PUBHLT 2030: Research Ethics and the Responsible Conduct of Research
1 credit | Fall Term 2023 | Wednesdays, 5:00 – 7:00 pm
Barco Law Building Room 111 (3900 Forbes Avenue)
Course instructor:
Lisa S. Parker, PhD
Professor of Human Genetics
Dickie, McCamey & Chilcote Professor of Bioethics
Director Center for Bioethics & Health Law
lisap@pitt.edu

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 a combination of lecture and 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).

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:
- Academic Integrity Policy:
Students in this course will be expected to comply with the University of Pittsburgh's Policy on Academic Integrity. Any student suspected of violating this obligation for any reason during the semester will be required to participate in the procedural process, initiated at the instructor level, as outlined in the University Guidelines on Academic Integrity. This may include, but is not limited to, the confiscation of the examination of any individual suspected of violating University Policy. Furthermore, no student may bring any unauthorized materials to an exam, including dictionaries and programmable calculators.

To learn more about Academic Integrity, visit the Academic Integrity Guide for an overview of the topic. For hands- on practice, complete the Understanding and Avoiding Plagiarism tutorial.

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.

- 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.

- 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.

- 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.

- Disability Services:
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 (DRS), 140 William Pitt Union, (412) 648-7890, drsrecep@pitt.edu, (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.

- 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.

-    **Equity, Diversity, and Inclusion**
The University of Pittsburgh does not tolerate any form of discrimination, harassment, or retaliation based on disability, race, color, religion, national origin, ancestry, genetic information, marital status, familial status, sex, age, sexual orientation, veteran status or gender identity or other factors as stated in the University's Title IX policy. The University is committed to taking prompt action to end a hostile environment that interferes with the University's mission. For more information about policies, procedures, and practices, visit the Civil Rights & Title IX Compliance web page.

I ask that everyone in the class strive to help ensure that other members of this class can learn in a supportive and respectful environment. If there are instances of the aforementioned issues, please contact the Title IX Coordinator, by calling 412-648-7860, or e-mailing titleixcoordinator@pitt.edu. Reports can also be filed online. You may also choose to report this to a faculty/staff member; they are required to communicate this to the University's Office of Diversity and Inclusion. If you wish to maintain complete confidentiality, you may also contact the University Counseling Center (412-648-7930).

- 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.
From the Office of Diversity, Equity, and Inclusion

Schedule of Fall 2023 Sessions and Assignments:

#1 **October 25**	**I. Course introduction, and introduction to ethical reasoning** **II. Academic and research integrity, publication, and authorship** **In advance of the class discussion, read:** - 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 - Boyd, RW, et al. (2020). On Racism: A New Standard For Publishing On Racial Health Inequities. *Health Affairs Blog.* https://www.healthaffairs.org/do/10.1377/hblog20200630.939347/full/ - International Committee of Medical Journal Editors. (2023, May). Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals. *ICMJE.* http://www.icmje.org/recommendations/ **(Read Section 2 A-C)** - Ferguson, C, Marcus, A, Oransky, I. (2014). Publishing: The peer review scam. *Nature, 515*, 480-482. https://doi.org/10.1038/515480a **Recommended:** - Parker, L, et al. (2019). Normative and conceptual ELSI research: what it is, and why it's important. *Genet Med, 21*(2), 505-509. https://doi.org/10.1038/s41436-018-0065-x **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 **November 1**	**I. Data management, data sharing, and privacy protection** **II. Avoiding research misconduct and fulfilling obligations** **In advance of the class discussion, read:** - Gonzales, S, Carson, MB, Holmes, K. (2022). Ten simple rules for maximizing the recommendations of the NIH data management and sharing plan. *PLOS Computational Biology, 18*(8). https://doi.org/10.1371/journal.pcbi.1010397 - Maher, B. (2010). Research integrity: Sabotage!. *Nature, 467*, 516-518. https://doi.org/10.1038/467516a - Nutt, A. (2016). This scientist nearly went to jail for making up data. *The Washington Post.* https://www.washingtonpost.com/news/speaking-of-science/wp/2016/04/01/when-scientists-lie-about-their-research-should-they-go-to-jail/ - Bauchner, H, Golub, RM, Fontanarosa, PB. (2016). Data Sharing: An Ethical and Scientific Imperative. *JAMA, 315*(12), 1238-1240. https://doi.org/10.1001/jama.2016.2420

- Longo, D, Drazen, J. (2016). Data Sharing. *N Engl J Med*, *374*, 276-277. https://doi.org/10.1056/NEJMe1516564
- Sullivan, T. (2018, May 5). JAMA: Research Parasites Wanted. *Policy & Medicine*. https://www.policymed.com/2016/04/jama-research-parasites-wanted.html
- Johnson, CY. (2016). Drug companies are sharing their data — but few are looking. *The Washington Post*. https://www.washingtonpost.com/news/wonk/wp/2016/03/29/pharma-companies-are-sharing-their-data-but-few-are-looking/
- Kolata, G. (2019). Your Data Were 'Anonymized'? These Scientists Can Still Identify You. *The New York Times*. 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)

Recommended:
- Grey, A, et al. (2020). Check for publication integrity before misconduct. *Nature*, *577*, 167-169. https://doi.org/10.1038/d41586-019-03959-6
- Offord, C. (2020). The Surgisphere Scandal: What Went Wrong?. *The Scientist*, October. 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 November 8	**Human subjects research** **In advance of the seminar discussion, read:** - Emanuel, EJ, Wendler, D, Grady, C. (2000). What Makes Clinical Research Ethical?. *JAMA*, *283*(20), 2701-2711. https://doi.org/10.1001/jama.283.20.2701 **(Read through the section 'Necessary Expertise' on page 2708)**

Recommended:
- National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (1979). *The Belmont Report*. U.S. Department of Health, Education, and Welfare. 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 **November** **15**	**Research and its impact on communities** **In advance of the seminar discussion, read:** • Weijer, C, Emanuel, EJ. (2000). Protecting Communities in Biomedical Research. *Science, 289*(5482), 1142-1144. https://doi.org/10.1126/science.289.5482.1142 • Participants in the 2001 Conference on Ethical Aspects of Research in Developing Countries. (2001). Fair Benefits for Research in Developing Countries. *Science, 298*(5601), 2133-2134. https://doi.org/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
November **17** **Friday**	**By midnight, i.e., at the end of the day Friday, submit** **Commentary A1 (if you choose Option A for your Written Assignment)** **or** **the Proposal for your essay (if you choose Option C).**
November **22** **Wednesday**	**No class – Thanksgiving Holiday**
#5 **November** **29**	**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: Jenna Carlson, PhD Assistant Professor of Human Genetics and 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:** • Dastin, J. (2018). Amazon scraps secret AI recruiting tool that showed bias against women. *Reuters*. https://www.reuters.com/article/us-amazon-com-jobs-automation-insight/amazon-scraps-secret-ai-recruiting-tool-that-showed-bias-against-women-idUSKCN1MK08G • Igoe, KJ. (2021). Algorithmic Bias in Health Care Exacerbates Social Inequities –

How to Prevent It. *Harvard Public Health*. https://www.hsph.harvard.edu/ecpe/how-to-prevent-algorithmic-bias-in-health-care/
- Begley, S. (2020). Racial bias skews algorithms widely used to guide care from heart surgery to birth, study finds. *Statnews*. https://www.statnews.com/2020/06/17/racial-bias-skews-algorithms-widely-used-to-guide-patient-care/
- Gerke, S, Minssen, T, Cohen, G. (2020). Ethical and legal challenges of artificial intelligence-driven healthcare. *Artificial Intelligence in Healthcare*, 295-336. https://doi.org/10.1016/B978-0-12-818438-7.00012-5
- Evans, G, et al. (2021). The importance of ethnicity: Are breast cancer polygenic risk scores ready for women who are not of White European origin?. *International Journal of Cancer*, *150*(1), 73-79. https://onlinelibrary.wiley.com/doi/10.1002/ijc.33782
- Khullar, D. (2019). A.I. Could Worsen Health Disparities. *The New York Times*. https://www.nytimes.com/2019/01/31/opinion/ai-bias-healthcare.html
- Ross, C. (2021). Epic's AI algorithms, shielded from scrutiny by a corporate firewall, are delivering inaccurate information on seriously ill patients. *STAT News*. 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, read:
Kolata, G. (2011). How Bright Promise in Cancer Testing Fell Apart. *The New York Times*. https://www.nytimes.com/2011/07/08/health/research/08genes.html

Recommended:
Video of Keith Baggerly telling the whole story:
https://www.youtube.com/watch?v=gqX_n7pXzM4
(focus on Baggerly's attempts to bring problems to the attention of the scientific community, rather than the technical details)

Resource:
Journal article by Baggerly and Coombes pointing out errors in the Duke experiments:
https://arxiv.org/abs/1010.1092

December 6 Wednesday	**No class. By midnight, i.e., at the end of the day Wednesday, submit Commentary A2 (if you choose Option A for your Written Assignment).**
December 8 Friday	**By midnight, i.e., at the end of the day Friday, submit your Commentary (if you choose Option B for your Written Assignment).**
#6 December 13	**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, read:** - Three articles from: Gilbert, S, Kaebnick, GE, Murray, TH, eds. (2012). Animal Research Ethics: Evolving Views and Practices. *Hastings Center Special Report*, *42*(6), 1-40. http://animalresearch.thehastingscenter.org 　○ Latham, SR. (2013). U.S. Law and Animal Experimentation: A Critical Primer. *Hastings Center Special Report, 42*(6), 35-39. https://doi.org/10.1002/hast.107 　○ Marks, J. (2012). Accept No Substitutes: The Ethics of Alternatives. *Hastings Center Special Report*, *42*(6), 16-18.

https://doi.org/10.1002/hast.102
- ○ Zurlo, J. (2012). No Animals Harmed: Toward a Paradigm Shift in Toxicity Testing. *Hastings Center Special Report, 42*(6), 23-26. https://doi.org/10.1002/hast.104
- 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

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 models, Institutional Animal Care and Use Committee, power analysis

December 15 Friday	**By noon Friday, submit your Essay (if you choose Option C for your Written Assignment).**