

2021: EPID 810 – Controlled Clinical Trials

This course will cover material relevant to the design and conduct of controlled clinical trials. Design topics will include methods used to achieve unbiased results with improved precision, such as adequate sample size, randomization, blinding, pre- and post-stratification, cross-over designs, placebos and the counting of relevant events. Attention will be given to the problems of conducting multi-centre clinical trials. Other topics covered will include correlative science including biomarkers and precision medicine; patient reported outcomes; health economic evaluations and current issues involved in publishing and reporting trials.

Time: Fall Term (2021), Mondays 5:00 pm to 8:00 pm

Location: Cancer Research Institute Main Conference Room

Course Coordinator: Dr. Harriet Richardson, Dept. Public Health Sciences,
Queen's Cancer Research Institute, Room 220
Divisions of Canadian Cancer Trials Group and
Cancer Care and Epidemiology (hrichardson@ctg.queensu.ca)

Prerequisites:

No specific pre-requisites for students in Public Health Sciences or for health professionals. Students from other programs should contact the instructors

Course delivery: The general format of the course will consist of one lecture per week delivered in person, followed by assigned readings. Slides from each lecture will be posted onQ.

Digital Platforms: Zoom will be used to host occasional guest speakers. On those occasions, invitations will be sent to all students enrolled in EPID 810 at least 24 hours prior to class. All other communication will be through onQ and email.

Readings:

Supplemental readings will be posted to onQ.

Evaluation:

- Quizzes (4) - 10%
- Midterm – 30%
- Critical Appraisal 20%
- Protocol concept presentation - 10%
- Protocol concept report (10 pages; double-spaced) - 30%

Details on Course Evaluations

Quizzes (10% of your mark): Students will be asked to read an assigned article (posted to onQ) after each lecture. For the first half of the course only, a quiz on the assigned article will be posted following the lecture and students will have until 5 pm on the Sunday of that week to complete and submit the quiz onQ. A total of 4 quizzes will be administered. They will consist of 5-10 multiple choice and short answer questions.

Critical appraisal (20% of your mark): Students will be asked to answer a series of questions about the design, conduct and interpretation of a published clinical trial. During the critical appraisal session, students will be expected to participate in an in-class discussion and share their views with their peers and instructors. Students will be asked to submit a written copy of their critical appraisal onQ prior to the critical appraisal class.

Midterm exam (30% of your mark): This will be a closed book exam and students will answer questions that relate to a clinical trial methodology taught in the first half of the course. The exam will be a combination of multiple choice & true/false questions in addition to short answer questions. A list of topics will be provided ahead of time to help students review prior to the midterm exam.

Protocol presentation and Final Clinical Trial Protocol

Please email Harriet Richardson (hr1@queensu.ca) with your **research question and study objectives by October 25, 2021**. Feedback about appropriateness of the study question will be provided within 2 weeks.

Presentations (10% of your final mark):

You will be expected to present your clinical trial proposal to the class over Zoom, during the last two sessions of the term. Students will each be given 10 minutes to present, followed by 5-10 minutes for questions and discussion. Your presentation should be a summary of the information required in the Protocol including the gaps in evidence supporting the rationale for the current proposal. You will be assessed on the clarity of the presentation and understanding of issues discussed in the course *Presentation schedule: Week of December 6th*.

Term Paper (30% of your final mark):

You are asked to write a paper, no more than 8-10 pages (double spaced and not including references) addressing the following areas below with respect to designing a clinical trial. There are three main sections to consider including the Introduction (background) and rationale for the proposed trial, the Trial Methods and the Statistical Methods. Components to consider within each of these sections are listed below, adapted from the SPIRIT Statement. *The Term paper is due by 5 pm on December 10th, 2021.*

Introduction

- Background and rationale: (15 marks)
- Objectives: (10 marks)

Methods (Participants, interventions and outcomes)

- Trial design: (15 marks)
- Eligibility criteria: (10 marks)
- Interventions and participant timeline: (15 marks)
- Outcomes/Endpoints: (15 marks)
- Statistical analysis plan and sample size calculation (10 marks)

SCHEDULE 2021

Monday, Sept 13	Introduction to Clinical Trials.	Joe Pater/ Harriet Richardson (Assigned reading & on-line Quiz 1)
Monday, Sept 20	Components of Clinical Trials and Outcome Measures	Pater/Richardson (Assigned reading & on-line Quiz 2)
Monday, Sept 27	Special Designs	Pater/Richardson (Assigned reading & on-line Quiz 3)
Monday, October 4	Cluster Randomized Trials	Pater/Richardson (Assigned reading & on-line Quiz 4)
Monday, Oct 11	THANKSGIVING	No Class
Monday, Oct 18	Clinical Epidemiology	Pater/Richardson (Assigned readings)
Monday, Oct 25	Critical Appraisal Session	Class – Pater / Richardson (CA Assignment due)
Monday, Nov 1	MIDTERM	In-class mid-term
Monday, Nov 8	Special Topics: Quality of Life/ PROs	Richardson/Brundage
Monday, Nov 15	Special Topics: Health Economics	Annette Hay
Monday, Nov 22	Special Topics: 1. Tumour Banking 2. Correlative Sciences	Lois Shephard Chris O'Callaghan
Monday, Nov 29	Special Topics: 1. Effectiveness Trials 2. Trial Reporting	Chris Booth/ Bishal Gyawali Wendy Parulekar
Monday, Dec 6 Re-schedule (Date TBD)	Class Protocol Presentations	Class

Course objectives, reading materials, and lecture slides as presented in 2021 are available at onQ:

Academic Integrity

Queen's students, faculty, administrators and staff all have responsibilities for upholding the fundamental values of academic integrity; honesty, trust, fairness, respect, responsibility and courage (see www.academicintegrity.org). These values are central to the building, nurturing and sustaining of an academic community in which all members of the community will thrive. Adherence to the values expressed through academic integrity forms a foundation for the "freedom of inquiry and exchange of ideas" essential to the intellectual life of the University (see the Senate Report on Principles and Priorities <http://www.queensu.ca/secretariat/policies/senate/report-principles-and-priorities>).

Students are responsible for familiarizing themselves with the regulations concerning academic integrity and for ensuring that their assignments and their behaviour conform to the principles of academic integrity. Information on academic integrity is available in the SGS Calendar (<https://www.queensu.ca/sgs/graduate-calendar/academic-integrity-policy>) and from the instructor of this course. Departures from academic integrity include plagiarism, use of unauthorized materials, facilitation, forgery, falsification and unauthorized use of intellectual property, and are antithetical to the development of an academic community at Queen's. Given the seriousness of these matters, actions which contravene the regulation on academic integrity carry sanctions that can range from a warning or the loss of grades on an assignment to the failure of a course to a requirement to withdraw from the university.

- Plagiarism – including guides on how to use sources correctly.
 - *Regardless of how and where you retrieve information, the principles of academic integrity apply. Please visit these helpful websites to help you make sure that you are able to write things in your own words:*
 - <https://www.queensu.ca/academicintegrity/students/avoiding-plagiarismcheating>
 - <https://integrity.mit.edu/handbook/academic-writing/avoiding-plagiarism-paraphrasing>
 - http://writing.wisc.edu/Handbook/QPA_paraphrase.html
- Groupwork:
 - You are permitted to work with a partner or in groups of up to 3 to encourage collaboration, cooperation, and collective learning on lab assignments. You are not permitted to share answers among large groups or as a tutorial group. You must work independently on quizzes and "pop questions".

Statement on Copyright of Course Materials

Course materials created by the course instructor, including all slides, presentations, handouts, tests, exams, and other similar course materials, are the intellectual property of the instructor. It is a departure from academic integrity to distribute, publicly post, sell or otherwise disseminate an instructor's course materials or to provide an instructor's course materials to anyone else for distribution, posting, sale or other means of dissemination, without the instructor's express consent. A student who engages in such conduct may be subject to penalty for a departure from academic integrity and may also face adverse legal consequences for infringement of intellectual property rights.

Statement on Academic Accommodations for Students with Disabilities

Queen's University is committed to achieving full accessibility for people with disabilities. Part of this commitment includes arranging academic accommodations for students with disabilities to ensure they have an equitable opportunity to participate in all of their academic activities. The Senate Policy for Accommodations for Students with Disabilities was approved at Senate in November 2016 (see <https://www.queensu.ca/secretariat/sites/webpublish.queensu.ca.uslclwww/files/files/policies/senateandtrustees/ACADACCOMMPOLICY2016.pdf>). If you are a student with a disability and think you may need academic accommodations, you are strongly encouraged to contact the Queen's Student Accessibility Services (QSAS) and register as early as possible. For more information, including important deadlines, please visit the QSAS website at: <http://www.queensu.ca/studentwellness/accessibility-services/>

Statement on Academic Consideration for Students with Extenuating Circumstances

Queen's University is committed to providing academic consideration to students experiencing extenuating circumstances that are beyond their control and are interfering with their ability to complete academic requirements related to a course for a short period of time. The Senate Policy on Academic Consideration for Students in Extenuating Circumstances is available at <http://www.queensu.ca/secretariat/sites/webpublish.queensu.ca.uslclwww/files/files/policies/senateandtrustees/Academic%20Considerations%20for%20Extenuating%20Circumstances%20Policy%20Final.pdf>

Each Faculty has developed a protocol to provide a consistent and equitable approach in dealing with requests for academic consideration for students facing extenuating circumstances. SGS students can find the Academic consideration information at: <https://www.queensu.ca/sgs/accommodation-and-academic-consideration>. If you need to request academic consideration for this course, you will be required to provide the name and email address of the instructor/coordinator. Please use the following:

- Instructor/Coordinator Name:
- Instructor/Coordinator email address:

Statement on Use and Retention of Video Recording

If / when Synchronous (live) classes are delivered in this course through a video conferencing platform, it will be supported by the University [MS Teams, Zoom]. Steps have been taken by the University to configure these platforms in a secure manner. Classes will be recorded with video and audio (and in some cases transcription) and will be made available to students in the course for the duration of the term. The recordings may capture your name, image or voice through the video and audio recordings. By attending these live classes, you are consenting to the collection of this information for the purposes of administering the class and associated coursework. If you are concerned about the collection of your name and other personal information in the class, please contact the course instructor to identify possible alternatives.

To learn more about how your personal information is collected, used and disclosed by Queen's University, please see the general [Notice of Collection, Use and Disclosure of Personal Information](#).