

# PUBHBIO 6260- Ethics in Biostatistics 1 credit hour - Autumn 2025 Wednesdays, 12:40pm-1:35pm Eastern Cunz Hall 330 (in person section) or Zoom (online section)

#### **Course Instructors:**

Instructor	Degree Information	Office	Contact Information
Michael Pennell	PhD in Biostatistics UNC-Chapel Hill 2006	246 Cunz Hall	Ph: 614-247-7936 pennell.28@osu.edu
Abigail Shoben	PhD in Biostatistics University of Washington 2010	249 Cunz Hall	Ph: 614-247-8092 shoben.1@osu.edu

**Instructor's Office Hours:** Wednesdays, 1:35-2:05 pm Eastern, In person (Cunz 246 or 249) and Online

### Faculty Feedback & Response Time:

The following gives you an idea of our intended availability during the course:

- **Grading:** You can generally expect feedback within 7 days.
- **E-mail:** We will reply to e-mails within one business day.

**Course Description:** The course examines ethical challenges related to research design, data collection, data integrity and stewardship, data analysis and interpretation, and data reporting in the conduct of public health and biomedical research. Through presentation of historical and current case studies we discuss ethical concerns commonly faced by biostatisticians and provide tools to address future quandaries.

**Prerequisites:** Enrollment in MPH-Biostatistics specialization, MS-Biostatistics specialization, Interdisciplinary PhD in Biostatistics, or permission of instructor.

**Class Format:** Weekly in-person discussion-based class meetings. Students will complete weekly readings and complete a short reflection paper/journal entry each week (with prompt provided by instructors). Instructors will lead weekly discussions of the readings. Some weeks will consist of indepth discussion of hypothetical case studies of ethical issues in medicine/public health that students may encounter.

#### **Course Learning Objectives:**

- 1. Identify potential ethical concerns in situations commonly confronting biostatisticians.
- 2. Explain how current and historical events affect current ethical issues for biostatisticians.
- 3. Analyze the potential impact of research on different communities from an ethical perspective.

## **Core Competencies:**

## Foundational Public Health Knowledge:

- 3. Explain the role of quantitative and qualitative methods and sciences in describing and assessing a population's health.
- 6. Explain the critical importance of evidence in advancing public health knowledge.

## **Foundational MPH Competencies:**

20. Describe the importance of cultural competence in communicating public health content.

A complete list of College of Public Health Competencies is located in Appendix C of the CPH Graduate Student Handbook that can be found at: https://cph.osu.edu/students/competencies

**Text/Readings:** Readings will come from peer-reviewed literature, news sources, blog posts, and other sources. See the course schedule for details.

**Carmen:** There is a Carmen site for this course (<a href="https://carmen.osu.edu">https://carmen.osu.edu</a>). All readings and assignments will be distributed via Carmen, and submission of all assignments will be done via Carmen.

You will need to use BuckeyePass (<u>buckeyepass.osu.edu</u>) multi-factor authentication to access your courses in Carmen. To ensure that you are able to connect to Carmen at all times, it is recommended that you take the following steps:

- Register multiple devices in case something happens to your primary device. Visit the BuckeyePass - Adding a Device help article for step-by-step instructions (<a href="https://admin.resources.osu.edu/buckeyepass/adding-a-device">https://admin.resources.osu.edu/buckeyepass/adding-a-device</a>)
- Request passcodes to keep as a backup authentication option. When you see the Duo login screen on your computer, click Enter a Passcode and then click the Text me new codes button that appears. This will text you ten passcodes good for 365 days that can each be used once
- Download the Duo Mobile application (<a href="https://admin.resources.osu.edu/buckeyepass/installing-the-duo-mobile-application">https://admin.resources.osu.edu/buckeyepass/installing-the-duo-mobile-application</a>) to all of your registered devices for the ability to generate one-time codes in the event that you lose cell, data, or Wi-Fi service

If none of these options will meet the needs of your situation, you can contact the IT Service Desk at 614-688-4357(HELP) and IT support staff will work out a solution with you.

#### **Class Format: How this course works**

- Mode of delivery: This course is comprised of in person and online synchronous sections.
- Credit hours and work expectations: This is a 1-credit-hour course. According to Ohio State policy (go.osu.edu/credithours), students should expect around 1 hour per week of time spent on direct instruction in addition to 2 hours of homework/active learning activities (e.g., course readings, reflections) to receive a grade of (C) average.
- Attendance and participation requirements: See description under "Assignments."

### **Course Technology**

Technology skills needed for this course

- Basic computer and web-browsing skills
- Navigating Carmen (go.osu.edu/canvasstudent)
- CarmenZoom virtual meetings (go.osu.edu/zoom-meetings)

## Required equipment

- Computer: current Mac (Mac OSX) or PC (Windows 10+) with high-speed internet connection
- Other: a mobile device (smartphone or tablet) to use for BuckeyePass authentication
- Students in online section:

- o Webcam: built-in or external webcam, fully installed and tested
- o Microphone: built-in laptop or tablet mic or external microphone

## Required software

• Microsoft 365 Copilot (formerly Office 365)

All Ohio State students are now eligible for free Microsoft 365 Copilot (formerly Office 365). Full instructions can be found at <u>go.osu.edu/office365help</u>.

## Technology support

For help with your password, university email, Carmen, or any other technology issues, questions, or requests, contact the Ohio State IT Service Desk. Standard support hours are available at and support for urgent issues is available 24/7.

• Self-Service and Chat support: <a href="http://it.osu.edu/help">http://it.osu.edu/help</a>

Phone: 614-688-4357(HELP)Email: servicedesk@osu.edu

**Assignments**: Weight toward final grade in parentheses.

**Exams**: There are no exams in this course.

# Class Participation (20%):

Students are expected to come to class prepared by having completed the week's readings and reflection paper. In class, students are expected to engage with and discuss the week's material, in addition to answering polls and mini-reflections via Top Hat. Students are encouraged to:

- actively ask questions of the instructor and classmates;
- share their perspective;
- · challenge the ideas discussed in class.

We will strive to practice the following principles defined by Arao and Clemens (2013, In: *The Art of Effective Facilitation*, pp. 135-150):

- Controversy with civility
- Own your intentions and your impacts
- Challenge by choice
- Respect
- No attacks

All dialogue is expected to be collegial and open. If classroom discussion happens to elicit differences in opinion, these differing views will *focus on the issue or problem*, *rather than on the person* challenging us to consider different views.

Participation will be graded weekly based on contributions such as the following: sharing ideas and raising points during class discussions, asking questions, participating in individual and group in-class activities, and paying attention actively in class. Students who are active participants are actively engaged in their learning. Active learners are willing to share and learn from others, contribute to the learning of their classmates, and try to apply what they are learning to their life outside of the class. The weekly grading rubric and detailed expectations for students in the in-person and virtual sections are on the course Carmen page. We acknowledge that it may take some students a few weeks to get acclimated and become comfortable sharing

with classmates and the instructors. To account for this, your weekly grades will be differentially weighted with 20% of your final participation grade based on Weeks 1-5 and 80% based on Weeks 6-15.

## Weekly Reflection Papers (60%):

Each week a writing prompt related to that week's readings or case study will be provided on Carmen. Students should write a response that is approximately 400-500 words (roughly 4-5 paragraphs) in length that is informed by the readings and personal perspective. **The purpose of the assignment is to encourage critical thinking and reflection on the weekly topic, which will provide a "warm-up" for the course session each week.** Reflections should be completed individually without collaboration with other students or use of a generative artificial intelligence (GenAl) app such as ChatGPT. However, students are permitted and encouraged to share thoughts articulated in the reflection during in-class discussions.

Grades will be based on (a) relevance to the question/topic, (b) depth and diligence of critical thinking, (c) writing clarity, and (d) timeliness. Submissions of reflection papers after class discussion will be docked 20% (if turned in the same day) with additional 10% per day thereafter. The specific grading rubric for reflection papers is provided on Carmen.

# Final Paper (20%):

The final assignment will be a culminating paper reflecting on the student's learning in the course. Students will consider the *5 most important things* that they have learned in the course and explain (a) what each point or lesson is, and (b) why it is important, including specifically commenting on why or how it will be useful to them in their career. The 5 points may be anything at all from the course, however, one point must include something you learned about yourself. The key aspects of this assignment are that the student explains each item clearly and convincingly describes why each item was selected. The length should be approximately 1200-1500 words. Final papers must be written independently without collaboration with other students or use of a GenAl app. More details will be provided later.

Grades will be based on (a) depth and diligence of critical thinking, (b) demonstration of learning from the course (i.e., sophistication of reasoning about course topics), and (c) writing clarity. The specific grading rubric for the final paper will be provided on Carmen.

**Grading:** This course is letter graded. Final class grade will be determined as follows:

Participation	20%
Weekly Reflection Papers	60%
Final Paper	20%

This course will use the standard OSU grading scheme:

Α	93-100	B+	87-89.9	C+	77-79.9	D+	67-69.9	Ε	0-59
A-	90-92.9	В	83-86.9	С	73-76.9	D	60.66.9		
		B-	80-82.9	C-	70-72.9				

### **Class Policies:**

- Attendance: This course is primarily discussion-based. As such, it is expected that all students
  will regularly attend class and participate fully. If you cannot attend class, you are expected to
  contact the instructors as soon as possible. Decisions about how to calculate participation
  grades for missed classes will be made on a case-by-case basis. Prompt notification and clarity
  about any potential scheduling conflicts are essential. Note that all students are expected to
  complete all weekly reflections, regardless of class attendance.
- **Collaboration:** For specific policies on collaboration on assessments, please see the descriptions of individual assignments.
- Use of generative artificial intelligence (GenAl): Given that the learning goals of this class focus on analysis and personal reflections of different ethical issues, the use of generative artificial intelligence (GenAl) tools such as Copilot or ChatGPT, writers' aids like Grammarly, or translation platforms such as Google Translate are not permitted in this course. Any use of GenAl tools for work in this class may therefore be considered a violation of Ohio State's Academic Integrity policy and Code of Student Conduct because the work is not your own. The use of unauthorized GenAl tools will result in a referral to the Committee on Academic Misconduct. If we suspect that you have used GenAl on an assignment for this course, we will ask you to communicate with us to explain your process for completing the assignment in question. If you feel you need to use GenAl for translation, please contact us first. If you have any other questions regarding this course policy, please contact us.

# **Copyright Statement:**

This syllabus and all course materials (e.g., homework assignments, solution keys, course materials) are under copyright by the instructor and cannot be posted elsewhere without written permission.

## **Intellectual Diversity:**

Ohio State is committed to fostering a culture of open inquiry and intellectual diversity within the classroom. This course will cover a range of information and may include discussions or debates about controversial issues, beliefs, or policies. Any such discussions and debates are intended to support understanding of the approved curriculum and relevant course objectives rather than promote any specific point of view. Students will be assessed on principles applicable to the field of study and the content covered in the course. Preparing students for citizenship includes helping them develop critical thinking skills that will allow them to reach their own conclusions regarding complex or controversial matters.

#### **Classroom Code of Conduct:**

In this class, we expect that mutual respect and civility will prevail to ensure that every student has the optimum opportunity to learn and that all instructors have the best opportunity to teach. To achieve the most conducive learning environment, in which you can be challenged and supported, it is imperative that there be an atmosphere of trust and safety in the classroom. Please let us (the instructors) know if something said or done in the classroom is particularly troubling or causes discomfort or offense. This can be done by directly contacting one of the instructors, or you can notify the instructors of the issue through another source such as your academic advisor, a trusted faculty member, or a peer.

## Respect for Others' Privacy/Confidentiality

In this class we will discuss topics that may elicit strong statements from you and/or your classmates and/or your instructors. You are welcome, indeed encouraged, to talk generally about the content and discussion topics in the course with other students not enrolled in the course, but please use discretion and respect the privacy and confidentiality of your fellow students and instructors when doing so.

#### **Mental Health Services**

As a student you may experience a range of issues that can cause barriers to learning, such as strained relationships, increased anxiety, alcohol/drug problems, feeling down, difficulty concentrating and/or lack of motivation. These mental health concerns or stressful events may lead to diminished academic performance or reduce a student's ability to participate in daily activities. The Ohio State University offers services to assist you with addressing these and other concerns you may be experiencing. If you or someone you know are suffering from any of the aforementioned conditions, you can learn more about the broad range of confidential mental health services available on campus via the Office of Student Life's Counseling and Consultation Service (CCS) by visiting <a href="ccs.osu.edu">ccs.osu.edu</a> or calling 614-292-5766. CCS is located on the 4th Floor of the Younkin Success Center and 10th Floor of Lincoln Tower. You can reach an on call counselor when CCS is closed at 614-292-5766 and 24 hour emergency help is also available 24/7 by dialing 988 to reach the Suicide and Crisis Lifeline.

# **Religious Beliefs or Practices Accommodations**

Ohio State has had a longstanding practice of making reasonable academic accommodations for students' religious beliefs and practices in accordance with applicable law. In 2023, Ohio State updated its practice to align with new state legislation. Under this new provision, students must be in early communication with their instructors regarding any known accommodation requests for religious beliefs and practices, providing notice of specific dates for which they request alternative accommodations within 14 days after the first instructional day of the course. Instructors in turn shall not question the sincerity of a student's religious or spiritual belief system in reviewing such requests and shall keep requests for accommodations confidential.

With sufficient notice, instructors will provide students with reasonable alternative accommodations with regard to examinations and other academic requirements with respect to students' sincerely held religious beliefs and practices by allowing up to three absences each semester for the student to attend or participate in religious activities. Examples of religious accommodations can include, but are not limited to, rescheduling an exam, altering the time of a student's presentation, allowing make-up assignments to substitute for missed class work, or flexibility in due dates or research responsibilities. If concerns arise about a requested accommodation, instructors are to consult their tenure initiating unit head for assistance.

A student's request for time off shall be provided if the student's sincerely held religious belief or practice severely affects the student's ability to take an exam or meet an academic requirement and the student has notified their instructor, in writing during the first 14 days after the course begins, of the date of each absence. Although students are required to provide notice within the first 14 days after a course begins, instructors are strongly encouraged to work with the student to provide a reasonable accommodation if a request is made outside the notice period. A student may not be penalized for an absence approved under this policy.

If students have questions or disputes related to academic accommodations, they should contact their course instructor, and then their department or college office. For questions or to report discrimination

or harassment based on religion, individuals should contact the <u>Civil Rights Compliance Office</u>. (Policy: <u>Religious Holidays, Holy Days and Observances</u>)

# Office of Student Life: Disability Services

The university strives to maintain a healthy and accessible environment to support student learning in and out of the classroom. If you anticipate or experience academic barriers based on your disability (including mental health, chronic, or temporary medical conditions), please let me know immediately so that we can privately discuss options. To establish reasonable accommodations, I may request that you register with Student Life Disability Services. After registration, make arrangements with me as soon as possible to discuss your accommodations so that they may be implemented in a timely fashion.

If you are ill and need to miss class, including if you are staying home and away from others while experiencing symptoms of a viral infection or fever, please let me know immediately. In cases where illness interacts with an underlying medical condition, please consult with Student Life Disability Services to request reasonable accommodations. You can connect with them at <a href="mailto:slds@osu.edu">slds@osu.edu</a>; 614-292-3307; or <a href="mailto:slds.osu.edu">slds.osu.edu</a>.

## **Grievances and Solving Problems:**

A student who encounters a problem related to their educational program has a variety of avenues available to seek resolution. According to University Policies, if you have a problem with this class, you should seek to resolve the grievance concerning a grade or academic practice by speaking first with the instructor or professor. Then, if necessary, you may take your case to the department chairperson. Specific procedures are outlined in <a href="Faculty Rule 3335-8-23">Faculty Rule 3335-8-23</a>, the <a href="Faculty Rule 3335-8-23">CPH Graduate Student Handbook</a>, and the <a href="Faculty Rule 3335-8-23">CPH Undergraduate Student Handbook</a>. Grievances against graduate, research, and teaching assistants should be submitted first to the supervising instructor, then to the chairperson of the assistant's department.

#### Creating an Environment Free from Harassment, Discrimination, and Sexual Misconduct:

The Ohio State University is committed to building and maintaining a community to reflect diversity and to improve opportunities for all. All Buckeyes have the right to be free from harassment, discrimination, and sexual misconduct. Ohio State does not discriminate on the basis of age, ancestry, color, disability, ethnicity, gender, gender identity or expression, genetic information, HIV/AIDS status, military status, national origin, pregnancy (childbirth, false pregnancy, termination of pregnancy, or recovery therefrom), race, religion, sex, sexual orientation, or protected veteran status, or any other bases under the law, in its activities, academic programs, admission, and employment. Members of the university community also have the right to be free from all forms of sexual misconduct: sexual harassment, sexual assault, relationship violence, stalking, and sexual exploitation.

To report harassment, discrimination, sexual misconduct, or retaliation and/or seek confidential and non-confidential resources and supportive measures, contact the Civil Rights Compliance Office:

Online reporting form at <a href="http://civilrights.osu.edu/">http://civilrights.osu.edu/</a>, Call 614-247-5838 or TTY 614-688-8605, Or Email <a href="mailto:civilrights@osu.edu">civilrights@osu.edu</a>

The university is committed to stopping sexual misconduct, preventing its recurrence, eliminating any hostile environment, and remedying its discriminatory effects. All university employees have reporting

responsibilities to the Civil Rights Compliance Office to ensure the university can take appropriate action:

- All university employees, except those exempted by legal privilege of confidentiality or expressly identified as a confidential reporter, have an obligation to report incidents of sexual assault immediately.
- The following employees have an obligation to report all other forms of sexual misconduct as soon as practicable but at most within five workdays of becoming aware of such information: 1. Any human resource professional (HRP); 2. Anyone who supervises faculty, staff, students, or volunteers; 3. Chair/director; and 4. Faculty member.

#### **Academic Misconduct**

It is the responsibility of the Committee on Academic Misconduct to investigate or establish procedures for the investigation of all reported cases of student academic misconduct. The term "academic misconduct" includes all forms of student academic misconduct wherever committed; illustrated by, but not limited to, cases of plagiarism and dishonest practices in connection with examinations. Instructors shall report all instances of alleged academic misconduct to the committee (<u>Faculty Rule 3335-5-48.7</u> (B)). For additional information, see the <u>Code of Student Conduct</u>.

# **Course Outline**

Week	Date	Topics & Readings
1	8/27/25	Course Introduction
2	9/3/25	<ul> <li>Research Misconduct and Conflicts of Interest</li> <li>Saad K et al (2018). Randomized controlled trial of vitamin D supplementation in children with autism spectrum disorder. <i>Journal of Child Psychology and Psychiatry</i>, 59(1):20-29</li> <li>Letters to Editor about Saad et al. (2018)</li> <li>Retraction in: J Child Psychol Psychiatry. 2019 Jun;60(6):711.</li> </ul>
3	9/10/25	<ul> <li>Data Integrity and Stewardship</li> <li>Gelman A (2011). Ethics and Statistics: Open Data and Open Methods. <i>Chance</i>, 51-53.</li> <li>The Editors of the Lancet Group. (2020) Learning from a retraction. <i>The Lancet</i>, 396(10257), 1056.</li> </ul>
4	9/17/25	<ul> <li>Ethical Issues in Study Design</li> <li>Linie, S (2023). Data Ethics and Privacy in Biostatistics: Navigating the Ethical Landscape of Healthcare Data. <i>J Biom Biosta</i>, 14.</li> <li>Kho ME, Duffett M, Willison DJ, Cook DJ, Brouwers MC (2009). Written informed consent and selection bias in observational studies using medical records: systematic review. <i>BMJ</i>, 338.</li> </ul>
5	9/24/25	<ul> <li>Ethical Issues in Data Analysis</li> <li>Young SS, Karr A (2011) Deming, data and observational studies: A process out of control and needing fixing. Significance, 116-120.</li> <li>MacCoun R, Perlmutter S (2015). Blind Analysis: Hide results to seek the truth. Nature, 526, 187-189.</li> </ul>
6	10/1/25	Principles of Ethics in Statistics     American Statistical Association. Ethical Guidelines for Statistical Practice.
7	10/8/25	Case Study 1: "Just one more thing"  Reading: Case study background and summary
8	10/15/25	<ul> <li>Challenges in Measuring People: Gender, Race, and Other Sensitive Topics (Part 1)</li> <li>Oldehinkel AJ (2017). Editorial: Let's talk about sex – the gender binary revisited. The Journal of Child Psychology and Psychiatry, 58, 863-864.</li> <li>U.S. Census 2020 Questions on Sex</li> </ul>
9	10/22/25	<ul> <li>Challenges in Measuring People: Gender, Race, and Other Sensitive Topics (Part 2)</li> <li>Jones N, Jensen E, Battle K, Marks R (2024). Measuring the Racial and Ethnic Composition and Diversity of the United States Population: Historical Challenges and Contemporary Opportunities," NBER Chapters, in: Race, Ethnicity, and Economic Statistics for the 21st Century, National Bureau of Economic Research, Inc.</li> </ul>

Week	Date	Topics & Readings
10	10/29/25	<ul> <li>Considerations When Including Race in Multivariable Models</li> <li>Yudell M, Roberts D, DeSalle R, Tishkoff S, 70 signatories (2020). NIH must confront the use of race in science. Science, 369(6509):1313-4.</li> </ul>
		• Eneanya ND, Yang W, Reese PP. (2019) Reconsidering the Consequences of Using Race to Estimate Kidney Function. <i>JAMA</i> . 322(2), 113–114.
		Supplemental reading: Is It Time For A Race Reckoning In Kidney Medicine? NPR blog post, Dec. 28, 2020
11	11/5/25	Case Study 2: "Student survey consultation"
		Reading: Case study background and summary
12	11/12/25	Authorship in medical papers
		Defining the Role of Authors and Contributors. ICMJE recommendations.
		<ul> <li>Parker RA, Berman NG (1998). Criteria for authorship for statisticians in medical papers. Statistics in</li> </ul>
		Medicine, 17(20), 2289-2299.
		Discussion board post from a PhD candidate biostatistician. Jun 8, 2020.
13	11/19/25	Ethical Issues Surrounding the Use of Artificial Intelligence in Research
		<ul> <li>Van Noorden R, Perkel JM (2023). Al and science: what 1,600 researchers think. Nature, 621(7980), 672-675.</li> </ul>
		• Miao J, Thongprayoon C, Suppadungsuk S, Garcia Valencia OA, Qureshi F, Cheungpasitporn W (2023). Ethical dilemmas in using Al for academic writing and an example framework for peer review in nephrology academia: a narrative review. <i>Clin Pract</i> , 14(1), 89-105.
	11/26/25	NO CLASS – THANKSGIVING BREAK
14	12/3/25	Considerations for Vulnerable Populations
		<ul> <li>Garrison NA (2013). Genomic Justice for Native Americans: Impact of the Havasupai Case on Genetic Research. Sci Technol Human Values, 38(2):201-223.</li> </ul>
15	12/10/25	Student-directed topic
	12/15/25	Final Paper Due (day that exam would have been scheduled for course)

Degree Program Competencies with Aligned Assessments	Class Participation/ Discussion	Weekly Reflection Papers	Final Paper	
Foundational Public Health Knowledge				
3. Explain the role of quantitative and qualitative methods and sciences in describing and assessing a population's health.	х	х	х	
6. Explain the critical importance of evidence in advancing public health knowledge.	х	х	Х	
Foundational MPH Competencies				
20. Describe the importance of cultural competence in communicating public health content.	х	х		