PURDUE UNIVERSITY®

Course Information

Welcome to PUBH 59000: Design and Analysis of Randomized Trials in Public Health! This 3-credit course will be conducted synchronously on **Tuesdays and Thursdays** at **1:30-2:45 PM**. For most class sessions, we will meet in **Grissom Hall 126**, and you are encouraged to attend in-person whenever possible. However, if you not able, you can attend synchronously by Zoom via the following link:

https://purdue-edu.zoom.us/j/94656029969?pwd=VVZ2THo4OXJTNlZHSU1VNjRXc2hqdz09
Meeting ID: 946 5602 9969
Passcode: 096353

If you cannot attend in person or online in real time, the Zoom session will be recorded and posted on Brightspace for later viewing.

Exceptions: There will be a few class periods that will be conducted only by Zoom and not in person. These will be announced on Brightspace, so **please check the course page regularly**. Similarly, if we need to make changes mid-semester, any changes will be posted as announcements on Brightspace.

Instructors' Contact Information

Instructor: Nilupa S. Gunaratna, PhD
Preferred Pronouns: She/her/hers
Email: gunaratna@purdue.edu
Office Hours: Email for appointment

Teaching Assistant: Jeongho (Johnny) Han
Preferred Pronouns: He/him/his
Email: han202@purdue.edu
Office Hours: Mondays at 10:00 AM using the Zoom link above

The instructor and teaching assistant (TA) will be available via email on weekdays and will try to respond as soon as possible (generally within 24-48 hours). When emailing, please place the course number and topic in the subject line of the email (e.g., "PUBH 590 – Homework 2 Question"). This will help tremendously in locating and responding to your emails quickly.

Course Description

Randomized trials provide solid evidence on whether interventions and programs "work" to improve health outcomes. In this course, students will learn how to design a randomized study, handle practical issues that arise in data collection, analyze data using appropriate methods and good statistical practice, identify limitations to statistical evidence, and interpret and communicate findings in an audience-appropriate way. This is a hands-on course in which students will work with data and build skills using SAS statistical software in preparation for careers as biostatisticians, data scientists, and researchers.

Course Materials
There is no required text for this course. For certain topics, required readings will be made available on Brightspace. These include:

- Friedman, Furberg, DeMets, Reboussin, Granger (2015) Fundamentals of Clinical Trials, Fifth Edition
- Agresti (2007) An Introduction to Categorical Data Analysis, Second Edition

Learning Outcomes
By the end of the course, you will be able:
1. To identify and plan an appropriate randomized study design to answer a substantive question
2. To identify limitations to statistical evidence that arise in study design and implementation
3. To analyze data from randomized trials using appropriate methods and good statistical practice
4. To interpret and communicate findings from randomized trials in an audience-appropriate way.

Computing
This course will use SAS (Version 9.4). Sample SAS programs and data sets will be provided on Brightspace. You can obtain SAS at no cost by clicking [here](#).

Evaluation
Your grade in this course will be based on homework (due most weeks on Tuesdays at noon), two take-home midterm exams, and a take-home final exam. All of these will be assigned on and submitted via Brightspace. Each exam focuses on the new course material covered since the previous exam but will contain some earlier material, particularly relating to recurring concepts and good statistical practices.

Your homework must have the exercises presented in order. The solutions must be clearly readable and easy to follow. These solutions should include all relevant graphs and tables appropriately labeled and described. You are limited to a maximum of three pages per exercise. Any graph or table that is turned in without comment or spans across more than one page will be ignored. You can use a word processor or editor to edit or cut and paste specific software output. You are permitted to work together to solve the homework exercises, but each student must write up their own solution. Failure to follow this policy will result in an initial warning, followed by a reduction in grade.

The grade breakdown and due dates are as follows:

Assignments	Due at 12 PM on	Percentage of grade
Homework (drop lowest score)	Most Tuesdays	55
Exam 1 (assigned 2/18, covering material through 2/11)	2/23	15
Exam 2 (assigned 4/1, covering material through 3/25)	4/6	15
Final exam	Final exam period	15
Total		**100**

Late work policy: Ten percent of the total grade will be deducted per day for late homework. Homework more than four days late will receive a grade of zero. Rescheduling of exams must be discussed with the instructor. If you foresee that you will not be able to make a deadline (e.g., for a religious observance) or need accommodation to allow you to learn, please contact the instructor as soon as possible.

All this said, we all experience challenges. This includes your physical and mental health, illness in your family, the needs of children or elders whom you care for, or any number of other things. **If you find yourself struggling to make a deadline**, please contact the instructor as soon as you are able, and we will be happy to work with you to accommodate. Similarly, if you are concerned that you are falling behind in class, please contact the instructor as soon as you are able so we can work together on a solution.

Grading Scale

Your final grade will be calculated as a percentage according to the table in the Evaluation section above. Below is the lowest final percentage required to achieve a given letter grade. The instructor reserves the right to revise these cutoffs downward (for example, to allow someone getting a final grade of 89% to receive an A-), but the cutoffs will never be revised upward.

Grade	Lowest Final Grade (%)
A+	98
A	92
A-	90
B+	87
B	82
B-	80
C+	77
C	72
C-	70
D+	67
D	62
D-	60

Incompletes

A grade of incomplete (I) will be given only in unusual circumstances. To receive an "I" grade, a written request must be submitted (check with your graduate program advisor about deadlines) and approved by the instructor. The request must describe the circumstances, along with a proposed timeline for completing the course work. Submitting a request does not ensure that an incomplete grade will be granted. If granted, you will be required to fill out and sign an "Incomplete Contract" form that will be turned in with the course grades. Any requests made after the course is completed will not be considered for an incomplete grade.

Academic Guidance in the Event a Student is Quarantined/Isolated

If you become quarantined or isolated at any point in time during the semester, in addition to support from the Protect Purdue Health Center, you will also have access to an Academic Case Manager who can provide you academic support during this time. Your Academic Case Manager can be reached at acmq@purdue.edu and will provide you with general guidelines and resources around communicating with your instructors, be available for academic support, and offer suggestions for how to be successful while learning remotely. Importantly, if you find yourself too sick to progress in the course, notify your academic case manager and notify the instructor via email. We will make arrangements based on your particular situation. The Office of the Dean of Students (odos@purdue.edu) is also available to support you should this situation occur.

Course Topics and Schedule

Our course will cover the topics listed below. Please note that we will be observing Reading Days, and **there will therefore be no class or homework due on March 18 or April 13**.

- Overview, principles, and components of a randomized controlled trial
- Ethical considerations
- Hypothesis testing
- Comparing two groups
- Single factor studies - continuous outcomes
- Model diagnostics
- Hypothesis tests regarding means
- Random effects/multilevel models
- Power calculations
- ANCOVA
- Repeated measures
- Randomized complete block designs
- Factorial designs
- Crossover designs
- Cluster randomized designs
- Survival analysis
- Meta-analysis

Attendance Policy during the COVID-19 Pandemic

Whenever possible, please attend class in person, unless a specific class meeting has been designated as online only (see Brightspace for announcements of class periods that are not offered in person). If you are unable to attend in-person or opt not to do so out of health concerns, please aim to attend synchronously on Zoom. If this is also not possible, please watch the recorded video of our class session soon after it is posted.

It is important that you regularly check Brightspace for readings, homework, and other material. If your access to the internet is inadequate and negatively affecting your ability to engage in class, please let the instructor know as soon as possible.

Students should stay home and contact the Protect Purdue Health Center (765-496-INFO) if they feel ill, have any symptoms associated with COVID-19, or suspect they have been exposed to the virus. In the current context of COVID-19, in-person attendance will not be a factor in the final grades, but the student still needs to inform the instructor of any conflict that can be anticipated and will affect the submission of an assignment. Only the instructor can excuse a student from a course requirement or responsibility. When conflicts can be anticipated, such as for many University-sponsored activities and religious observances, the student should inform the instructor of the situation as far in advance as possible. For unanticipated or emergency conflicts, when advance notification to an instructor is not possible, the student should contact the instructor as soon as possible by email. When the student is unable to make direct contact with the instructor and is unable to leave word with the instructor's department because of circumstances beyond the student's control, and in cases of bereavement, quarantine, or isolation, the student or the student's representative should contact the Office of the Dean of Students via email or phone at 765-494-1747.

Classroom Guidance Regarding Protect Purdue

The Protect Purdue Plan, which includes the Protect Purdue Pledge, is campus policy and as such all members of the Purdue community must comply with the required health and safety guidelines. Required behaviors in this class include: staying home and contacting the Protect Purdue Health Center (765-496-INFO) if you feel ill or know you have been exposed to the virus, wearing a mask in classrooms and campus buildings at all times (e.g., no eating/drinking in the classroom), disinfecting desk/workspace prior to and after use, maintaining proper social distancing with peers and instructors (including when entering/exiting classrooms), refraining from moving furniture, avoiding shared use of personal items, maintaining robust hygiene (e.g., handwashing, disposal of tissues) prior to, during, and after class, and following all safety directions from the instructor.

Students who are not engaging in these behaviors (e.g., wearing a mask) will be offered the opportunity to comply. If non-compliance continues, possible results include instructors asking the student to leave class and instructors dismissing the whole class. Students who do not comply with the required health behaviors are violating the University Code of Conduct and will be reported to the Dean of Students Office with sanctions ranging from educational requirements to dismissal from the university.

Any student who has substantial reason to believe that another person in a campus room (e.g., classroom) is threatening the safety of others by not complying (e.g., not wearing a mask) may leave the room without consequence. The student is encouraged to report the behavior to and

discuss next steps with their instructor. Students also have the option of reporting the behavior to the Office of Student Rights and Responsibilities. See also Purdue University Bill of Student Rights.

Academic Integrity

Academic integrity is one of the highest values that Purdue University holds. Purdue's student guide for academic integrity is available to you. Incidents of academic misconduct in this course will be referred to the Office of Student Rights and Responsibilities (OSRR) for review at the university level. Students can also report issues of academic integrity that they observe, and may do so anonymously, to the OSRR by calling 765-494-8778 or emailing integrity@purdue.edu.

Purdue's Honor Pledge: *"As a boilermaker pursuing academic excellence, I pledge to be honest and true in all that I do. Accountable together - we are Purdue."*

Nondiscrimination Statement

Purdue University is committed to maintaining a community that recognizes and values the inherent worth and dignity of every person; fosters tolerance, sensitivity, understanding, and mutual respect among its members; and encourages each individual to strive to reach their own potential. In pursuit of its goal of academic excellence, the University seeks to develop and nurture diversity. The University believes that diversity among its many members strengthens the institution, stimulates creativity, promotes the exchange of ideas, and enriches campus life.

Diversity and Inclusion Statement

In our discussions, structured and unstructured, we will explore a variety of challenging issues, which can help us enhance our understanding of different experiences and perspectives. Everyone should remember the following points:
- We are all in the process of learning about others and their experiences. Please speak with the instructor, anonymously if needed, if something has made you uncomfortable.
- Intention and impact are not always aligned, and we should respect the impact something may have on someone even if it was not the speaker's intention.
- We all come to the class with a variety of experiences and a range of expertise. We should respect these in others while critically examining them in ourselves.

Accessibility

Purdue University strives to make learning experiences as accessible as possible. If you anticipate or experience physical or academic barriers based on disability, you are welcome to let the instructor know so that we can discuss options. You are also encouraged to contact the Disability Resource Center at drc@purdue.edu or by phone: 765-494-1247.

Mental Health Statement

If you find yourself beginning to feel some stress, anxiety, and/or feeling slightly overwhelmed, try WellTrack**.** Sign in and find information and tools available to you at any time.

If you need support and information about options and resources, please contact or see the Office of the Dean of Students. Call 765-494-1747. Hours of operation are Monday to Friday, 8 am - 5 pm.

If you find yourself struggling to find a healthy balance between academics, social life, stress, etc., sign up for free one-on-one virtual or in-person sessions with a Purdue Wellness Coach at RecWell. Student coaches can help you navigate through barriers and challenges toward your goals throughout the semester. Sign up is completely free and can be done on BoilerConnect. If you have any questions, please contact Purdue Wellness at evans240@purdue.edu.

If you're struggling and need mental health services: Purdue University is committed to advancing the mental health and well-being of its students. If you or someone you know is feeling overwhelmed, depressed, and/or in need of mental health support, services are available. For help, such individuals should contact Counseling and Psychological Services (CAPS) at 765-494-6995 during and after hours, on weekends and holidays, or by going to the CAPS office of the second floor of the Purdue University Student Health Center (PUSH) during business hours.

Basic Needs Security

Any student who faces challenges securing their food or housing is urged to contact the Dean of Students for support. There is no appointment needed and Student Support Services is available to serve students from 8 am to 5 pm, Monday through Friday. Considering the significant disruptions caused by the current COVID-19 global crisis, students may submit requests for emergency funds. Click here for details and the request form.

Emergency Preparation

In the event of a major campus emergency, course requirements, deadlines, and grading percentages are subject to changes that may be necessitated by a revised semester calendar or other circumstances beyond the instructor's control. Relevant changes to this course will be posted on Brightspace or can be obtained by contacting the instructor or TA via email. You are expected to read your @purdue.edu email on a frequent basis.

Copyright

As we conduct our class in hybrid format, with all materials available online, please note that students may not copy, reproduce, or post to any other outlet (e.g., YouTube, Facebook, or other open media sources or websites) any work in which they are not the sole or joint author or for which they have not obtained the permission of the author(s).

Netiquette

Your instructor and fellow students wish to foster a safe online learning environment. All opinions and experiences, no matter how different or controversial they may be perceived, must be respected in the tolerant spirit of academic discourse. You are encouraged to comment, question, or critique an idea, but you are not to attack an individual. Our differences will add richness to this learning experience. Please consider that sarcasm and humor can be misconstrued in online interactions and generate unintended disruptions. Working as a community of learners, we can build a polite and respectful course ambience. Please read the Netiquette rules for this course:

- Do not dominate any discussion. Give other students the opportunity to join in the discussion.
- Do not use offensive language. Present ideas appropriately.
- Be cautious in using Internet language. For example, do not capitalize all letters since this suggests shouting.
- Avoid using vernacular and/or slang language. This could possibly lead to misinterpretation.
- Keep an open mind and be willing to express even your minority opinion.
- Think and edit before you push the "Send" button.
- Do not hesitate to ask for feedback.

Course Evaluation

During the last two weeks of the semester, you will be provided with an opportunity to give feedback on this course and your instructors. Purdue uses an online course evaluation system. You will receive an official email from evaluation administrators with a link to the online evaluation site. You will have up to 10 days to complete this evaluation. We value your feedback and will use it to improve the course in future semesters.

Disclaimer

This syllabus is subject to change. All changes will be posted as announcements on Brightspace.