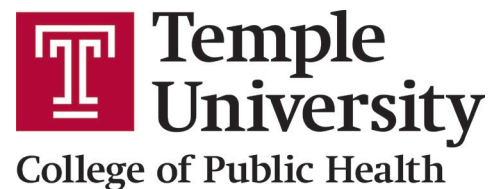


Clinical Research Methods in Public Health

EPBI 8301, Section 001
Spring 2023
3 Credits



Instructor Information

Instructor: Jingwei Wu, Ph.D.
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Telephone: 317-679-8250

Office Location: Ritter Annex, Room 903

Office Hours: Tue 12:00-2:00pm, Wed 1:00-2:00pm,
or by appointment (Zoom office hour will also be provided per request)

<https://temple.zoom.us/j/3076002699>

Course Day(s): Wednesday, Jan 17th to May 10th

Course Time: 5:30pm-8:00pm

Course Location: Ritter Hall, Room 100

Synchronous (In-Person Classroom) Session(s) [Ritter Hall, Room 100]:

Wednesday, January 18: 5:30-8:00 pm, EST
Wednesday, January 25: 5:30-8:00 pm, EST
Wednesday, February 1: 5:30-8:00 pm, EST
Wednesday, February 8: 5:30-8:00 pm, EST
Wednesday, February 15: 5:30-8:00 pm, EST
Wednesday, February 22: 5:30-8:00 pm, EST
Wednesday, March 1: 5:30-8:00 pm, EST
Wednesday, March 15: 5:30-8:00 pm, EST
Wednesday, March 22: 5:30-8:00 pm, EST
Wednesday, March 29: 5:30-8:00 pm, EST
Wednesday, April 5: 5:30-8:00 pm, EST
Wednesday, April 12: 5:30-8:00 pm, EST
Wednesday, April 19: 5:30-8:00 pm, EST
Wednesday, April 26: 5:30-8:00 pm, EST

Course Prerequisites or Co-Requisites

One graduate-level statistics/biostatistics course with a minimum grade of B-, or permission of instructor.

Course Description

This course provides an introduction to the core topics in clinical research. Beginning with practical issues in starting and advancing in a career in clinical investigation, the course proceeds to cover diagnosis and treatment studies, research on prognostic and causal risk factors, special types of study design and analyses, principles of measurement in human subjects, and studies using secondary databases. This course will be an elective class for all students enrolled in the Master of Science in Public Health, Clinical research and Translational medicine as well as the Doctor of Philosophy in Epidemiology. This graduate level course is principally aimed at health care professionals, not limited to the field of public health, usually with a doctoral level degree relevant to their clinical discipline, who desire advanced knowledge and skills in evaluating, designing and implementing clinical research studies.

The specific topics covered are outlined in the Course Schedule on the last page of this syllabus.

Course Format/Instructional Methods (How the Course Will be Taught)

This is a hybrid class that utilizes both in-person classroom sessions and asynchronous course work. The rationale for the hybrid approach is that the asynchronous activities allow students more time to research additional information (using course materials and outside readings/materials) to support their class contributions, as well as spaces for individual reflection. The in-person classroom sessions allow the instructor and students to engage in live discussions, raising and answering questions that stem from the course materials.

We will meet in-person on every Wednesday, 5:30pm-8:00pm at Ritter Hall, Room 100.

Course Expectations for Student Success

I am here to support your learning goals in this course, and I want to see everyone succeed. I encourage you to use all available resources, including advisors, teaching assistant, departmental graduate student tutor, the Writing Center and Library Resources to assist you with the course.

On average, over the semester, this course will require approximately 9 hours of your time per week. Please plan to spend approximately 6 hours each week reading materials and completing assignments. Additionally, please plan to spend an additional 3 hours each week for the scheduled class meeting time. These expectations are based on the premise that 1) this course is a 3 credit course that meets for 2.5 hours each week for 15 weeks and 2) Temple's policy on credit hours states that 1 semester credit is equivalent to 1 hour (50 minutes) of faculty instruction time per week for 16 weeks (inclusive of exam week) AND a minimum of 2 hours of out-of-class student work.

Statement on Diversity and Inclusion

The College of Public Health supports and encourages diversity and inclusion. I am committed to the principle of universal learning which means that I will do all that I can to make our classrooms, our virtual meetings and our interactions as inclusive as possible. To support universal learning, I will promote an environment of mutual respect, civility in our interactions and the ability to listen and observe others carefully – I expect that all participants in the class will work towards the same goal.

You have the right to be addressed by your preferred name and personal pronouns. Sharing your preferred pronouns publicly is one way we can all honor each other's preferences. I will address you how you wish to be addressed.

You have the right to full access to all course materials and you are welcome to translate the course materials (for example, you are welcome to use <https://translate.google.com/?sl=auto&tl=en&op=docs>). If you feel any form of harassment or discrimination, please contact our CPH and SW Equal Opportunity Ombudspersons. <https://cph.temple.edu/academics/academic-advising-and-student-resources>

If you need accommodations based on a documented disability, please contact Disability Resources and Services in Ritter Annex 100, 215-204-1280 or 215-204-1786 (TTY) or drs@temple.edu. Please reach out to me as soon as possible to discuss your needs and to share any documentation from DRS so that we can appropriately plan for success. (Accommodations are not retroactive). Please bear in mind that COVID-19 may result in a need for new or additional accommodations.

Course Technology Requirements

For all students who registered this course, you will need to check Canvas weekly or check email for regular announcements. You are required to comply with Temple University's Computer and Security Policy at <https://secretary.temple.edu/sites/secretary/files/policies/04.71.11.pdf>.

You are also expected to adhere to the Laptop Requirement:

<https://cphapps.temple.edu/wiki/it/student/laptop>.

Limited resources are available for students who do not have the technology they need for class. Students with educational technology needs, including no computer or camera or insufficient Wi-Fi access, should submit a Student Technology Assistance Application located in TUPortal and linked from the Dean of Students Support and Resources webpage. On-campus computer labs have resumed normal operations and are available for student use.

E-mail

To facilitate communication, the university requires you to have an e-mail account ending in @temple.edu (<https://secretary.temple.edu/sites/secretary/files/policies/04.74.11.pdf>). During the semester, I will try to return your e-mail within 36 hours unless I am out of the office or the university is closed. E-mails sent after noon on Fridays will generally not be returned until Monday—please plan accordingly. Please remember that e-mails regarding technological questions should be directed to Temple’s Help Desk at help@temple.edu

Course Materials

There are **two required textbooks** for this course. Both books are excellent resources for those desiring readings that will complement and expand upon topics covered in the course.

Good news: your textbook for this class is available for free online! Temple University Library has licensed textbooks (both two textbooks are online-available through: EBSCOhost Academic eBook Collection (North America)).

Designing Clinical Research, Fourth Edition. Hulley SB, Cummings SR, Browner WS, et al. Philadelphia: Lippincott, Williams & Wilkins, 2013.

Clinical Epidemiology: The Essentials, Fifth Edition. Fletcher RH, Fletcher SW, Fletcher GS. Philadelphia: Lippincott, Williams & Wilkins, 2014.

Course Objectives and Competencies

OVERALL COURSE OBJECTIVES

- Apply the practical skills needed to advance in clinical investigation, including starting and completing research projects, working with mentors, and developing a research career.
- Design and evaluate studies on diagnostic tests and calculate key operating characteristics such as sensitivity, specificity, predictive value, likelihood ratios, and ROC curves.
- Evaluate studies on therapy -- both treatment and compliance – and calculate key variables such as absolute risk reduction, relative risk reduction, and number needed to treat.
- Design and evaluate studies on risk, including prognosis and causation.
- Evaluate and implement other study designs, including chart review, case-control, and cohort studies.
- A more in-depth coverage of treatment studies – Clinical Trials.
- Interpret psychometric concepts in research reports and apply special measurement techniques in questionnaire design, and interpreting inter-observer agreement.
- Apply concepts learned in the course to a class presentation.

The following table is intended to be a pathway to guide you through the course so that you can see the connections between the course learning objectives and how you will be assessed.

#	LEARNING OBJECTIVE	DEGREE COMPETENCIES ADDRESSED	DIRECT/INDIRECT ASSESSMENT TOOL
1.	Apply the practical skills needed to advance in clinical investigation, including starting and completing research projects, working with mentors, and developing a research career	Apply epidemiological methods to settings and situations in public health practice Apply negotiation and mediation skills to address organizational or community challenges	Weekly homework #8, Final Exam
2.	Design and evaluate studies on diagnostic tests and calculate key operating characteristics such as sensitivity, specificity, predictive value, likelihood ratios, and ROC curves.	Apply awareness of cultural values and practices to the design, implementation or critique of public health policies or programs	Weekly homework #1, #3, Final Exam, Students Project
3.	Evaluate studies on therapy -- both treatment and compliance – and calculate key variables such as absolute risk reduction, relative risk reduction, and number needed to treat.	Analyze quantitative and qualitative data using biostatistics, informatics, computer-based programming and software, as appropriate	Weekly homework #2, Final Exam, Students Project
4.	Design and evaluate studies on risk, including prognosis and causation. Evaluate and implement other study designs, including chart review, case-control, and cohort studies.	Analyze quantitative and qualitative data using biostatistics, informatics, computer-based programming and software, as appropriate	Weekly homework #4, #5, #6 Final Exam, Students Project
5.	A more in-depth coverage of treatment studies – Clinical Trials.	Select methods to evaluate public health programs	Weekly homework #8, Final Exam, Students Project
6.	Interpret psychometric concepts in research reports and apply special measurement techniques in questionnaire design, and interpreting inter-observer agreement.	Select quantitative and qualitative data collection methods appropriate for a given public health context	Weekly homework #7, Final Exam, Students Project
7.	Apply concepts learned in the course to a class presentation.	Communicate audience-appropriate (i.e., non-academic, non-peer audience) public health content, both in writing and through oral presentation Interpret results of data analysis for public health research, policy or practice	Final Exam, Students Project

Required Course Assignments

Some class sessions will have advance reading assignments from journal articles or handouts. A few sessions may have problems, cases or questions to complete in advance of the class or, in some instances, during the class session itself.

TAKE HOME ASSIGNMENTS

Take home assignment will typically be due 1-2 weeks after it was assigned (due date noted on schedule). Must be submitted on time (no later than 8:00pm on due date) via Canvas for full credit. Late submissions (before noon of next day) may receive a 20% deduction grade score on the assignments. Any late submission after noon time of next day will not be graded, and no make-up assignment is allowed. Exceptions will be made if PRIOR arrangements have been made with the instructor or under extraordinary circumstances. Answer keys for each weekly take home assignments will be posted at noon of next day. Students should expect feedback on graded assignments within 7 weekdays of the due date.

Take Home Assignments for Clinical Research Methods and % of Final Grade (Total = 50%)			
1. Study Design	5.0%	5. Causation and Case-Control	10.0%
2. Therapy (Simple Math)	5.0%	6. Risk Factor	8.0%
3. Diagnostic Tests	6.0%	7. Inter-observer Agreement (Kappa)	6.0%
4. Prognosis	10.0%	8. CITI Certificate*	5.0%

* CITI Certificate Assignment:

The Temple University utilizes The Collaborative Institutional Training Initiative (CITI) Program to provide research ethics education to the research community. The CITI program offers both initial and refresher courses covering human subjects research. All key research personnel engaged in Human Research at Temple University or affiliated sites must complete the online CITI program. Therefore, for this assignment, you are given time to finish these selected CITI certificates:

1. Please access the CITI training program here: <https://www.citiprogram.org>
2. Please make sure you have created your own CITI profiles after you logged in.
3. For this assignment, please add the following CITI courses and complete these training courses:
 - a. Biomedical Research (0.5 points)
 - b. CITI Good Clinical Practice (1 points)
 - c. Group 3: Students and Instructors (0.5 points)
 - d. Practice Runs Training (0.5 points)
 - e. Research with data or laboratory specimens- ONLY (0.5 points)
 - f. Responsible Conduct of Research (RCR) (0.5 points)
 - g. Social/Behavioral Research Course (1 points)
 - h. Students conducting no more than minimal risk research (0.5 points)
4. Please finish these training courses and upload both "completion report" and "completion certificate" by the assignment due date to Canvas.

FINAL EXAMS

There will be an open-book, online final exam. Student needs to complete the exam independently within 3 days. Any conversations and discussions with other students during the exam are prohibited. The Final is cumulative - will cover all topics from the semester. The exam dates are on the course schedule. Students should expect feedback on graded exams within 7 weekdays of the due date.

If you need to be absent for any reason, you must inform the instructor in advance (not afterwards); otherwise you get a zero for the exam. A make-up exam may be possible, but that will depend on verifiable reasons beyond your control for missing the exam and whether you qualify for an "Incomplete" as your course grade.

CLASS PRESENTATION

1. Find an article in the literature (e.g, through Ovid, PubMed, Google Scholar, etc.) that illustrates or applies something related to one of the lectures or sessions that have already been covered in the course. You may select something because it is ...
 - a. Relevant to your research focus
 - b. Relevant to your clinical practice
 - c. Something you have found that is interesting in terms of research methodology (e.g., something in course that you wanted to find out more about or apply). It could be weakness(s) in the article that you have an idea to improve, or it could be strength(s) that you want to highlight.
 - d. Something of teaching value for the class that reinforces or applies a topic we have covered in the course
 - e. A topic we have not covered in the course that you would like to share
2. Each presentation will be allotted a 15-minute time block, with the expectation that at least 5 minutes or more involves class interaction, either with questions, an exercise, or something else that involves the class.
3. The purpose is not to be complete, but to focus selectively on one or a few aspects of the article only. The focus of your presentation should not be on the particular clinical area, but on something that illustrates one or two principles related to clinical research methodology.
4. The grading will be evaluated by organization & clarify; time management; teaching style (including handouts & audiovisuals) and scientifically sound (including application of clinical research principles).

More detailed presentation instructions will be provided during the lecture.

Course Grading

Take Home Assignment	55%
Course Project	10%
Attendance	5%
Final Exam	30%

Grading Scale

93-100 A	87-89 B+	77-79 C+	67-69 D+	0-59 F
90-92 A-	83-86 B	73-76 C	63-66 D	
	80-82 B-	70-72 C-	60-62 D-	

Each assignment will receive a numerical grade and be weighted in the calculation of a final numerical grade as indicated above.

- Bonus points are given in the final exam
- Final numerical grade is rounded to the nearest integer
- Please do not refer to the letter grade in Canvas as the default grading scales in Canvas does not reflect the weighting factors based on the chart below.

Assignments will not be accepted after the due date. If there are conflicts or medical reasons why an assignment is submitted late, the student must raise these concerns before the assignment due date and arrangements may be made on a case-by-case basis for a late submission. All submissions after the due date without prior notice and faculty approval, unless under extenuating circumstances will be given a "0".

Attendance Protocols and Your Health

You are expected to attend and to participate actively in at least 80% of the class sessions. For this semester, there are 15 in-person classroom sessions (including two exam dates). Thus, if there are more than 3 absences for these 15 sessions, there will be a decrement in the attendance portion of the

grade. Attendance will include regularly attending class, showing up promptly for class, and participating in class discussions. Each absence after missing 3 of the 15 sessions leads to a 10% (0.5 points) decrease in the proportion of attendance grade.

Arriving habitually late or leaving early during in-class sessions may be counted as an absence. Not participating in assigned discussion threads may also be considered an absence.

1. You are expected to attend class, participate in group activities, quizzes, in-class discussions, online discussion boards, and complete all exams and assignments. The instructor should be notified of absences in advance (when possible) so arrangements can be made for any make-up of missed material.
2. You are expected to review reading materials before each lecture and be prepared for in-class discussions.
3. You are expected to contact the instructor with concerns, ideas, or for clarification of class material.
4. All assignments must be handed in on the date and time prescribed. Late assignments will not be accepted unless previously arranged and agreed to by you and the instructor or under extenuating circumstances. (Note- 1 minute late is considered late, so plan accordingly to submit assignments and projects on time in Canvas).

To achieve course learning goals, you must attend in-person classes, and/or participate in classes or portions of classes that are taught remotely, to the extent that they are able. However, if you feel unwell or if you are under quarantine because you have been exposed to Covid-19 or tested positive for it, you should not come to campus or attend in-person classes or activities. It is your responsibility to contact your instructors to create a plan for participation and engagement in the course as soon as they can do so, and to plan to complete all assignments in a timely fashion when illness delays their completion.

It is your right to observe religious holidays without negative consequences within the course. Please reach out to discuss with your instructor at the start of the semester so that deadlines can be reviewed in advance of the religious observation. You will still be held responsible for course content and any assignments, but you will not lose points for attendance and participation that day.

Course Minimum Grade

The College of Public Health requires a minimum grade of B- in all required courses (not electives) and a 3.0 minimum GPA to graduate. For further question, please speak with your graduate program director.

General Policies

All University (www.temple.edu/grad/policies/index.htm) and College of Public Health policies will be upheld. The Graduate Student Handbooks for the College of Public Health details College expectations: (<https://cph.temple.edu/student-handbooks>).

Temple and Covid-19

Temple University's motto is Perseverance Conquers, and we will meet the challenges of the COVID pandemic with flexibility and resilience. The university has made plans for multiple eventualities. Working together as a community to deliver a meaningful learning experience is a responsibility we all share: we're in this together so we can be together. For the most current information on Covid-related plans and policies, please refer to <https://www.temple.edu/coronavirus>

Incomplete

You will be eligible for a grade of “Incomplete” only if he/she: 1) has completed at least 51% of the work at a passing level, 2) is unable to complete the work for a serious reason beyond his or her control, and 3) files a signed agreement with the instructor outlining the work to be completed and the timeframe in which that work will be completed. You are responsible for initiating this process and all incomplete forms must be sent to the Associate Dean for Academic Affairs prior to the start of study days in that semester. (Please refer to the following link for more details:

<http://policies.temple.edu/PDF/41.pdf>).

Withdrawal from the Course

If you wishes to withdraw from a course, it is your responsibility to meet the deadline for the last day to withdraw within the current semester (www.temple.edu/registrar/documents/calendars/). Please consult the University policy on withdrawals (<http://policies.temple.edu/PDF/337.pdf>).

Statement on Academic Rights & Responsibilities

Freedom to teach and freedom to learn are inseparable facets of academic freedom. Please refer to the university policy on Student and Faculty Academic Rights and Responsibilities (Policy #03.70.02), available at: <http://policies.temple.edu/PDF/99.pdf>.

Academic Honesty

According to the University Student Code of Conduct, you must not commit, attempt to commit, aid, encourage, facilitate, or solicit the commission of academic dishonesty and impropriety including plagiarism, academic cheating, and selling lecture notes or other information provided by an instructor without the instructor’s authorization. Violations may result in failing the assignment and/or failing the course, and/or other sanctions as enumerated in the University Code of Conduct, which can be accessed at <http://studentconduct.temple.edu/policies>.

The Department of Epidemiology and Biostatistics takes issues of academic honesty violations seriously. On any assignment (e.g. quiz, test, written assignment, presentation) where there are suspected violations, the faculty reserves the right to give a zero on that assignment and will inform the Department of those violations. For specific guidance about what materials are acceptable to use on assignment, see the assignment description.

Penalties for academic honesty violations could include:

- Zero on the assignment
- Failing the course
- Other sanctions as outlined in the University Code of Conduct

A faculty member who suspects academic impropriety has occurred, will report the incident immediately to the Department Program Director. Academic impropriety on assignments <10% will result in a zero (0) on the assignment. Issues on assignments worth >10% of the grade will be escalated to the Departmental Academic Honesty Committee for evaluation. The committee will notify you in writing within 3 business days from when the offense was reported, and you will have 3 business days to respond in writing to the offense and organize a face to face meeting with the committee (at least 2 members will be present) and the faculty member to decide the best course of action (a zero on the assignment/ failing the course or other sanctions as outlined in the University Code of Conduct). The offense will be documented in your file and shared with faculty members across the department to prevent future offenses.

Avoiding Plagiarism

You are expected to meet standards of academic honesty, which includes proper citation of sources, use of quotations when appropriate, and proper paraphrasing and putting writing into your own words when not in quotations. If you have questions on whether you have cited appropriately, please visit the writing center (<https://www.temple.edu/class/programs/writing/index.html>).

Faculty in the Department of Epidemiology and Biostatistics regularly use Turnitin, software linked through Canvas that evaluates student products for plagiarism. In Canvas, the 'Turnitin' score provides guidance but it does not highlight all incorrect citations. You should strive to have a 'Turnitin' score of less than 20%, however this is just a guide and the total score itself is not indicative of the presence or absence of plagiarism.

See the following websites for additional information about proper paraphrasing and citation:

<https://writing.wisc.edu/handbook/assignments/quoting/sources/>

<https://columbiacollege-ca.libguides.com/apa/paraphrase>

https://owl.purdue.edu/owl/research_and_citation/apa_style/apa_formatting_and_style_guide/in_text_citations_the_basics.html

<https://www.plagiarism.org/article/how-to-paraphrase>

See the Temple Library Resources section in the Syllabus for additional information.

Counseling Services

As the instructor of the course, I recognize that you may experience mental health challenges at times throughout the semester. I am committed to creating an inclusive and welcoming classroom space and encourage you to access resources provided by the university or speak with me privately if you need support connecting with appropriate resources. Here are some of the campus resources to assist you: Tuttleman Counseling Services (TCS) – <http://counseling.temple.edu> - (available for group and individual therapy, Resiliency Resource Center, drop-in groups, and referral services to students seeking long-term care or support outside of Pennsylvania) and the Wellness Resource Center (WRC) – <http://wellness.temple.edu> (peer-led workshops, campus-wide events, and wellness consultations to connect students to resources..

Sexual Misconduct

Temple University is committed to providing a learning and working environment that emphasizes the dignity and worth of every member of its community, free from discriminatory conduct. Sexual harassment in any form or context is contrary to this commitment and will not be tolerated. Please refer to the University policy on sexual harassment at:

<https://secretary.temple.edu/sites/secretary/files/policies/04.82.02.pdf>. Additional resources related to sexual harassment and ways in which to report an incident can be found at:

<http://sexualmisconduct.temple.edu/>

Permission to Record

Please speak with the instructor in advance of recording a class to be respectful of classmates. Recording of lectures as a disability accommodation is permitted. You are not permitted to copy, publish, or redistribute any recordings without express permission from the instructor and any students recorded; distribution without permission may be a violation of educational privacy laws (FERPA) and copyright laws. Instructors may record live/synchronous class sessions to share through Canvas for students unable to attend class or as a study tool. The instructor will inform the class in advance and can pause the recording, upon request, if sensitive topics are being discussed. All instructor recordings are property of Temple University.

Netiquette Statement

It is important to foster a respectful and productive online learning environment. Our differences, some of which are outlined in the University's nondiscrimination statement, add richness to this learning experience. All opinions/experiences must be respected in the spirit of academic discourse. Treat your classmates and instructor with respect in all communication, class activities, and meetings; do not attack any individual. Avoid the use of profanity, sarcasm, slang, and the use of all capital letters in discussion threads, as these forms of communication, may be disruptive.

Library Resources

You may request appointments with Librarians, who can provide targeted assistance at all stages of your project, including exploring a topic, test-driving Temple's academic research tools, and identifying and citing sources. A Subject Librarian has particular skills to focus on your major or the class you are taking. If you don't know your Subject Librarian feel free to reach out to any librarian who will help you make that connection. Schedule appointments individually or in small groups. Easy access to program specific resources may be found in Library research guides <http://guides.temple.edu/hsl>.

Continuity of Instruction in Event of Emergency

Please register for the TUAAlert System (<https://safety.temple.edu/get-educated/tualerts/how-to-receive-sms-tualerts>) to be made aware of University closures due to weather or other emergency situations and follow all additional university-wide emergency instruction. In the event of an emergency, class materials/instructions will be provided in a web-based format via Canvas or zoom. Students registered for the class will be alerted to any other modifications from the instructor via email.

Course Schedule

Jan. 30th **Last day to drop the course**
May. 1st **Last day to withdraw from the course**

Course schedule below may be subject to change with advanced written notification.

Date	Topics	Assignments
Week 1 (1/18)	Course Introduction <ul style="list-style-type: none"> • Warm-up introduction • Course overview Getting Started in Research <ul style="list-style-type: none"> • Highlight practical issues from readings and personal experiences • Discuss any challenges that you have had or anticipate having while conducting clinical research 	
Week 2 (1/25)	Anatomy & Physiology of Clinical Research <ul style="list-style-type: none"> • Understand clinical research from two viewpoints: anatomy and physiology • Practice exercise: Outline of a Study 	Take Home Assignment 1 DUE: 2/7
Week 3 (2/1)	Deciding on the Best Therapy <ul style="list-style-type: none"> • Understand decision for best therapy from two approaches: quantitative and qualitative • Practice exercise: ARR, RRR and NNT 	Take Home Assignment 2 DUE: 2/14
Week 4 (2/8)	Diagnostic Tests <ul style="list-style-type: none"> • Familiar with basic principles when interpreting diagnostic tests • Practice exercise: SE, SP, PPV, NPV, +LR and -LR 	Take Home Assignment 3 DUE: 2/21
Week 5 (2/15)	Prognosis & Cohort Studies <ul style="list-style-type: none"> • Understand strength and limitations for prognosis and cohort study • Practice exercise: prospective cohort study and retrospective cohort study (recruitment method, exposure, outcome, statistical analysis plan, strength, limitation) 	Take Home Assignment 4 DUE: 2/28
Week 6 (2/22)	Case-Control Studies <ul style="list-style-type: none"> • Understand strength and limitations for causation and case-control study • Practice exercise: case-control study (recruitment method, exposure, outcome, statistical analysis plan, strength, limitation) 	Take Home Assignment 5 DUE: 3/14
Week 7 (3/1)	Chart Review Studies <ul style="list-style-type: none"> • Understand issues and best practices for chart review study 	Take Home Assignment 6 DUE: 3/21
Week 7 (3/8)	SPRING BREAK, NO CLASS	
Week 9 (3/15)	Questionnaire Design Interobserver Agreement and other Reliability Types <ul style="list-style-type: none"> • Understand issues and principles of designing good questionnaires • Review highlights from selected readings. Note: This can be fairly technical information so we will also review in detail during class • Learn how to do simple Kappa calculation when there are 2 observers • Be familiar with weighted Kappa and Kappa with more than 2 observations 	Take Home Assignment 7 DUE: 3/28
Week 10 (3/22)	Clinical Trial 1 <ul style="list-style-type: none"> • Understand issues and principles of designing a randomized blinded trial 	Take Home Assignment 8 DUE: 4/18

Week 11 (3/29)	Clinical Trial 2 • Understand additional topics of designing a randomized blinded trial	
Week 12 (4/5)	Clinical Trial 3 • Understand additional topics of alternative clinical trial designs and implementation issues	
Week 13 (4/12)	Sample Size • Understand critical values for determining sample sizes for different types of variables and how to calculate simple sample size estimates via online calculator	
Week 14 (4/19)	Scientific Presentation • Presentation skills	
Week 15 (4/26)	Student Presentations	Student Presentation DUE 4/26
Week 16 (5/3)	FINAL EXAM (Online, Open Book)	Final Exam DUE: 5/5