

PUBHLT 2030: Research Ethics and the Responsible Conduct of Research

1 credit

Course instructor:

Lisa S. Parker, PhD

Professor of Human Genetics

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Faculty Availability: Your questions and suggestions are welcome. Please feel free to use email to set up an appointment. Begin the email's Subject line with **PUBHLT 2030** to facilitate more immediate attention.

COVID-19 and other contagious conditions: Even though class attendance and participation are important, if you are experiencing any symptoms of COVID-19 or another serious contagious condition, do not come to class, and contact the instructor as soon as possible to make alternate arrangements.

Summary of the Course:

This course provides an introduction to topics in research ethics and the responsible conduct of research particularly pertinent to basic and non-clinical, population-based research employing a variety of methods. Students will learn key concepts and methods of ethical reasoning and requirements of human subjects protection and non-human animal research. The course will analyze historical and contemporary examples of research misconduct, as well as ethical concerns arising in participants' own work. Using lecture and small group discussion of assigned readings and participants' research, the course will develop students' skills requisite to design and conduct ethical research, avoid research misconduct, and ethically negotiate the tasks and milestones of academic education and careers (e.g., issues of mentorship and publication). Students will be evaluated (by letter grade) on the basis of the quality of their discussion contributions and writing assignments.

Learning Objectives:

At the end of this course, participants should be able to:

- Identify ethical issues in their own research and interactions with colleagues, current reported research, and the history of the fields of public health
- Consult relevant resources—including published guidelines and literature, the Institutional Review Board office, and other consultants—to analyze these ethical issues
- Analyze ethical issues by articulating relevant facts and normative considerations, and support a particular course of action to address the issue(s)
- Identify and avoid both research and academic misconduct
- Explain the reasoning that supports the requirements in a research proposal's Human Subjects Protections section, informed consent document, and Non-human Animal Use protocol

Texts/assigned materials and Canvas:

Prior to each class session, participants will need to read and prepare to discuss assigned materials that will be posted for personal use on Canvas.

Student Performance Evaluation:

All course requirements must be completed to receive credit for the course. Students who miss more than 1 class are not eligible for a course grade of A or better; those who miss more than 2 classes are not eligible for a course grade of B or better. Students who are experiencing symptoms of COVID-19 should contact the instructor as soon as possible to make alternate arrangements regarding class attendance. Evaluation will be based on the following components:

- Attendance (20% contribution to course grade)

- Quality of Contribution to Discussion (40% contribution to course grade)

Active participation in class discussions and evidence of being prepared for class (including having read the assigned readings and completion of assignments) are required. Please do not use cell phones and laptops/tablets during class time for non-class purposes. Use your name tent at your seat in every class.

- Writing Assignment (40% of final grade)

Specific instructions for the writing assignment are posted separately (see: Instructions for Written Assignment). Written assignments are to be submitted to the instructor by email, and PUBHLT 2030 must begin the email's Subject line.

Grade option:	Grading scale:			
Letter grade	97 - 100% A+	77 – 79.9% C+	< 60% F	
	93 – 96.9% A	73 – 76.9% C		
	90 – 92.9% A-	70 – 72.9% C-		
	87 – 89.9% B+	67 – 69.9% D+		
	83 – 86.9% B	63 – 66.9% D		
	80 – 82.9% B-	60 – 62.9% D-		

Course Policies

- Course communication and internet use policy:

Students should check their email regularly to ensure receipt of relevant communication regarding the course. The Internet generally should not be accessed during class, except to access course slides or assigned readings, help resolve a disputed point in discussion, or otherwise enhance discussion.

- Academic Integrity Policy:

All individuals (students, faculty, post-doctoral researchers, and staff) at Pitt Public Health abide by the University's policy on academic integrity. In accordance with this policy, the school maintains an outline of the procedural sequence of events to occur when violations of academic integrity are brought to the attention of administrative leaders. The full policy is available in the Academic Handbook.

All students are expected to adhere to the school's standards of academic honesty. Cheating/plagiarism will not be tolerated. The University's Guidelines on Academic Integrity, available at https://www.policy.pitt.edu/sites/default/files/Policies/Academic/Policy_AC39.pdf, is in effect. This policy includes obligations for faculty and students, procedures for adjudicating violations, and other critical information. Please take the time to read this policy.

Students should be especially mindful of guidelines on academic integrity and take care to avoid plagiarizing the work—including the ideas or words—of their colleagues (fellow course participants) or other authors. Students are encouraged to discuss their ideas and work together; however, a citation to a fellow student should be provided when appropriate.

- Diversity and Academic Civility Statement:

In this course, students, faculty and guests represent a diversity of individual perspectives, backgrounds, and experiences, which enriches our classes. We urge all to be respectful of others.

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

- 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 and Disability Resources and Services, 140 William Pitt Union, 412-648-7890 as early as possible in the term.

- Copyright Notice:

Course materials may be protected by copyright. United States copyright law, 17 USC section 101, et seq., 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](#).

- Classroom Recording:

To ensure the free and open discussion of ideas and participants' research experiences and projects, students may not record classroom lectures, discussion and/or activities without the advance permission of the instructor, and any such recording properly approved in advance can be used solely for the student's own private use or for all students enrolled in this class only but may not be further copied, distributed, published, or otherwise used for any other purpose without the express written consent of the course instructor. Any student who records a class session must provide a copy of the recording to the instructor if requested to do so. Any student who needs the accommodation of recording should consult the instructor.

- Sexual Misconduct, Required Reporting, and Title IX

If you are experiencing sexual assault, sexual harassment, domestic violence, and stalking, please report it to me and I will connect you to University resources to support you.

University faculty and staff members are required to report all instances of sexual misconduct, including harassment and sexual violence to the Office of Civil Rights and Title IX. When a report is made, individuals can expect to be contacted by the Title IX Office with information about support resources and options related to safety, accommodations, process, and policy. I encourage you to use the services and resources that may be most helpful to you.

As your professor, I am required to report any incidents of sexual misconduct that are directly reported to me. You can also report directly to Office of Civil Rights and Title IX: 412-648-7860 (M-F; 8:30am-5:00pm) or via the Pitt Concern Connection at: [Make A Report](#)

An important exception to the reporting requirement exists for academic work. Disclosures about sexual misconduct that are shared as a relevant 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 wish to make a confidential report, Pitt encourages you to reach out to these resources:

- The University Counseling Center: 412-648-7930 (8:30 A.M. TO 5 P.M. M-F) and 412-648-7856 (AFTER BUSINESS HOURS)
- Pittsburgh Action Against Rape (community resource): 1-866-363-7273 (24/7)

If you have an immediate safety concern, please contact the University of Pittsburgh Police, 412-624-2121. Any form of sexual harassment or violence will not be excused or tolerated at the University of Pittsburgh. For additional information, please visit the [full syllabus statement](#) on the Office of Diversity, Equity, and Inclusion webpage.

**PUBHLT 2030: Research Ethics and the Responsible Conduct of Research
Schedule of Topics and Readings**

#1	<p>I. Course introduction, and introduction to ethical reasoning</p> <p>II. Academic and research integrity, publication, and authorship</p> <p>In advance of the class discussion, read:</p> <ul style="list-style-type: none"> • Dance A. 2012. Who's on first? (including Aggravation free authorship, and Ghosts and guests). Nature 489: 591-593. https://www.nature.com/articles/nj7417-591a.pdf
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- Boyd RW, et al. 2020. [On Racism: A New Standard For Publishing On Racial Health Inequities](#). *Health Affairs Blog*. July 2, 2020. DOI: 10.1377/hblog20200630.939347
<https://www.healthaffairs.org/doi/10.1377/hblog20200630.939347/full/>
- International Committee of Medical Journal Editors. 2019. [Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals](#) (ICMJE Recommendations). Available at: <http://www.icmje.org/recommendations/> **Read Section 11.A-C.**
- Ferguson C, Marcus A, Oransky I. 2014. [Publishing: The peer review scam](#). *Nature* 515, 480-482. doi:10.1038/515480a

Recommended:

- Parker 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
<https://www-nature-com.pitt.idm.oclc.org/articles/s41436-018-0065-x.pdf>

Resources:

- Regarding mentoring and getting the mentoring you need, some potentially useful information can be found in the 'Pitt Public Health Academic Handbook', <https://www.publichealth.pitt.edu/academic-handbook>, and at: <http://www.rackham.umich.edu/downloads/publications/mentoring.pdf> (more comprehensive).

Concepts:

Academic integrity, blind review, conflict of interest (vs. conflict of commitment); open access, peer review, predatory/pseudo journals, race, racism, research misconduct, responsibilities of authorship, scientific integrity, trust, trustworthiness

#2

**I. Data management, data sharing, and privacy protection
II. Avoiding research misconduct and fulfilling obligations**

In advance of the class discussion, read and listen to:

- Gonzales S, Carson MB, Holmes K. Ten simple rules for maximizing the recommendations of the NIH data management and sharing plan. *PLoS Comput Biol*. 2022 Aug 3;18(8):e1010397. doi: [10.1371/journal.pcbi.1010397](https://doi.org/10.1371/journal.pcbi.1010397). PMID: 35921268; PMCID: PMC9348704.
<https://journals.plos.org/ploscompbiol/article?id=10.1371/journal.pcbi.1010397>
- **Podcast – Research Misconduct:** Listen to this installment of [NIH's All About Grants podcast](#) with Dr. Christine Ring on addressing research misconduct ([MP3 / Transcript](#)). As an NIH Research Integrity Officer, she shares what is meant by fabrication, falsification, and plagiarism, how it affects the integrity of research, what to do if you suspect research misconduct, how NIHs work with the HHS Office of Research Integrity when responding to an allegation, and much more.
- [Sabotage!](#) by Brendan Maher: <https://www.nature.com/articles/467516a>
- Should scientists who commit fraud go to jail? asks Amy Ellis Nutt at the *Washington Post*: [This scientist nearly went to jail for making up data](#)

Recommended:

- Data Sharing: An Ethical and Scientific Imperative; <https://jamanetwork.com/journals/jama/fullarticle/2504790>
- JAMA: Research Parasites Wanted; <https://www.policymed.com/2016/04/jama-research-parasites-wanted.html>
- NEJM Editorial: Data sharing. Dan Longo and Jeffrey Drazen (The editorial that referred to research parasites): <https://www.nejm.org/doi/full/10.1056/NEJMe1516564>

- Drug companies are sharing their data — but few are looking: <https://www.washingtonpost.com/news/wonk/wp/2016/03/29/pharma-companies-are-sharing-their-data-but-few-are-looking/>
- Your Data Were ‘Anonymized’? These Scientists Can Still Identify You (NYT, July 23, 2019): <https://www.nytimes.com/2019/07/23/health/data-privacy-protection.html> (Original paper in *Nature Communications*: <https://www.nature.com/articles/s41467-019-10933-3>)
- Check for publication integrity before misconduct: <https://www.nature.com/articles/d41586-019-03959-6>
- The Surgisphere Scandal: What Went Wrong?: <https://www.the-scientist.com/features/the-surgisphere-scandal-what-went-wrong--67955>

Resources:

I. Data management, data sharing, and privacy protection

- Scientific Data Sharing, NIH, <https://orcid.pitt.edu/>
- Requirement for ORCID iDs for Individuals Supported by Research Training, Fellowship, Research Education, and Career Development Awards Beginning in FY 2020, <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-109.html>
- ORCID@Pitt, <https://orcid.pitt.edu/>

II. Avoiding research misconduct and fulfilling obligations

- The Office of Research Integrity (ORI) oversees and directs Public Health Service (PHS) research integrity activities on behalf of the Secretary of Health and Human Services with the exception of the regulatory research integrity activities of the Food and Drug Administration: <http://ori.hhs.gov/>
- Write ethically (infographic): https://ori.hhs.gov/sites/default/files/2017-12/8_Ethical_Write.pdf
- NIH 2023 data sharing policy: <https://www.oir.nih.gov/sourcebook/intramural-program-oversight/intramural-data-sharing/2023-nih-data-management-sharing-policy>
- On research misconduct: www.retractionwatch.com
- The Guidelines for Responsible Conduct of Research of the University of Pittsburgh, available at: <http://rcco.pitt.edu/sites/default/files/Guidelines.ResponsibleConductOfResearch.pdf>
- The Research Integrity Policy of the University of Pittsburgh, available at: https://www.policy.pitt.edu/sites/default/files/Policies/Research-Innovation/RI_07_Policy.pdf

Concepts:

Data sharing; unique, falsification and fabrication of data; manipulation of images; persistent identifier; research integrity officer; research misconduct; scientific integrity

#3

Human subjects research

In advance of the seminar discussion, read:

- Emanuel EJ, Wendler D, Grady, C. 2000. [What makes clinical research ethical?](https://jamanetwork.com/pitt.idm.oclc.org/journals/jama/fullarticle/192740) *JAMA* 283(20):2701-2711. doi: 10.1001/jama.283.20.2701 <https://jamanetwork.com/pitt.idm.oclc.org/journals/jama/fullarticle/192740> **Read through the section ‘Necessary Expertise’ on page 2708.**

Recommended:

- National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *The Belmont Report*, 1979. Available at: <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>

Resources:

- Office of Human Research Protections. 2018. Human Subject Regulations Decision Charts. <https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html>
- Code of Federal Regulations. Protection of Human Subjects. 2018. [45CFR46](#)

Concepts:

Capacity (decisional capacity, competence), compensation (for injury or for participation), direct vs. ancillary benefits of participation, emergency research, fair selection of subjects / participants, inclusion and exclusion criteria, informed consent (goals and elements), independent review, institutional review board (IRB), informed consent form, potential benefit / risk ratio, respect for subjects / participants, social value, validity, vulnerable populations, withdrawal from study

#4

Research and its impact on communities

In advance of the seminar discussion, read:

- Weijer C & Emanuel EJ. [Protecting Communities in Biomedical Research](#). *Science* 2000; 289(5482): 1142-1144. DOI:10.1126/science.289.5482.1142 <https://www-science-org.pitt.idm.oclc.org/doi/10.1126/science.289.5482.1142>
- Participants in the 2001 Conference on Ethical Aspects of Research in Developing Countries. [Fair Benefits for Research in Developing Countries](#). *Science* 2001; 298(5601): 2133-2134. Enhanced online at <https://www-science-org.pitt.idm.oclc.org/doi/10.1126/science.1076899>
- The Tuskegee Syphilis Study: Background Information Sheet

Concepts:

Community consultation, community engagement, community consent, community-based participatory research, cultural competence / cultural humility, exploitation, recruitment, trust vs. trustworthiness

#5

Ethics and roles of the data analyst: “So you think ethics isn’t your job because you’re just the analyst? You’re wrong. Here are some big examples of why.”

Guest lecturer/discussion facilitator:

Eleanor Feingold, PhD

Professor of Human Genetics and of Biostatistics, University of Pittsburgh

I. Biases in machine learning/AI/personalized medicine algorithms (including polygenic risk scores)

In advance of the class discussion, pick and read any two of these:

- Amazon AI recruiting tool shows sex bias: <https://www.reuters.com/article/us-amazon-com-jobs-automation-insight/amazon-scrap-secret-ai-recruiting-tool-that-showed-bias-against-women-idUSKCN1MK08G>
- Podcast on racism in healthcare AI: <https://www.hsph.harvard.edu/ecpe/how-to-prevent-algorithmic-bias-in-health-care/>
- Racial bias in healthcare AI: <https://www.statnews.com/2020/06/17/racial-bias-skews-algorithms-widely-used-to-guide-patient-care/>
- Scholarly article on ethical challenges in healthcare AI: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7332220/>
- Polygenic risk scores: <https://onlinelibrary.wiley.com/doi/10.1002/ijc.33782>
- NYTimes on healthcare AI and health disparities: <https://www.nytimes.com/2019/01/31/opinion/ai-bias-healthcare.html>
- Stat+ on failure and non-transparency of healthcare AI algorithms: <https://www.statnews.com/2021/07/26/epic-hospital-algorithms-sepsis-investigation/>

II. Reproducibility and discovery and reporting of errors and deception (with a focus on Duke and Keith Baggerly)

In advance of the class discussion, pick and read:

NYTimes article on the Duke case:

<https://www.nytimes.com/2011/07/08/health/research/08genes.html>

Recommended (focus on Baggerly's attempts to bring problems to the attention of the scientific community, rather than the technical details):

Video of Keith Baggerly telling the whole story:

https://www.youtube.com/watch?v=gqX_n7pXzM4

Resource:

Journal article by Baggerly and Coombes pointing out errors in the Duke experiments:

<https://arxiv.org/abs/1010.1092>

#6

Research with nonhuman animals

Guest lecturer/discussion facilitator:

Amy Hartman, PhD

Associate Professor of Infectious Disease & Microbiology, University of Pittsburgh

In advance of the class discussion, assignment TBA

Recommended:

- Gilbert S, Kaebnick GE, Murray TH, eds. *Animal Research Ethics: Evolving Views and Practices*. *Hastings Center Special Report* 2012; 42(6):S1–S40. (Selected articles) <http://animalresearch.thehastingscenter.org>
- Grimm, D. (25 June 2020) Is it time to replace one of the cornerstones of animal research? *Science*. <https://www.sciencemag.org/news/2020/06/it-time-replace-one-cornerstones-animal-research>
- How the COVID-19 pandemic highlights the necessity of animal research (Current Biology, Sept 2020): <https://www.sciencedirect.com/science/article/pii/S0960982220311842>
- U.S. Law and Animal Experimentation: A Critical Primer, Stephen Latham (also attached): <http://animalresearch.thehastingscenter.org/report/u-s-law-and-animal-experimentation-a-critical-primer/>

Resources:

- **Pitt Animal Research Protections:** <http://www.iacuc.pitt.edu/>
- **Vertebrate animals section (VAS), NIH grants:** <https://olaw.nih.gov/guidance/vertebrate-animal-section.htm>
- The ARRIVE guidelines (Animal Research: Reporting of In Vivo Experiments) are a checklist of recommendations to improve the reporting of research involving animals: <https://arriveguidelines.org/>
- Video on improving rigor and reproducibility of animal research: <https://www.youtube.com/watch?v=KlXjoTfgAt0>
- Video on maintaining standards of animal care and use in research <https://pitt.hosted.panopto.com/Panopto/Pages/Viewer.aspx?id=6ff441f4-11c7-48f3-9910-aab900f33b4e>

Interesting: Pitt's new website featuring the positive impact of animal research:

<https://www.animalresearch.pitt.edu/>

Concepts:

Animal model, Institutional Animal Care and Use Committee, power analysis

