Ethical Frameworks of Public Health Genetics PHG 522/BH 516 (3 Credits)

University of Washington Winter Quarter 2011

Mondays & Wednesdays 1:30-2:50 p.m.

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Summary of Course

This course introduces students to frameworks for understanding ethical principles, concepts and their application in public health genetics. This approach allows for detailed examination and discussion of ethical issues in genetics that arise in research, practice and policy affecting both individuals and populations. Part I focuses on foundational issues, including: (a) introduction and review of approaches to and tools for understanding ethics and ethical analysis, and (b) early approaches to ethical issues arising in genetics, particularly the historical experience with early screening programs and counseling practices, and genetic engineering. Part II explores the application of ethical frameworks in the context of public health genetics. The potential for tension between individual and societal perspectives is considered throughout the course. Of particular focus will be issues that arise in thinking about how advances in genetic technology can benefit or pose a threat to public health, particularly in the areas of health promotion and disease prevention.

Course Objectives

Through lectures, class discussions, and oral and written presentations, students will: further develop basic skills in ethical analysis; be able to recognize, research, and analyze ethical issues arising in the context of public health genetics; and increase the competence with which they make ethical decisions as issues arise in their practice and professional training.

Required Course Materials

There are two required "texts" for this course:

 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 via Catalyst CommonView: https://catalyst.uw.edu/workspace/kschuda/17823/ 2. Mary Shelley, *Frankenstein* (any unabridged edition). This book is available for purchase at the Health Sciences branch of the University Bookstore. You are expected to have read the book by the date of class discussion, January 26.

Scientific and medical advancements with potential ethical implications are being reported practically every day. From time to time throughout the course I 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.

Course Policies

<u>Attendance</u>: Because this class will use a seminar format to discuss the readings, your attendance and participation are critical to the success of the class. Two excused absences will be allowed (you must notify me in advance either by email, phone/voice mail, or in person); you will lose participation points for other absences.

<u>Class participation</u>: This course provides an opportunity for students to discuss potentially controversial issues in a seminar format. 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.

<u>Electronic submissions</u>: Written assignments will be accepted as an electronic copy using Catalyst Drop box. All submissions must be received by the due date and time.

<u>Late assignments</u>: In the interest of fairness to other students, any assignments received after the due date and time will receive 2 points off for each day late. If you have extenuating circumstances that will require renegotiating deadlines, please give the instructor as much warning as possible. You must have prior approval to avoid late penalties.

Quality of your writing: High-quality writing is the standard for graduate education. Thus, I expect that you will have proof-read your papers 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 addition, a free consultation service is 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. In addition, the following webpage has links to useful resources in multidisciplinary communication:

http://depts.washington.edu/phgen/resources/writing.shtml.

<u>Disability Accommodation</u>: If you would like to request academic accommodations due to a disability, please contact Disability Resources for Students (DRS), 448 Schmitz, 543-8924 (V/TDD), http://www.washington.edu/students/drs/. If you have a letter from DRS indicating you have such a disability, please present the letter to me so that we can discuss appropriate accommodations.

<u>Feedback</u>, <u>suggestions</u>, <u>assessment and summative evaluations</u>: Seminar members are encouraged to suggest alternative readings and topics for seminar discussion and otherwise recommend ways to maximize our study time together. I welcome continual feedback and assessment of seminar substance and process. A formal course evaluation will be collected and assessed by the Educational Assessment Center during the last class session. Participation in the evaluation process is voluntary.

Course Assignments and Grading

Course assignments are described below. Your course grade will be based upon the following:

Assignment	Weight in Final Grade (%/points)	Due Date/Time
Critique—Article Selection from Part II (3 choices, ranked, include class date and author name)	CR/NC	January 10, hard copy to class or email instructor in advance of class
Written Critique (3-4 pages)	20%/80 points	Draft written critique: 1 copy to class for personal reference on date material covered in class/beginning of class Final written critique: by 2:30 pm
		the day following student presentation
Oral Brief Presentation of Critique (3-5 minutes)		In class presentation on date material covered
Catalyst Go Post (Blog) Response on Frankenstein	5%/20 points	No later than January 24, 1:30 pm
Ethical Analysis Essay and Annotated Bibliography Topic Description	CR/NC	January 19, hard copy to class or email instructor in advance of class

Annotated Bibliography	20%/80 points	First draft: February 10, 9:30 am
		Final: March 10, 9:30 am
Ethical Analysis Essay(4-5 pages)	30%/120 points	First Draft: February 24, 9:30 am
		Final: March 10, 9:30 am
Class Participation	25%/100 points	Total of two excused absences permitted without penalty. See course policies for details.
Total	100%/400 points	

Other important due dates:

Frankenstein Discussion—January 26

Important instructions for all papers: Format, Submission and Late Papers

All papers should be typed, double-spaced in 12-point Times New Roman font, with 1-inch margins, and must include page numbers. Unless otherwise indicated, written papers are to be delivered by Catalyst Collect-It dropbox submission at

https://catalyst.uw.edu/collectit/dropbox/parkervt/13308. Points will be deducted for formatting and length, as well as spelling and grammar errors, if appropriate. In fairness to all other students, papers will receive a 2-point deduction for each day late (calculated in 24-hour periods following due date and time). Students <u>must</u> abide by the stated page limits to avoid penalty.

Assignments

Catalyst Go Post (Blog) Response on Frankenstein.

This assignment requires that you read Mary Shelley's *Frankenstein* and join the Discussion Board [https://catalyst.uw.edu/gopost/board/amastroi/19836/] in thoughtfully responding to the question posted as well as to posted comments by at least two of your classmates. Your response is valued at 5% of your grade and is due no later than January 24 at 1:30 PM.

Critique and Brief Presentation

This assignment is a short paper that critiques one of the assigned readings. In the second class, students will each select one assigned reading from Part II of the course to critique. Final selection is subject to instructor's permission. Papers should be at least 3 pages, and should not exceed 4 pages. The paper should consist of a very brief (no more than one short paragraph) summary of the article followed by a critique. The paper should reflect your ability to analyze critically the data and arguments presented by the author(s). Important: Please do not conduct any additional research. You should plan on reading the article several times before writing your essay. The critique is due on the date the material is covered in class. The student is expected to make a brief (3-5 minutes) presentation of the critique to the class. As you should assume that the other students have read the material, the summary of the article should be quite brief, *i.e.*, the focus of the paper and presentation should be your critique. This critique and brief presentation will constitute 20% of your grade (12% for written essay, 8% for oral presentation). Students may revise the written critique after class discussion and turn in the final version of the critique by 2:30 PM on the day following class discussion.

Ethical Analysis Essay

In this writing assignment, you will use either the Beauchamp and Childress principles or the Belmont Report principles, as appropriate, to analyze an ethical issue arising in public health genetics. You may select a topic of your choice arising in public health genetics or alternatively, a topic that we have discussed in class that presents an ethical dilemma. In this 4-5 page essay, you will describe the relevant facts, specify the ethical issue, describe each principle and its application to the relevant facts, discuss any areas of conflict, anticipate counter arguments, and arrive at a conclusion. If you choose an issue we have discussed in class, you may draw on readings and class discussions in developing your own argument, but you should not summarize the readings or class discussions. Refer to the "Guidelines for Ethical Analysis Essay and Annotated Bibliography" posted on the course web site for additional guidance. The Ethical Analysis Essay will constitute 30% of your grade. You must (1) identify a topic by January 19; (2) submit a first draft by Feb. 24, 9:30 AM; and (3) submit your final draft by March 10, 9:30 AM.

Annotated Bibliography

The Annotated Bibliography should present a review of the published ethics literature on an ethical issue arising in a current topic of interest in public health genetics or a topic we have discussed in class. Grading will be based on evidence of facility with diverse sources of ethics literature, ability to identify ethical issues related to the topic, and proper citation of literature. Because of the many disciplinary perspectives represented in this course, the student may choose the reference or citation format customarily used within his or her discipline, but must use it consistently. Please identify your chosen reference/citation style in your topic proposal. The Bibliography should have 8-15 cited sources. Refer to the "Guidelines for Ethical Analysis Essay and Annotated Bibliography" posted on the course web site for additional guidance. The Annotated Bibliography will constitute 20% of your grade. You must (1) identify a topic by January 19, which must be the same topic selected for the Ethical Analysis Essay; (2) submit a first draft by Feb. 10, 9:30 AM; and (3) submit your final draft by March 10, 9:30 AM.

Class Participation

This course is designed to engender active discussion of the issues. An essential component of this course will be your attendance in class and your active and voluntary participation in class discussion. The expectation is that you will attend all classes, have read the assigned readings and be prepared to engage fully in the discussion. Class participation will constitute 25% of your grade. Two excused absences will be allowed (you must notify the instructor in advance either by email, phone/voice mail, or in person); you will lose points for other absences.

COURSE OUTLINE

PART I: FOUNDATIONS—APPROACHES AND TOOLS

- A. Introduction to Course
- B. In-Class Exercise
- C. Introduction and Review: Moral Reasoning, Ethical Theory and Principles, and Public Health Ethics
- D. Ethics in the Evolution of Genetics in Science and Medicine

- 1. Early Experiences with Testing, Screening and Counseling
- 2. Confronting New Technologies: Genetic Engineering

PART II: APPLICATIONS

- A. Recognizing, Respecting and Protecting Interests: Individuals, Families, Communities and Populations
 - 1. Privacy and Confidentiality: Definitions, Limitations and Applications
 - 2. Genetic Counseling and Nondirectiveness
 - 3. Family Issues
 - 4. Communities, Populations and Research
 - 5. Challenges to Informed Consent: Testing and Children
 - 6. Enhancement and Prevention
- B. Accounting for "Difference" in Access and Impact
 - 1. Gender
 - 2. Disability
 - 3. Class
 - 4. Race and Ethnicity

COURSE SYLLABUS

The following syllabus outlines the course and reading assignments and sets forth a *preliminary* timetable. It is possible that the timetable and reading assignments will be amended during the course, depending on our pace and new developments in public health genetics. However, this outline should serve as a rough guide as you plan your reading and study schedule. Please note that the reading assignments should be read prior to our coverage of that portion of the outline in class.

С
in
, CA:

Kahn J., Mastroianni A. 2007. "Implications of Public Health for Bioethics," Ch. 28 in

http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm.

Bonnie Steinbock (ed.) *Oxford Handbook of Bioethics*, NY, Oxford: Oxford University Press, 671-695.

Childress J., Faden R., Gaare R., Gostin L., Kahn J., Bonnie R., Kass N., Mastroianni A., Moreno J., and Nieburg P. (2002) "Public Health Ethics: Mapping the Terrain," *Journal of Law, Medicine and Ethics*, 30 (2): 170-178.

Jonsen et al. 1996. The Advent of the "Unpatients." Nature Medicine, 2: 622-624

January 17 [No class: MLK Holiday]

January 18 Make-up Class (for Jan. 3) 4:00-5:00 pm <u>Turner Auditorium</u>, <u>HSD 209</u> 2011 Charles W. Bodemer Lecture:

Ruth R. Faden, PhD, MPH, Johns Hopkins Berman Institute of Bioethics

Henrietta Lacks: Ethics at the Intersection of Health Care and Biomedical Science Reading Assignment:

Rebecca Skloot, "The Miracle Woman" (excerpt from: The Immortal Life of Henrietta Lacks) *O, The Oprah Magazine* 22 Jan. 2010 http://www.oprah.com/world/Excerpt-From-The-Immortal-Life-of-Henrietta-Lacks_1

January 19

Ethics in the Evolution of Genetics in Science and Medicine

Early Experiences with Testing, Screening and Counseling

Confronting New Technologies: Genetic Engineering

Reading Assignment:

Jonsen, Albert R. 1998. *Splicing Life: Genetics and Ethics*. Chap. in The Birth of Bioethics. New York: Oxford University Press Pp. 166-195.

President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. 1983. *Screening and Counseling for Genetic Conditions: A Report on the Ethical, Social and Legal Implications of Genetic Screening, Counseling, and Education Programs.* Washington, D.C.: U.S. Government Printing Office. Pp. 1-8, 41-86.

President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. 1982. *Splicing Life: A Report on the Social and Ethical Issues of Genetic Engineering with Human Beings.* Washington, D.C.: U.S Government Printing Office. Pp. 1-5, 51-79.

Andrews, Lori et al. eds. 1994. *Executive Summary*. In Assessing Genetic Risks, Washington, DC: National Academy Press. Pp. 1-28.

PART II: APPLICATIONS

January 24

Recognizing, Respecting and Protecting Interests: Individuals, Families, Communities and Populations

Privacy and Confidentiality: Definitions, Limitations and Applications Families and Confidentiality

Reading Assignment:

Wertz, Dorothy C. and John C. Fletcher. 1991. *Privacy and Disclosure in Medical Genetics Examined in an Ethics of Care*. Bioethics 5(3): **212-219 only**.

Arnason, V. 2010. Bioethics in Iceland, Cambridge Quarterly of Healthcare Ethics. Jul;19(3):299-305 only,

http://journals.cambridge.org.offcampus.lib.washington.edu/action/displayFulltext?type=1&fid=7785549&jid=CQH&volumeId=19&issueId=03&aid=7785547&bodyId=&m

embershipNumber=&societyETOCSession=

You are required to read the Target article and will be assigned up to three of the commentaries (you may read all the commentaries if you are interested)

TARGET ARTICLE M. Rothstein, Is Deidentification Sufficient to Protect Health Privacy in Research? Am J Bioeth. 2010 Sep;10(9):3-11.

http://www.informaworld.com.offcampus.lib.washington.edu/smpp/content~db=all?content=10.1080/15265161.2010.494215

Comment in:

- Melissa M. Goldstein, Guiding Deidentification Forward, Am J Bioeth. 2010 Sep;10(9):27-8.
- Leonard H. Glantz, et al., Gift Giving to Biobanks, Am J Bioeth. 2010 Sep;10(9):33-4.
- Henry T. Greely, To the Barricades, Am J Bioeth. 2010 Sep;10(9):1-2.
- Nicolas P. Terry, More Than One Binary, Am J Bioeth. 2010 Sep;10(9):31-2.
- Deven McGraw, Data Identifiability and Privacy, Am J Bioeth. 2010 Sep;10(9):30-1.
- Robert Gellman, Why Deidentification Fails Research Subjects and Researchers, Am J Bioeth. 2010 Sep;10(9):28-30.
- Joan McGregor, Racial, Ethnic, and Tribal Classifications in Biomedical Research With Biological and Group Harm, Am J Bioeth. 2010 Sep;10(9):23-4.
- Shawneequa L. Callier, & Harald Schmidt, Managing Patient Expectations About Deidentification, Am J Bioeth. 2010 Sep;10(9):21-3.
- Misha Angrist, Urge Overkill: Protecting Deidentified Human Subjects at What Price? Am J Bioeth. 2010 Sep;10(9):17-8.
- Kyle Bertram Brothers & Ellen Wright Clayton, "Human Non-Subjects Research": Privacy and Compliance, Am J Bioeth. 2010 Sep;10(9):15-7.
- Sharon Hoffman, , Electronic Health Records and Research: Privacy Versus Scientific Priorities, Am J Bioeth. 2010 Sep;10(9):19-20.
- Daniel A. Moros & Rosamond Rhodes, Privacy Overkill, Am J Bioeth. 2010 Sep;10(9):12-5.
- Mark A. Rothstein, Deidentification and Its Discontents: Response to the Open Peer Commentaries, Am J Bioeth. 2010 Sep;10(9):W1-2.
- Leslie Pickering Francis & John G. Francis, Group Compromise: Perfect Cases Make Problematic Generalizations, Am J Bioeth. 2010 Sep;10(9):25-7.

January 26

Guest Discussion Leader: Kelly Edwards PhD, Dept. of Bioethics & Humanities, School of Medicine

Applying a narrative ethics framework: Discussion of Mary Shelley's Frankenstein

Reading Assignment:

Mary Shelley's Frankenstein

Other Writing Assignment: **No later than January 24**, **1:30 pm**, post a response to the following question and respond to at least two other student comments on the Catalyst Go Post Discussion Board

https://catalyst.uw.edu/gopost/board/amastroi/19836/: What lessons can researchers learn today from Frankenstein regarding ethical research practices?

January 31 & February 2

Communities, Populations and Research

Reading Assignment:

Weijer C, Goldsand G, Emanuel EJ. Protecting communities in research: current guidelines and limits of extrapolation. *Nature Genetics* 1999; 23: 275-280.

Sharp RR, Foster MW Involving study populations in the review of genetic research. *Journal of Law, Medicine & Ethics.* 28(1):41-51, 3, 2000 Spring.

Juengst ET. Commentary: what "community review" can and cannot do. Journal of Law, Medicine & Ethics. 28(1):52-4, 3, 2000 Spring.

National Institutes of Health, Report of the First Community Consultation on the Responsible Collection and Use of Samples for Genetic Research, September 25-26, 2000 [EXECUTIVE SUMMARY ONLY]

http://www.nigms.nih.gov/news/reports/community_consultation.html.

Clayton EW, The complex relationship of genetics, groups, and health: what it means for public health. Journal of Law, Medicine & Ethics. 30(2):290-7, 2002 Summer.

Knoppers et al.. 2010. Framing Genomics, Public Health Research and Policy: Points to Consider Public Health Genomics, 13:224–234

February 7

Challenges to informed consent

Genetic testing and children

Reading Assignment:

Dena Davis. 1997. Genetic Dilemmas and the child's right to an open future, *The Hastings Center Report*. March –April 1997 27(2): 7

Each student will be assigned two of the following six position statements

ASHG/ACMG. 1995. ASHG/ACMG Report: Points to Consider: Ethical, Legal, and Psychosocial Implications of Genetic Testing in Children and Adolescents. American Journal of Human Genetics 57(5): 1233-1241

http://www.ashg.org/pages/statement ajhg57.shtml

National Society of Genetic Counselors. 1995. Position statement: Prenatal and Childhood Testing for Adult-Onset Disorders.

http://www.nsgc.org/Media/PositionStatements/tabid/330/Default.aspx#PrenatalChildTestingAdultOnset

Bioethics Committee, Canadian Paediatric Society. 2003. Guidelines for genetic testing of healthy children. *Paediatrics & Child Health* 8(1): 42-45 (reaffirmed Feb 2010) http://www.cps.ca/english/statements/B/b03-01.htm.

American Medical Association. 1996. *Code of Ethics E-2.138: Genetic Testing of Children.* http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion2138.shtml

American Academy of Pediatrics (AAP), Committee on Bioethics, Ethical Issues with Genetic Testing in Pediatrics, Pediatrics 107 (6): 1451-1455 (June 2001), reaffirmed May 2009

http://aappolicy.aappublications.org/cgi/content/full/pediatrics;107/6/1451 European Society of Human Genetics (ESHG), Genetic testing in asymptomatic minors recommendations of the European Society of Human Genetics, Eur J Hum Genet. 2009 June; 17(6): 720–721,

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2947109/?tool=pubmed

February 9 & 14 Enhancement and Prevention Reading Assignment: Juengst, Eric T. 1997. Can Enhancement Be Distinguished from Prevention in Genetic *Medicine?* The Journal of Medicine and Philosophy, 22: 125-142. McGee, Glenn. 1997. The Not-So-Deadly Sins of Genetic Enhancement. In The Perfect Baby: A Pragmatic Approach to Genetics, pp. 111-33. London: Rowman & Littlefield. Murray TH. 2002. Reflections on the ethics of genetic enhancement. Genet Med. 2002 Nov-Dec;4(6 Suppl):27S-32S. Savulescu J et al. 2006. Behavioural genetics: why eugenic selection is preferable to enhancement. J Appl Philos. 23(2):157-71. Caplan RL. 2004. Ch. 27: What's Morally Wrong with Eugenices? in Health, Disease and Illness: Concepts in Medicine, pp. 278-288, Washington, DC: Georgetown University Press. Excerpts from: President's Council on Bioethics. Beyond Therapy: Biotechnology and the Pursuit of Happiness (2003): ☐ Ch. 1, section V (The Limitations of the "Therapy vs. Enhancement" Distinction) http://bioethics.georgetown.edu/pcbe/reports/beyondtherapy/chapter1.html#section ☐ Ch. 1, section VI (Beyond Natural Limits: Dreams of Perfection and Happiness) http://bioethics.georgetown.edu/pcbe/reports/beyondtherapy/chapter1.html#section Ch. 2 (Better Children) http://bioethics.georgetown.edu/pcbe/reports/beyondtherapy/chapter2.html February 16 [No class February 21: President's Day Holiday] Accounting for "Difference" in Access and Impact Gender Reading Assignment: Mahowald, Mary B., Dana Levinson, Christine Cassell, et al. 1996. The New Genetics and Women. Milbank Quarterly 74(2): 239-283. Mary B. Mahowald, Reproductive Genetics and Gender Justice, in Women and Prenatal Testing: Facing the Challenges of Genetic Technology, ed. by Rothenberg, KH and Thomson, EJ. (Columbus: Ohio State University Press, 1994), 67-87. http://www.bioethics.net/articles.php?viewCat=6&articleId=60. World Health Organization, Gender and Genetics, http://www.who.int/genomics/gender/en/index.html WHO, What is a Gender Based Approach to Public Health? (April 2007) http://www.who.int/features/ga/56/en/index.html February 23 & 28 Accounting for "Difference" in Access and Impact (cont'd) Disability Race and Ethnicity Reading Assignment: Patterson A. Satz M., Genetic counseling and the disabled: feminism examines the stance of those who stand at the gate. Hypatia. 17(3):118-42, 2002 Summer. http://muse.jhu.edu/journals/hypatia/v017/17.3patterson.pdf. Excerpt from Buchanan A. et al. 2000. Genetic Intervention and the Morality of Inclusion. In Contemporary Issues in Bioethics, 7th edition 2008.

King, PA, The dangers of difference, revisited, in *The Story of Bioethics: From*

Seminal Works To Contemporary Explorations, JK Walter and EP Klein, eds. Washington DC: Georgetown Univ. Press (2003).

Yu, J., Goering S and Fullerton, SM, Race-Based Medicine and Justice as Recognition: Exploring the Phenomenon of BiDil, Cambridge Quarterly of Healthcare Ethics 2009, 18:57-67.

Foster MW, Sharp RR. 2004. Beyond race: towards a whole-genome perspective on human populations and genetic variation. Nature Reviews Genetics Oct;5(10):790-6. Lee SS. 2003. Race, distributive justice and the promise of pharmacogenomics: ethical considerations. American Journal of Pharmacogenomics. 3(6):385-92.

March 2

Instructor-Student Meetings: Advance Sign-up

March 7 & 9

In class discussions of Ethical Analysis Essays