



POPM*6230 Applied Clinical Research

Winter 2021

Section(s): C01

Department of Population Medicine

Credit Weight: 0.50

Version 1.00 - December 04, 2020

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

Wednesdays and Fridays, 1:00pm-2:20pm

Online in a synchronous (and recorded) format

1.4 Final Exam

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 |

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 or arrange ahead of time for one to be provided by the instructor.

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/>).

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 and identify the advantages, disadvantages and bias associated with each.
3. Plan a well-designed clinical trial
4. Analyze the results from clinical trials
5. Write a well-organized grant proposal

5 Teaching and Learning Activities

5.1 Class Schedule

| Session | Day | Date | Instructor | Room | Topic |
|----------------|------------|------------------|-------------------|--------|---|
| 1 | Wednesday | January 13, 2020 | Bauman | Online | Course Introduction, Applied Research, Evidence Based Medicine (EBM and EBVM) |
| 2 | Friday | January 15, 2020 | Bauman | Online | Research Questions/ Strength of evidence/Study Designs |
| 3 | Wednesday | January 20, 2020 | Bauman | Online | Study Designs Exercise |
| 4 | Friday | January 22, 2020 | Bauman | Online | Study Design review - Intro. to RCTs, Trial registration |
| 5 | Wednesday | January 27, 2020 | Bauman | Online | Publication Bias Intervention/Controls, inclusion, exclusion criteria, outcomes |
| 6 | Friday | January 29, 2020 | Bauman | Online | CT Phases and types |
| 7 | Wednesday | February 3, 2020 | Bauman | Online | Adverse Events/Early termination/Interim measurements |
| 8 | Friday | February 5, 2020 | Bauman | Online | Sample size generation |

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|----|-----------|----------------------|--------|-----------------|---|
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| 9 | Wednesday | February 10, 2020 | Bauman | Online | Grant Proposals/Pilot studies |
| | Friday | February 12, 2020 | Bauman | Online | Randomization and blinding |
| 10 | Wednesday | February 17, 2020 | Bauman | No class | Winter break |
| 11 | Friday | February 19, 2020 | Bauman | No class | Winter break |
| 12 | Wednesday | February 23, 2020 | Bauman | Online | Recruitment, budgets, timelines |
| 13 | Friday | February 26, 2020 | Bauman | Online | Human ethics/AUP/ACC |
| 14 | Wednesday | March 3, 2020 | Bauman | Online | Data collection, Quality Control, Database set-up management, R/RStudio |
| 15 | Friday | March 5, 2020 | Bauman | Online | Descriptive Statistics |
| 16 | Wednesday | March 10, 2020 | Bauman | Online | Grant proposal review committee |
| 17 | Friday | March 12, 2020 | Bauman | Online | Inferential: Continuous variables |
| 18 | Wednesday | March 17, 2020 | Bauman | Online | Correlation and agreement, repeat measures |

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|----------|----|-----------|----------------|--------|---------------------|---|
| 6 | 19 | Friday | March 19, 2020 | Bauman | Online | Inferential: Categorical variables |
| | 20 | Wednesday | March 24, 2020 | Bauman | Online | Inferential: Categorical variables |
| | 21 | Friday | March 26, 2020 | Bauman | Online | Linear Regression |
| | 22 | Wednesday | March 31, 2020 | Bauman | Online | Logistical Regression and Hierarchical Analysis |
| | 23 | Friday | April 2, 2020 | Bauman | No class | Good Friday |
| | 24 | Wednesday | April 7, 2020 | Bauman | Online | Survival Analysis |
| | 25 | Friday | April 9, 2020 | Bauman | Online | Survival Analysis/Review |
| | 25 | | | Bauman | To be determined | 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: 1) discuss in written format how to answer an assigned research question using three different study designs and 2) from the discussed designs choose and justify the most appropriate study design to answer your specific question. One submission will be made per group.

Statistician Assignment (5%)

Individually or in groups of two, you will make an appointment with the department statistician William Sears. During this appointment you will either: 1) discuss the statistical aspects of your graduate research project or 2) discuss the posted list of research questions (refer to Courselink) if your program (coursework MSc/MBS) 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 and participating in a grant review committee wherein you will present and evaluate the submitted proposals. Complete details are provided on CourseLink.

Statistical Assignments (20%)

There is one statistical assignment to be submitted in the second half of the course. It will require the analysis and interpretation of data in R/RStudio.

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>

Associate Diploma Calendar - Academic Consideration, Appeals and Petitions

<https://www.uoguelph.ca/registrar/calendars/diploma/current/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.

For Guelph students, information can be found on the SAS website

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

For Ridgetown students, information can be found on the Ridgetown SAS website

<https://www.ridgetownc.com/services/accessibilityservices.cfm>

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>

7.9 Disclaimer

Please note that the ongoing COVID-19 pandemic may necessitate a revision of the format of course offerings and academic schedules. Any such changes will be announced via CourseLink and/or class email. All University-wide decisions will be posted on the COVID-19 website (<https://news.uoguelph.ca/2019-novel-coronavirus-information/>) and circulated by email.

7.10 Illness

The University will not normally require verification of illness (doctor's notes) for fall 2020 or winter 2021 semester courses. However, requests for Academic Consideration may still require medical documentation as appropriate.
