



POPM*6230 Applied Clinical Research

Fall 2019

Section(s): C01

Department of Population Medicine

Credit Weight: 0.50

Version 1.00 - September 09, 2019

1 Course Details

1.1 Calendar Description

This course is designed to help clinical researchers design, fund, and analyze their clinical research. Emphasis is placed upon planning a well-designed clinical trial and writing a well-organized grant proposal.

1.2 Course Description

This is a 0.5 credit introductory graduate course for veterinary clinicians and human or veterinary clinical researchers on how to design, fund, and analyze clinical research. Observational study designs and studies of medical tests will be explored. Emphasis, however, will be placed upon the design and analysis of clinical trials.

Applied Clinical Research is offered in two 80-minute sessions twice per week to allow time for meaningful in-class learning activities to take place. New information will often be introduced through readings done in preparation for the next classroom session. Classroom time will usually be devoted to the application of new information and exploration of its implications. You can expect to take an active role during class sessions in learning activities and small and large group discussion.

Classroom activities and assignments will give you experience choosing a clinical research design, critiquing clinical trial designs, choosing the “right” statistical test, and using the statistical program R to run some statistical tests on data. The major project is to prepare a research grant proposal requesting funding to carry out a clinical or experimental trial. Preparing a grant proposal will help you to learn how to develop a research idea, put the idea into its proper scientific context, and convince other people that the research is important and should be funded. The skills that you develop in this project should be useful to you in your graduate research program and your future attempts to secure funding for research.

1.3 Timetable

Tuesdays and Thursdays, 1:00pm-2:20pm

Room 1812 Pathobiology

1.4 Final Exam

December 6, 2019 Time yet to be determined

2 Instructional Support

2.1 Instructional Support Team

Instructor:	Cathy Bauman DVM, MPH, PhD
Email:	cbauman@uoguelph.ca
Telephone:	+1-519-824-4120 x54035
Office:	OVCS 2542

2.2 Teaching Assistants

Teaching Assistant:	Abhinand Thaivalappil
Email:	athaival@uoguelph.ca
Teaching Assistant:	Inthuja Selvaratnam
Email:	iselvara@uoguelph.ca

3 Learning Resources

3.1 Required Resources

Required software for the course (Software)

The statistics section of the course will make use of the open and free “R” software package in combination with “RStudio”. You will have to install R and RStudio on your own computer (as will be demonstrated in class) and you will have to bring your own laptop to the final exam.

Courselink (Website)

Additional course materials and information regarding all assignments will be posted on the CourseLink website. The website can only be accessed by persons who are registered for the class, therefore it is imperative that students ensure that they are registered for the class and have access to CourseLink. If you have any problems accessing CourseLink, contact CCS at x58888 or 58888help@uoguelph.ca

3.2 Recommended Resources

Recommended Textbook Resources (Textbook)

There is no required textbook for this course. Pre-class readings will be derived from some of the following textbooks and journal articles posted online. Students can access books on reserve as links via Ares. Ares can be accessed at: <https://ares.lib.uoguelph.ca/ares/>) Please note that all reserve items are now housed at the McLaughlin Main Library.

Study Design and Clinical Trials:

Friedman LM, Furberg, CD, DeMets, DL, Reboussin, DM, Granger, CB. **Fundamentals of Clinical Trials, 5th ed.** New York: Springer Verlag, 2015. ISBN 978-3-319-18538-5 (e-book ISBN 978-3-319-18539-2)

Grant Proposal Writing:

Friedland AJ, Folt CL. **Writing Successful Science Proposals. 2nd Edition.** New Haven: Yale University Press, 2009.

Day RA. **How To Write & Publish a Scientific Paper, 8th ed.** Phoenix: Oryx Press, 1998. Call # T11.D33 1998.

Gilpin AA, Patchet-Golubev P. **A Guide to Writing in the Sciences.** Toronto: University of Toronto Press, 2000.

Statistics Portion:

Petrie A and Watson P. **Statistics for Veterinary and Animal Science.** London: Blackwell Science Ltd., 2013.

Dalgaard (2008) *Introductory Statistics with R (2nd Edn.)*. Springer, New York.

4 Learning Outcomes

4.1 Course Learning Outcomes

By the end of this course, you should be able to:

1. Formulate good clinical research questions
2. Evaluate the appropriateness of different clinical research designs

3. Plan a well-designed clinical trial
 4. Analyze the results from clinical trials
 5. Write a well-organized grant proposal
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5 Teaching and Learning Activities

5.1 Class Schedule

Session	Day	Date	Instructor	Room	Topic
1	Thursday	Sept. 5, 2019	Bauman	1812	Course Introduction, Applied Research, Evidence Based Medicine (EBM and EBVM)
2	Tuesday	Sept. 10, 2019	Bauman	1812	Research Questions/ Strength of evidence/Study Designs
3	Thursday	Sept. 12, 2019	Bauman	1812	Study Designs Exercise
4	Tuesday	Sept. 17, 2019	Bauman	1812	Study Design review - Intro. to RCTs, Trial registration
5	Thursday	Sept. 19, 2019	Bauman	1812	Publication Bias Intervention/Controls, inclusion, exclusion criteria, outcomes
6	Tuesday	Sept. 24, 2019	Bauman	1812	CT Phases and types

7	Thursday	Sept. 26, 2019	Bauman	1812	Adverse Events/Early termination/Interim measurements
8	Tuesday	Oct. 1, 2019	Bauman	1812	Sample size generation
9	Thursday	Oct. 3, 2019	Bauman	1812	Grant Proposals/Pilot studies
	Tuesday	Oct. 8, 2019	Bauman	1812	Randomization and blinding
10	Thursday	Oct. 10, 2019	Bauman	1812	Recruitment, budgets, timelines
11	Tuesday	Oct. 15, 2019	NA	NA	No class
12	Thursday	Oct. 17, 2019	Bauman	1812	Human ethics/AUP/ACC
13	Tuesday	Oct. 22, 2019	Bauman	1812	Data collection, Quality Control, Database set-up management, R/RStudio
14	Thursday	Oct. 24 2019	Bauman	1812	Descriptive Statistics
15	Tuesday	Oct. 29, 2019	Bauman	To be determined	Grant proposal review committee
16	Thursday	Oct. 31, 2019	Bauman	1812	Inferential: Continuous variables

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17	Tuesday	Nov. 5, 2019	Bauman	1812	Correlation and agreement, repeat measures
18	Thursday	Nov. 7, 2019	Bauman	1812	Inferential: Categorical variables
19	Tuesday	Nov. 12, 2019	Bauman	1812	Inferential: Categorical variables
20	Thursday	Nov. 14, 2019	Bauman	1812	Linear Regression
21	Tuesday	Nov. 19, 2019	Bauman	1812	Logistical Regression and Hierarchical Analysis
22	Thursday	Nov. 21, 2019	Bauman	1812	Survival Analysis
23	Tuesday	Nov. 26, 2019	Bauman	1812	Survival Analysis
24	Thursday	Nov. 28, 2019	Bauman	1812	Review
	Friday	Dec. 6, 2019	Bauman	To be determined	Final Exam

Assessments

6.1 Assessment Details

Online Quizzes (10%)

Multiple choice quizzes are offered online. Your best 5 of 6 quiz marks will be counted (2% each) towards your final mark.

Study Design Assignment (5%)

In groups of 2-3 students you will identify and discuss the best study design to use to answer your assigned research question. One submission will be made per group.

Statistician Assignment (5%)

You will make an individual appointment with the department statistician William Sears. During this appointment you will either discuss the statistical aspects of your graduate research project or discuss a posted list of research questions (CourseLink) if your program does not have a research project. You will write and submit a reflective piece of what you have learned from your appointment.

Grant Proposal Assignment (30%)

The midterm project worth 30% of the final mark will involve designing a grant proposal to address a specific research question. Complete details will be provided on CourseLink.

Statistical Assignments (20%)

There are 2 statistical assignments to be submitted in the second half of the course. One on descriptive statistics (10%) and the other on inferential statistics (10%).

Final Exam (30%)

The final exam will be based on all components of the course. You will need to bring your own WiFi ready laptop with R and RStudio installed to the exam (R does NOT run on a tablet or smartphone).

7 University Statements

7.1 Email Communication

As per university regulations, all students are required to check their e-mail account regularly: e-mail is the official route of communication between the University and its students.

7.2 When You Cannot Meet a Course Requirement

When you find yourself unable to meet an in-course requirement because of illness or compassionate reasons please advise the course instructor (or designated person, such as a teaching assistant) in writing, with your name, id#, and e-mail contact. The grounds for Academic Consideration are detailed in the Undergraduate and Graduate Calendars.

Undergraduate Calendar - Academic Consideration and Appeals

<https://www.uoguelph.ca/registrar/calendars/undergraduate/current/c08/c08-ac.shtml>

Graduate Calendar - Grounds for Academic Consideration

<https://www.uoguelph.ca/registrar/calendars/graduate/current/genreg/index.shtml>

7.3 Drop Date

Students will have until the last day of classes to drop courses without academic penalty. The deadline to drop two-semester courses will be the last day of classes in the second semester. This applies to all students (undergraduate, graduate and diploma) except for Doctor of Veterinary Medicine and Associate Diploma in Veterinary Technology (conventional and alternative delivery) students. The regulations and procedures for course registration are available in their respective Academic Calendars.

Undergraduate Calendar - Dropping Courses

<https://www.uoguelph.ca/registrar/calendars/undergraduate/current/c08/c08-drop.shtml>

Graduate Calendar - Registration Changes

<https://www.uoguelph.ca/registrar/calendars/graduate/current/genreg/genreg-reg-regchg.shtml>

Associate Diploma Calendar - Dropping Courses

<https://www.uoguelph.ca/registrar/calendars/diploma/current/c08/c08-drop.shtml>

7.4 Copies of Out-of-class Assignments

Keep paper and/or other reliable back-up copies of all out-of-class assignments: you may be asked to resubmit work at any time.

7.5 Accessibility

The University promotes the full participation of students who experience disabilities in their academic programs. To that end, the provision of academic accommodation is a shared responsibility between the University and the student.

When accommodations are needed, the student is required to first register with Student Accessibility Services (SAS). Documentation to substantiate the existence of a disability is required; however, interim accommodations may be possible while that process is underway.

Accommodations are available for both permanent and temporary disabilities. It should be noted that common illnesses such as a cold or the flu do not constitute a disability.

Use of the SAS Exam Centre requires students to book their exams at least 7 days in advance and not later than the 40th Class Day.

More information can be found on the SAS website

<https://www.uoguelph.ca/sas>

7.6 Academic Integrity

The University of Guelph is committed to upholding the highest standards of academic integrity, and it is the responsibility of all members of the University community—faculty, staff, and students—to be aware of what constitutes academic misconduct and to do as much as possible to prevent academic offences from occurring. University of Guelph students have the responsibility of abiding by the University's policy on academic misconduct regardless of their location of study; faculty, staff, and students have the responsibility of supporting an

environment that encourages academic integrity. Students need to remain aware that instructors have access to and the right to use electronic and other means of detection.

Please note: Whether or not a student intended to commit academic misconduct is not relevant for a finding of guilt. Hurried or careless submission of assignments does not excuse students from responsibility for verifying the academic integrity of their work before submitting it. Students who are in any doubt as to whether an action on their part could be construed as an academic offence should consult with a faculty member or faculty advisor.

Undergraduate Calendar - Academic Misconduct

<https://www.uoguelph.ca/registrar/calendars/undergraduate/current/c08/c08-amisconduct.shtml>

Graduate Calendar - Academic Misconduct

<https://www.uoguelph.ca/registrar/calendars/graduate/current/genreg/index.shtml>

7.7 Recording of Materials

Presentations that are made in relation to course work - including lectures - cannot be recorded or copied without the permission of the presenter, whether the instructor, a student, or guest lecturer. Material recorded with permission is restricted to use for that course unless further permission is granted.

7.8 Resources

The Academic Calendars are the source of information about the University of Guelph's procedures, policies, and regulations that apply to undergraduate, graduate, and diploma programs.

Academic Calendars

<https://www.uoguelph.ca/academics/calendars>
