib.law.washington.edu/content/guides/healthlawtips>

OCTOBER 14 – Blog Posting due

Prenatal Screening: Techniques, Liability, Eugenics [PPT 

Reading Assignment:

AMR 320-346 (techniques, liability); 48-56 (eugenics laws)

OCTOBER 16 - Blog Posting Due

Newborn Screening Programs [PPT 

Reading Assignment:

AMR 381-408

AMR Supp at 17 

Creason v. Dept of Health Services, 18 Cal.4th 623 (1998) (edited 

Recommended, but Optional, Readings:

Mary Carmichael, A spot of trouble , Nature, Vol. 475, 156-185 (July 14, 2011)

Higgins v. Texas Dept of Health Services, 801 F.Supp.2d 541 (2011) (edited 

Texas officials agree to destroy babies' blood samples after settling lawsuit (multiple articles) available at <http://www.texascivilrightsproject.org/1822/texas-officials-agree-to-destroy-babies-blood-samples-after-settling-lawsuit/>

Lewis et al. State laws regarding the retention and use of residual newborn screening blood samples , 127 Pediatrics 703 (2011)

Websites: <http://www.savebabies.org/> and <http://www.babysfirsttest.org/>

OCTOBER 21 Blog Posting Due

Parentage and Family Law [PPT] 

Reading Assignment:

AMR 600-606; 610-613; 624-634; 638-645

Ruth Padawer, Who Knew I Was Not the Father?, New York Times Magazine, Nov. 22, 2009, at 38, available at <http://www.nytimes.com/2009/11/22/magazine/22Paternity-t.html>

Matthew Rosenbaum, Who's Your Daddy? Mobile Truck Offers DNA Tests to Go, ABCnews.com, August 16, 2012, available at

<http://abcnews.go.com/blogs/health/2012/08/16/whos-your-daddy-mobile-truck-offers-dna-tests-to-go/>

OCTOBER 23

Genetic Exceptionalism and Genetic Privacy [PPT] 

Reading Assignment:

AMR 798-825 (genetic exceptionalism, genetic privacy)

OCTOBER 28 Blog Posting Due

Genetics and Employment Discrimination [PPT] 

Reading Assignment:
AMR 880-909

OCTOBER 30 Blog Posting Due [PPT 
Genetics and Insurance Discrimination

Reading Assignment:
AMR 832-860; 872-879
AMR Supp at 20-24 

NOVEMBER 4

Genetics and Patents Part 1: Basic Concepts & Commercialization [PPT 

Reading Assignment:
AMR 194-208 (Diamond); 224-232 (Fisher, Amgen); 240-243 (Amgen); 247-260 (concerns)
UC-OTT, The Bayh-Dole Act: A Guide To The Law And Implementing Regulations,
<http://www.ucop.edu/ott/faculty/bayh.html> (technology transfer)
In re Deuel, 51 F.3d 1552 (1995) (edited 
Optional Reading
AMR 277-282 (technology transfer)

NOVEMBER 6

Genetics and Patents Part 2: The Prometheus and Myriad Litigation

Reading Assignment:
AMR Supp at 3-16 
Tony Dutra, Leahy Calls for NIH March-In Against Myriad But Some Patents Not Subject to
Bayh-Dole, BloombergLaw.com,

NOVEMBER 11—VETERAN'S DAY
UW HOLIDAY- NO CLASS

NOVEMBER 13 Blog Posting Due

Genetic Testing for Identification [PPT 

Reading Assignment:
AMR 677-706 (Criminal); 740-744 (Non-Criminal)
Frye v. US, 293 F. 1013 (1923) (edited 
Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993) (edited 
Optional Reading
<http://www.scotusblog.com/case-files/cases/maryland-v-king>

NOVEMBER 18 Blog Posting Due

Genetics and Exoneration [PPT 

Reading Assignment:
AMR 706-716
<http://www.innocenceproject.org/>
<http://www.nij.gov/nij/topics/forensics/postconviction/welcome.htm>
<http://www.law.washington.edu/Clinics/IPNW/>

NOVEMBER 20 Blog Posting Due

Regulation of Genetic Testing; Direct-to-Consumer Genetic Testing [PPT

Reading Assignment:

AMR 310-320 (regulation); 471-483 (DTC)

Review website: www.23andme.com

NOVEMBER 25

Genetics Research Part 1: Approval Process for Drugs and Biologics; Regulation; Gene "therapy" [PPT

Reading Assignment:

AMR 93-109 (federal regulation); 121-122 (state regulation); 488-523 (gene "therapy")
Gelsinger v. University of Pennsylvania ("Gelsinger Complaint" and "University of Pennsylvania Statements" only), available at <http://www.sskrplaw.com/lawyer-attorney-1475659.html>

Recommended, but Optional, Reading: RAC website (NIH, OBA, RAC)

<http://oba.od.nih.gov/rdna/rdna.html>

NOVEMBER 27 Blog Posting Due

Genetics Research Part 2: Research with Tissue Samples; Obligations to Research Subjects [PPT

Reading Assignment:

AMR 122-138 & 150-156 (Tissue Samples); 283-299 (Moore, Greenberg); 184-193 (Obligations)

Hudson & Collins, Biospecimen Policy: Family Matters (August 2013)

<http://www.nature.com/nature/journal/v500/n7461/full/500141a.html>

DECEMBER 2

Movie Day: GATTACA (1997) [HANDOUT]

GATTACA provides an opportunity for you to integrate a number of concepts raised in the course. Even if you have seen the movie before, you should be able to view it with a different perspective. This assignment is an issue spotting and analysis exercise. Please come to the last day of class prepared to discuss the questions below.

While watching the movie, identify at least 5 topics that we covered during the course. For each, be prepared to:

- a. Compare your understanding of the current realities of genetic technologies, concepts and applications to the treatment of the topic by the movie's writers and directors
- b. Describe the role that law could and/or should have had in addressing each

DECEMBER 4

GATTACA Discussion

Course Wrap Up

Course Evaluations

Reading Assignment:

Gautam Naik, 'Designer Babies:' Patented Process Could Lead to Selection of Genes for Specific Trait,' Wall Street Journal, October 4, 2013, page A3.