THE OHIO STATE UNIVERSITY
COLLEGE OF PUBLIC HEALTH

PUBHBIO 7215: Design and Analysis of Clinical Trials
2 credit hours – Autumn 2025
Mondays, 5:15pm-7:05pm Eastern
Online via Zoom

Course Instructor
Abigail Shoben, PhD in Biostatistics, University of Washington, 2010
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Instructor's Office Hours
Mondays, 7:05pm-8:05pm (after class, on Zoom) or by appointment

Faculty Feedback & Response Time:
The following gives you an idea of my intended availability during the course:

- **Grading:** You can generally expect feedback within 7-10 days.
- **E-mail:** I will typically reply to e-mails (sent via Carmen) within 24 hours on school days. Please feel free to email again if it has been longer than 3 school days (72 hours).

Graduate Teaching Assistant (GTA)
Jeongjin Lee
lee.10449@buckeyemail.osu.edu

GTA Responsibilities
The GTA assigned to the course will hold regular office hours and lead review sessions for any students who need help with class material. The TA may assist with scoring assignments; however, final grades will be assigned by the professor. **Any questions regarding grading should be directed to the professor and not the TA.**

Course Description
Design, monitoring, and analysis of clinical trials; includes protocol devel- opment, randomization schemes, sample size methods, and ethical issues.

Prerequisites
PUBHLTH 6001, PUBHBIO 6210, or STAT 5301 or instructor permission.

Course Learning Objectives

1. Identify sources of random and systematic error (bias) in clinical trials
2. Describe common designs used in clinical trials
3. Use appropriate methods of randomization and blinding in the design of clinical trials.
4. Calculate appropriate sample sizes for sufficient power in common clinical trial designs
5. Identify the issues associated with common design decisions such as blinding, inclusion / exclu- sion criteria, and interim analyses.
6. Determine an appropriate outcome measure for a trial, given various scientific settings.

7. Describe common ethical issues present in clinical trials, such as informed consent and placebo control

Interdisciplinary PhD Program in Biostatistics Learning Goals

1. Understands the theoretical foundations of statistical methods (1)
2. Critique general scientific research articles and assess the appropriateness of the statistical applications and methodology involved (2)
3. Can work effectively and collaboratively in a team on a biological or health-related scientific question (3)
4. Can design biological or health-related research studies and construct and implement statistical analysis plans appropriate for such studies (4)

MS-BIO Specialization Competencies:

- Address problems arising in public health and medicine through appropriate statements of hypotheses, study design, data collection, data management, statistical analysis, and interpretation of results (7)
- Recognize strengths and weaknesses of study designs, data sources, and analytic methods (8)

MPH-BIO Specialization Competencies:

- Recognize strengths and weaknesses of study designs and data sources commonly encountered in public health (2)
- Identify strengths and weaknesses of standard analytic methods (3)
- Address problems arising in public health and medicine through appropriate statements of hypotheses, study design, data collection, data management, statistical analysis, and interpretation of results (7)

A complete list of College of Public Health Competencies is located on the College of Public Health website: https://cph.osu.edu/students/competencies.

Text/Readings:

Required readings come from the literature and will be posted to Carmen. A free reference text, Friedman, Furberg, DeMets, Reboussin, & Granger. Fundamentals of Clinical Trials, 5th Edition, is available through the OSU library.

Carmen

There is a Carmen site for this course: https://carmen.osu.edu. All course materials are available via Carmen.

You will need to use BuckeyePass (buckeyepass.osu.edu) 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 (https://admin.resources.osu.edu/buckeyepass/adding-a-device)
- 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 (https://admin.resources.osu.edu/buckeyepass/installing-the-duo-mobile-application) 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:** Synchronous online class with asynchronous lecture material.
- **Credit hours and work expectations:** This is a **2-credit-hour course**. According to Ohio State policy (go.osu.edu/credithours), students should expect around 2 hours per week of time spent on direct instruction (e.g., synchronous class activity, recorded lectures) in addition to 4 hours of homework/active learning activities (e.g., preparing for mock trials, homework assignments, reading and reviewing materials) to receive a grade of (C) average.
- **Attendance and participation requirements:** As the synchronous class mock trials require students to be active participants, it is expected that all students will regularly attend class and participate fully. Additional details regarding expectations for Zoom participation are available on Carmen. Students anticipating more than sporadic absence (>2 class days) should discuss their situation with the instructor as soon as possible.

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
- **Webcam:** built-in or external webcam, fully installed and tested
- **Microphone:** built-in laptop or tablet mic or external microphone
- **Other:** a mobile device (smartphone or tablet) to use for BuckeyePass authentication

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 go.osu.edu/office365help.
- **Statistical software (student choice)**
  Some limited use of a statistical software package of your choice (e.g., Stata, R, SAS) is required.
- **Some use of a statistical software package of your choice (e.g., Stata, R, SAS) is required. In class examples and homework keys will use Stata.**

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:** http://it.osu.edu/help
- **Phone:** 614-688-4357(HELP)
- **Email:** servicedesk@osu.edu

Assignments/Assessments

Mock trial participation: 20%
Most class periods will include a mock trial review of an actual published trial. During the mock review, a group of 3-6 students will prepare and act as the research team proposing the trial or defending the results (the "investigators") and the rest of the class will prepare questions for the team to answer based on the proposed design or results (the "peer reviewers"). Students serving as the investigators are encouraged to plan ahead for who will be experts in various areas (e.g., statistics, outcome selection, general design, etc). Students serving as reviewers are expected to prepare appropriate questions for the investigators to answer. The reviewers should submit 3 potential questions to the instructor via Carmen before the class period in which the review is held, although reviewers are permitted to ask questions that were not submitted ahead of time. The full rubric for mock trial participation is available on Carmen. All students will serve as investigators twice during the semester with two different groups.

Due to their necessity for a properly functioning class period, submissions after the start of the class period will receive no credit. Due to the nature of the class format, it is expected that all students will regularly attend class and participate fully. Students anticipating more than sporadic absence (>2 class days) should discuss their situation with the instructor as soon as possible.

Homework: 30%
There will be approximately 6 homework assignments that will include statistical calculations and analysis and critique of published articles. Students are permitted to work together on homework, but submitted assignments must be written independently, including all code and output from statistical software. The use of GenAI is permitted, with appropriate citation, unless otherwise specified in the homework.

Late homework will be scaled to 80% and 50% of the earned score if submitted up to 48 or 96 hours late, respectively (2 days and 4 days). Beyond 4 days, no credit will be given. All students may turn in one homework up to 24 hours late with no penalty and with no need to contact the instructor.

GenAI Homework Projects: 15%
There will be two projects during the semester that require the use of GenAI to complete. These projects will prompt exploration of the benefits, challenges, and limits to using Generative AI in the context of clinical trial design and analysis. GenAI projects may be discussed with other students; however, all work submitted (including prompts submitted) must be the student's own.

Final Project: 30%
The final project will consist of creating a set of 1-page "study guides" for key topics from the class. Rubrics and additional information will be provided during the semester. The final project must be completed independently, and students may only consult with the instructor if they have questions (not the TA). The use of Generative AI is permitted with appropriate citation.

All projects (final or GenAI) submitted late without an accepted and documented excuse will be penalized a fixed 10 percentage points per 24-hour period for projects submitted within 72-hours of the deadline. Note that this is an absolute deduction, (e.g., a project that would have earned a 85% but was turned in 12 hours late receives the earned score (85) minus 10%, resulting in a final score of 75.

Grading

Final class grade will be determined as follows:

Lecture Reflections: 5%
Mock trial participation: 20%
Homework: 30%
GenAI Homework Projects: 15%
Final Project: 30%

This course will use the standard OSU grading scheme:

A	**93 to 100**	Outstanding work that reflects mastery of the material and the ability to apply it
A-	**90 to <93**	Excellent work that reflects mastery of the material
B+	**87 to <90**	Good work that reflects mastery of most of the material
B	**83 to <87**	Good work that reflects mastery of some of the material
B-	**80 to <83**	Good work that reflects mastery of a few aspects of the material
C+	**77 to <80**	Mediocre work that reflects familiarity with, but not mastery of the material
C	**73 to <77**	Mediocre work that reflects familiarity with most of the material
C-	**70 to <73**	Mediocre work that reflects little familiarity with the material
D+	**67 to <70**	
D	**60 to <67**	
E	**Below 60**	

Class Policies

As the synchronous class mock trials require students to be be active participants, it is expected that all students will regularly attend class and participate fully. Additional details regarding expectations for Zoom participation are available on Carmen. Students anticipating more than sporadic absence (>2 class days) should discuss their situation with the instructor as soon as possible.

Copyright Statement

Generative AI Policy

Given the learning goals of this course, students are welcome to explore innovative tools and technologies for assistance with written assignments, including generative artificial intelligence (GenAI). All final written assignments, including mock trial questions, homework, and final project, should be your own work and must provide a clear statement of how GenAI was used (if at all).

While GenAI can be a valuable tool, academic integrity remains paramount. You are responsible for developing and articulating your own ideas, so addressing how GenAI contributed to those ideas (as you would for any sources you use) is centrally important to your learning. Attribute GenAI-generated content with proper citations and avoid plagiarism. Additionally, consider the accuracy of information incorporated in your assignment and the ethical implications of using GenAI in educational contexts. You are responsible for ensuring that the information you submit based on a GenAI query does not contain misinformation, unethical content, or violate intellectual property laws.

If I suspect that you have used GenAI in a way that is prohibited (such as without attribution), I will ask you to explain your process for completing the assignment in question. Submission of un-attributed and/or un-

edited GenAI-generated content as your own original work is considered a violation of Ohio State's Academic Integrity policy and Code of Student Conduct because the work is not your own. The unauthorized use of GenAI tools will result in referral to the Committee on Academic Misconduct.

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 slds@osu.edu; 614-292-3307; or slds.osu.edu.

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 ccs.osu.edu 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 Civil Rights Compliance Office. (Policy: Religious Holidays, Holy Days and Observances)

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 (Faculty Rule 3335-5-48.7 (B)). For additional information, see the Code of Student Conduct.

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.

Grievances and Solving Problems

A student who encounters a problem related to his/her 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 Faculty Rule 3335-8-23, the CPH Graduate Student Handbook, and the CPH Undergraduate Student Handbook. 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 http://civilrights.osu.edu/,
Call 614-247-5838 or TTY 614-688-8605,
Or Email civilrights@osu.edu

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.

Course Outline

Week	Class Date	Topic	Class activity
1	9/1 (Labor Day)	Course welcome	n/a
2	9/8	Overview, What are clinical trials?	Brief introductions, Zoom overview
3	9/15	Outcome selection	Mock trial #1
4	9/22 (no class)	Sample size and power	None – AI project #1 due 9/26
5	9/29	Randomization and blinding	Mock trial #2
6	10/6	Bias in clinical trials	Mock trial #3
7	10/13	Population effect summaries	Mock trial #4
8	10/20	Intercurrent events	Mock trial #5
9	10/27	Multiple testing	Mock trial #6
10	11/3	Subgroup analysis	Mock trial #7
11	11/10 (no class)	Midterm review	None – AI project #2 due 11/14
12	11/17	Interim analysis	Mock trial #8
13	11/24	Early phase studies	Mock trial #9
14	12/1	Late stage designs	Mock trial #10
15	12/8	Ethics in clinical trials	Mock trial #11
Finals	n/a	n/a	Final Exam due 12/12

Alignment of Competencies with Assessments

	Mock Trial Reviews	Homework	GenAI Homework Projects	Final Project
Interdisciplinary PhD in Biostatistics Learning Goals				
Understands the theoretical foundations of statistical methods (1)		X	X	
Can critique general scientific research articles and assess the appropriateness of the statistical applications and methodology involved (2)	X	X	X	
Can work effectively and collaboratively in a team on a biological or health-related scientific question (3)	X			
Can design biological or health-related research studies and construct and implement statistical analysis plans appropriate for such studies (4)			X	
MS-Biostatistics Specialization Competencies				
Address problems arising in public health and medicine through appropriate statements of hypotheses, study design, data collection, data management, statistical analysis, and interpretation of results (7)		X	X	
Recognize strengths and weaknesses of study designs, data sources, and analytic methods (8)	X	X	X	X
MPH-Biostatistics Specialization Competencies				
Address problems arising in public health and medicine through appropriate statements of hypotheses, study design, data collection, data management, statistical analysis, and interpretation of results (1)		X	X	
Recognize strengths and weaknesses of study designs and data sources commonly encountered in public health (2)	X	X	X	X
Identify strengths and weaknesses of standard analytic methods (3)	X	X	X	X