

**Department of Epidemiology and Biostatistics**  
**Epidemiology 9566S**  
Clinical Trials

**Lecture:**

Tuesday 9:00 am - 10:20 am, K116  
Thursday 9:00 am - 10:20 am, K116

**Instructor: Neil Klar**

**Office Hours:** By appointment

**E-mail:** [nklar@uwo.ca](mailto:nklar@uwo.ca)

**Phone Extension:** 86275

## Course Information

Graduate Pre-requisites: Biostatistics 3110B

Unless you have either the requisites for this course or written special permission to enroll in it, you may be removed from this course and it will be deleted from your record. Graduate students may do so through the Graduate Chair. This decision may not be appealed. You will receive no adjustment to your fees in the event that you are dropped from a course for failing to have the necessary prerequisites.

## Course Syllabus

The purpose of this course is to introduce students to clinical trials design and analysis.

### Lecture Weeks

1	Jan 7	Course introduction
2	Jan. 14	Clinical trials history and ethics
3	Jan. 21	Study question, population, basic designs
4	Jan. 28	Randomization and blinding
5	Feb. 4	Sample size estimation
6	Feb. 11	Baseline assessment, recruitment and data collection
7	Feb. 17	Work on project

## Course Materials

Freedman LM, Furberg DC, DeMets DL, et al. *Fundamentals of Clinical Trials* 5th Edition; Springer, 2015.

## Methods of Evaluation

The final grade for the course will be allocated as follows:

**Assignments: 30%**

**Project: 60%**

**Class participation: 10%**

## **Policy on Accommodation for Medical and Non-Medical Absences**

All non-medical absences must be approved in advance. In the case of an unexpected absence on compassionate grounds, documentation may be requested. If documentation is required for either medical or non-medical academic accommodation, then such documentation must be submitted by the student to the instructor.

## **Statement on Academic Offences**

Scholastic offences are taken seriously and students are directed to read the appropriate policy, specifically, the definition of what constitutes a Scholastic Offence:

[https://www.uwo.ca/univsec/pdf/academic\\_policies/appeals/scholastic\\_discipline\\_grad.pdf](https://www.uwo.ca/univsec/pdf/academic_policies/appeals/scholastic_discipline_grad.pdf)

All required papers may be subject to submission for textual similarity review to the commercial plagiarism detection software under license to the University for the detection of plagiarism. All papers submitted for such checking will be included as source documents in the reference database for the purpose of detecting plagiarism of papers subsequently submitted to the system. Use of the service is subject to the licensing agreement, currently between The University of Western Ontario and Turnitin.com (<http://www.turnitin.com>).

Computer-marked multiple-choice tests and/or exams may be subject to submission for similarity review by software that will check for unusual coincidences in answer patterns that may indicate cheating.

## **Support Services**

As part of a successful student experience at Western, we encourage students to make their health and wellness a priority. Western provides several on campus health-related services to help you achieve optimum health and engage in healthy living while pursuing your degree. For example, to support physical activity, all students, as part of their registration, receive membership in Western's Campus Recreation Centre. Numerous cultural events are offered throughout the year. Please check out the Faculty of Music web page <http://www.music.uwo.ca/>, and our own McIntosh Gallery <http://www.mcintoshgallery.ca/>. Information regarding health- and wellness-related services available to students may be found at <http://www.health.uwo.ca/>

Registrarial Services: <http://www.registrar.uwo.ca>

USC Student Support Services: <http://westernusc.ca/services/>

Student Development Centre: <http://www.sdc.uwo.ca/>

SGPS Life & Community web page: [https://grad.uwo.ca/life\\_community/self/index.html](https://grad.uwo.ca/life_community/self/index.html)

Students seeking help regarding mental health concerns are advised to speak to someone they feel comfortable confiding in, such as their faculty supervisor, their program director (graduate or undergraduate chair), or other relevant administrators in their unit.

Students who are in emotional/mental distress should refer to Mental Health@Western <http://www.uwo.ca/uwocom/mentalhealth/> for a complete list of options about how to obtain help.

## **Student Accessibility Services**

Western is committed to achieving barrier-free accessibility for all its members, including graduate students. As part of this commitment, Western provides a variety of services devoted to promoting, advocating, and accommodating persons with disabilities in their respective graduate program.

Graduate students with disabilities (for example, chronic illnesses, mental health conditions, mobility impairments) are encouraged to register with Student Accessibility Services, a confidential service designed to support graduate and undergraduate students through their academic program. With the appropriate documentation, the student will work with both SAS and their graduate programs (normally their Graduate Chair and/or Course instructor) to ensure that appropriate academic accommodations to program requirements are arranged. These accommodations include individual counselling, alternative formatted literature, accessible campus transportation, learning strategy instruction, writing exams and assistive technology instruction.

## **Department & Faculty Offices**

The Epidemiology & Biostatistics main office is located in K201 in the Kresge Building on Main campus.

## **Technology Requirements**

You are responsible for all required course materials and announcements posted to the course's OWL website. Please ensure after the first class that when you log in you are able to access the course site. A copy of the course outline will be available on both OWL and the departmental website.

## **Cell Phone and Electronic Device Policy**

The Schulich School of Medicine & Dentistry is committed to ensuring that testing and evaluation are undertaken fairly across all our departments and programs. For all tests and exams, it is the policy of the School and the Department of Epidemiology and Biostatistics that any electronic devices, i.e., cell phones, tablets, cameras, or iPod are strictly prohibited. These devices **MUST** be left either at home or with the student's bag/jacket at the front of the room and **MUST NOT** be at the test/exam desk or in the individual's pocket.

Any student found with one of these prohibited devices will receive a grade of zero on the test or exam. Non-programmable calculators are only allowed when indicated by the instructor. The Department of Epidemiology and Biostatistics is not responsible for stolen/lost or broken devices.