Graduate School of Public Health
Department of Human Genetics
Ethical Issues in Clinical and Public Health Genetics
HUGEN 2052
MPH Public Health Genetics Section
Tuesday 1:00-2:00 PM, A216 Public Health
Credit Hours: 1.0
Spring 2022

Course Faculty and Contact Information

Course Directors and Lecturers:

Robin E. Grubs, PhD, LCGC
Office: 3138 Public Health
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Faculty Availability: We welcome your questions and suggestions. Please feel free to use email to set up an appointment with us. If you are having any problems with the course, please contact one of us as soon as possible. Since we receive many e-mails, please put into the Subject line: HUGEN 2052.

Lecturers:

Brenda Diergaarde, PhD
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Lisa S. Parker, PhD
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Jodie M. Vento, MGC, CGC
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Course Description

This course is designed to explore ethical issues as they relate to genetics and genomics in both clinical and public health contexts. Class sessions provide an ethical framework for analyzing arguments in the literature and cases arising in clinical, public health and research settings, and proceeds throughout the semester with a discussion-based format that encourages students to assume responsibility for engaging in ethical analysis.

Learning Objectives

At the end of the course, each student will be able to:
(1) demonstrate critical reasoning about ethical issues;
(2) present arguments in support of normative positions; and,
(3) identify ethical concerns and pertinent discussions in the bioethics literature, as well as in the clinical, public health genetics and scientific literature.

Course Format and Delivery

This class utilizes Canvas for class content and grading. Notifications will be sent regarding course content throughout the semester. Please make sure to set up your Canvas to receive email notifications from Canvas and please check for announcements and notifications on a regular basis.

For the first two and half weeks of the semester, class will take place remotely using Zoom. It is expected that after this period, class will take place in person beginning on January 27th. Due to the shifting nature of the pandemic, it may be necessary to alter this plan and the delivery of the course. Any changes will be shared with students via announcements on Canvas. Given the pandemic, it is important that students abide by public health regulations and University of Pittsburgh health standards and guidelines. For example, at this time, face coverings are required indoors for everyone regardless of vaccination status. For the most up-to-date information and guidance, please visit https://www.coronavirus.pitt.edu/. If you are sick, please do not come to class in-person. Please email the course directors, and we will determine the most appropriate make-up plan for class depending on the content.

When classes occur remotely via Zoom, they will take place in a synchronous format. Students should keep their cameras on during the Zoom discussions, unless internet access makes this impossible. If that is the case, students should consult the course director who will help identify a solution

Course materials will be posted on Canvas. The course will employ a combination of recorded powerpoint presentations to be viewed prior to class, readings to be completed prior to class, and class discussions.

The goal of each class is to engage in ethical discussion, debate, and analysis. The class will not be recorded since recording has the potential to diminish engagement.

Requirements

To tailor content and enhance opportunity for engagement, the course is divided into two sections. One section is for the MPH students and one section is for the MS genetic counseling students. The section for the MPH students will take place on Tuesdays from

1:00 to 2:00 PM and the section for the genetic counseling students will take place on Thursdays from 1:15 to 2:15 PM.

For each class there will be material to review prior to class. This will include items such as a short, recorded lecture and readings. All students are expected to demonstrate that they completed the pre-class work and are expected to actively participate in the discussions.

Texts/assigned materials

Participants will need to read and be prepared to discuss assigned materials that will be posted on Canvas. There is no required textbook for this course.

Student Performance Evaluation and Grading

Grading is based on quality of contribution to the discussion. A sign-in sheet is available to document attendance, and the instructors will provide feedback on discussion and participation. An S (satisfactory) grade is given when no more than 3 classes are missed and participation is adequate while attending. A NC (no credit) grade is given when there are 3 or more unexcused absences.

Academic Integrity

All students are expected to adhere to the school's standards of academic honesty. Cheating/plagiarism will not be tolerated. The Graduate School of Public Health's policy on academic integrity, which is based on the University policy, is available online in the Pitt Public Health Academic Handbook www.publichealth.pitt.edu/home/academics/academic-requirements. The policy includes obligations for faculty and students, procedures for adjudicating violations, and other critical information. Please take the time to read this policy.

Accommodation for Students with Disabilities

If you have a disability for which you are or may be requesting an accommodation, you are encouraged to contact both your instructor(s) and Disability Resources and Services, 140 William Pitt Union, (412) 648-7890, (412) 228-5347 for P3 ASL users, as early as possible in the term. DRS will verify your disability and determine reasonable accommodations for this course.

Sexual Misconduct, Required Reporting and Title IX Statement

The University is committed to combatting sexual misconduct. As a result, you should know that University faculty and staff members are required to report any instances of sexual misconduct, including harassment and sexual violence, to the University's Title IX office so that the victim may be provided appropriate resources and support options. What this means is that as your professors, we are required to report any incidents of sexual misconduct that are directly reported to us, or of which we are somehow made aware.

There are two important exceptions to this requirement about which you should be aware:

A list of the designated University employees who, as counselors and medical professionals, do not have this reporting responsibility and can maintain confidentiality, can be found here: https://www.diversity.pitt.edu/civil-rights-title-ix/make-report/report-form

An important exception to the reporting requirement exists for academic work. Disclosures about sexual misconduct that are shared as part of an academic project, classroom discussion, or course assignment, are not required to be disclosed to the University's Title IX office.

If you are the victim of sexual misconduct, Pitt encourages you to reach out to these resources:

- Title IX Office: 412-648-7860
- SHARE @ the University Counseling Center: 412-648-7930 (8:30 A.M. TO 5 P.M. M-F) and 412-648-7856 (AFTER BUSINESS HOURS)

If you have a safety concern, please contact the University of Pittsburgh Police, 412-624-2121.
Other reporting information is available here: https://www.diversity.pitt.edu/civil-rights-title-ix-compliance/make-report

Statement from the Department of Gender, Sexuality, and Women's Studies
[This statement was developed by Katie Pope, Title IX Coordinator, in conjunction with GSWS instructors.]

Diversity Statement

The University of Pittsburgh Graduate School of Public Health considers the diversity of its students, faculty, and staff to be a strength and critical to its educational mission. Pitt Public Health is committed to creating and fostering inclusive learning environments that value human dignity and equity and promote social justice. Every member of our community is expected to be respectful of the individual perspectives, experiences, behaviors, worldviews, and backgrounds of others. While intellectual disagreement may be constructive, no derogatory statements, or demeaning or discriminatory behavior will be permitted.

If you feel uncomfortable or would like to discuss a situation, please contact any of the following:

- the course director or course instructors;
- the Pitt Public Health Associate Dean responsible for diversity and inclusion;
- the University's Office of Diversity and Inclusion at 412-648-7860 or
- https://www.diversity.pitt.edu/civil-rights-title-ix/make-report/report-form (anonymous reporting form)

Copyright Notice

Course material may be protected by copyright. United States copyright law, 14 USC section 101, et sec., in addition to University policy and procedures, prohibit

unauthorized duplication or retransmission of course materials. See Library of Congress Copyright Office and the University Copyright Policy**.**

Schedule of Sessions

Date	Topic	Readings
January 11, 2022	Introduction to the course and Public health ethics: Normative and conceptual research, Dr. Lisa Parker	Parker LS, et al. Normative and conceptual ELSI research: what it is, and why it's important. Genet Med. 2019 Feb;21(2):505-509. doi: 10.1038/s41436-018-0065-x. Childress, J.F., et al. (2002), Public Health Ethics: Mapping the Terrain. The Journal of Law, Medicine & Ethics, 30: 170-178. https://doi.org/10.1111/j.1748-720X.2002.tb00384.x
January 18, 2022	Informed consent, capacity to consent, research and screening programs, Dr. Deem	Tabor HK, Berkman BE, Hull SC, Bamshad MJ. 2011. Genomics really gets personal: How exome and whole genome sequencing challenge the ethical framework of human genetics research. Am J Med Genet Part A 155:2916–2924. Paul S. Appelbaum, Erik Parens, Cameron R. Waldman, Robert Klitzman, Abby Fyer, Josue Martinez, W. Nicholson Price II, and Wendy K. Chung, "Models of Consent to Return of Incidental Findings in Genomic Research," *Hastings Center Report* 44 (2014): 22-32. Barbara A. Koenig, "Have We Asked Too Much of Consent?," *Hastings Center Report* 44, no. 4 (2014): 33-34.
January 25, 2022	Privacy and confidentiality, HIPAA and GINA, Dr. Deem	https://www.jax.org/education-and-learning/clinical-and-continuing-education/ccep-non-cancer-resources/gina-overview https://www.jax.org/education-and-learning/clinical-and-continuing-education/ccep-non-cancer-resources/gina-overview/case-studies-of-gina-in-clinical-settings# Recommended: Rodriguez, L.L. et al. (2013). The complexities of genomic identifiability. Science 339(6117):275-276.
February 1, 2022	Population genetic screening, Dr. Grubs	Andermann, A., Blancquaert, I., Beauchamp, S., & Déry, V. (2008). Revisiting Wilson and

		Jungner in the genomic age: A review of screening criteria over the past 40 years. *Bulletin of the World Health Organization*, *86*(4), 317–319. https://doi.org/10.2471/blt.07.050112 Ross LF. Ethical and policy issues in newborn screening of children for neurologic and developmental disorders. Pediatr Clin North Am. 2015 Jun;62(3):787-98. doi: 10.1016/j.pcl.2015.03.009. King MC, Levy-Lahad E, Lahad A. Population-based screening for BRCA1 and BRCA2: 2014 Lasker Award. JAMA. 2014 Sep 17;312(11):1091-2. doi: 10.1001/jama.2014.12483.
February 8, 2022	Polygenic Risk Scores, Dr. Diergaarde	Marteau and Weinman: Self-regulation and the behavioural response to DNA risk information: A theoretical analysis and framework for future research. Social Science & Medicine Volume 62, Issue 6, March 2006, Pages 1360-1368 Hollands et al. The impact of communicating genetic risks of disease on risk-reducing health behaviour: systematic review with meta-analysis BMJ. 2016 Mar 15;352:i1102. doi: 10.1136/bmj.i1102. Roberts et al. Perspective: The Clinical Use of Polygenic Risk Scores: Race, Ethnicity, and Health Disparities. Ethn Dis. 2019 Jul 18;29(3):513-516. doi: 10.18865/ed.29.3.513 Recommended: Ali Torkamani, Nathan E. Wineinger & Eric J. Topol. The personal and clinical utility of polygenic risk scores. *Nature Reviews Genetics* volume 19, pages581–590 (2018). https://www.nature.com/articles/s41576-018-0018-x
February 15, 2022	Direct-to-consumer testing, Dr. Grubs	Majumder MA, Guerrini CJ, McGuire AL. Direct-to-Consumer Genetic Testing: Value and Risk. Annu Rev Med. 2021 Jan 27;72:151-166. doi: 10.1146/annurev-med-070119-114727. PMID: 32735764.
February 22, 2022	Community engagement for genetic research, Dr. Grubs	Weijer, C., and E. J. Emanuel. “Protecting Communities in Biomedical Research.”

		Science, vol. 289, no. 5482, 2000, pp. 1142–1144.
March 1, 2022	Return of individualized results and management of incidental findings of genetic research, Dr. Deem	Beskow LM, Burke W. Offering individual genetic research results: context matters. Sci Transl Med. 2010 Jun 30;2(38):38cm20. doi: 10.1126/scitranslmed.3000952. Parker LS. Rethinking respect for persons enrolled in research. *ASBH Exchange* 2006; 9(2):1, 6-7. Thorogood, A., Dalpé, G. & Knoppers, B. Return of individual genomic research results: are laws and policies keeping step?. *Eur J Hum Genet* **27,** 535–546 (2019). https://doi.org/10.1038/s41431-018-0311-3
March 8, 2022	Spring Break	
March 15, 2022	Management of data and biological samples, Dr. Diergaarde	Byrd et al. Responsible, practical genomic data sharing that accelerates research. Nature Reviews Genetics volume 21, pages: 615–629 (2020) Siu et al. Facilitating a culture of responsible and effective sharing of cancer genome data. *Nature Medicine* volume 22, pages: 464–471 (2016)
March 22, 2022	Precision medicine, pharmacogenomics and health disparities, Dr. Deem	Haga SB, Burke W. Pharmacogenetic testing: not as simple as it seems. Genet Med. 2008 Jun;10(6):391-5. doi: 10.1097/GIM.0b013e31817701d4. Morley KI, Hall WD. Using pharmacogenetics and pharmacogenomics in the treatment of psychiatric disorders: some ethical and economic considerations. J Mol Med (Berl). 2004 Jan;82(1):21-30. doi: 10.1007/s00109-003-0496-x.
March 29, 2022	*All of Us* and ethical issues it presents, precision medicine and public health, Dr. Deem	Sankar PL, Parker LS. The Precision Medicine Initiative's All of Us Research Program: an agenda for research on its ethical, legal, and social issues. Genet Med. 2017 Jul;19(7):743-750. doi: 10.1038/gim.2016.183. Flores M, et al. P4 medicine: how systems medicine will transform the healthcare sector and society. Per Med. 2013;10(6):565-576. doi: 10.2217/pme.13.57.

		Vogt H, et al. How precision medicine and screening with big data could increase overdiagnosis BMJ 2019; 366:l5270
April 5, 2022	Disability studies and genetics, expressivist objection, selecting for disability, Dr. Grubs	Davis DS. Genetic dilemmas and the child's right to an open future. Hastings Cent Rep. 1997 Mar-Apr;27(2):7-15. Garrett JR, et al; Clinical Sequencing Exploratory Research (CSER) Consortium Pediatrics Working Group. Rethinking the "open future" argument against predictive genetic testing of children. Genet Med. 2019 Oct;21(10):2190-2198. doi: 10.1038/s41436-019-0483-4. PMID: 30894702.
April 12, 2022	Global Health and Biotechnology, Dr. Deem	Masum H, Chakma J, and Daar AS. Biotechnology and global health. In Benetar S and Brock G (eds.), *Global Health and Global Health Ethics* (Cambridge University Press, 2011), 251-260.