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**Description:** This is a 0.5 credit introductory graduate course for veterinary clinicians and 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.

**Objectives**

Students who complete this course should be able to:

- Formulate good clinical research questions.
- Evaluate the appropriateness of different clinical research designs.
- Plan a well-designed clinical trial.
- Analyze the results from clinical trials.
- Write a well-organized grant proposal.

**Course Approach**

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, preparing to visit and visiting a statistician, choosing the “right” statistical test, and using Minitab 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 to determine if a new intervention (treatment, preventive technique, surgical procedure) is better than no intervention or an older intervention. 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.

**Prerequisites**

There are no specific prerequisites for this course. Your undergraduate statistics course will be helpful. If your research involves observational study designs more than the clinical and experimental trial designs emphasized in this course, you might consider taking Epidemiology I (POPM\*6200) and Epidemiology II (POPM\*6210) offered by this department.

**Statistical Software: To Be Determined.** There are a number of freely available software packages which run most of the statistical tests you will need. These programs will be made available to you on the network once class begins and you are registered.

### Textbooks

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

Hulley SB, Cummings SR, Browner WS et al. *Designing Clinical Research, 3<sup>rd</sup> Edition.* Philadelphia: Lippincott, Williams & Wilkins, 2007.

The textbooks will be used extensively during the course. They are available as paperback editions for about \$30 and \$90 Cdn respectively in the University bookstore.

**Reference Books:** These offer supplemental material or alternative views on topics to be covered in the course and are available through the U of Guelph Library.

Holmes M, Cockcroft, P. *Handbook of Veterinary Clinical Research.* Oxford: Blackwell Publishing Ltd., 2008.

Friedman LM, Furberg, CD, DeMets, DL. *Fundamentals of Clinical Trials, 3<sup>rd</sup> ed.* New York: Springer-Verlag, 1998. Call # R853.C55 F75 1996.

Petrie A and Watson P. *Statistics for Veterinary and Animal Science.* London: Blackwell Science Ltd., 1999. Call # SF760.S73 P48

Sackett DL, Haynes RB, Guyatt GH, Tugwell P. *Clinical Epidemiology: A Basic Science for Clinical Medicine, 2<sup>nd</sup> ed.* Toronto: Little, Brown and Company, 1991. Call # RA652.C45 1991.

Day RA. *How To Write & Publish a Scientific Paper, 5<sup>th</sup> 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.

### Evaluation and Grading

The course grade will be comprised of points from the following areas:

Classroom preparatory work	10	Pass/Fail
Assignments	10	Pass/Fail
Midterm exam	25	
Research grant proposal	25	
Cumulative final exam	30	
Total points	100	

To help with learning during classroom activities, you will be asked at the beginning of certain classes to submit a brief written piece that documents you have read an original article or a chapter in the textbook and thought about the reading. Each submitted piece of preparatory work will be marked on a pass/fail basis. To receive the full 10 points for *Classroom preparatory work* you must have achieved a “pass” on 70% of these documents. A “pass” on less than 70% will result in a 0 for classroom preparatory work.

There will be two assignments worth 5 points each. To receive the 5 points on a specific assignment, you

must attain a mastery (“pass”) mark of at least 70%. If you attain less than 70%, you will be assigned a “fail” for that assignment and given 0 points. You will then have one opportunity to write a “make-up” assignment. If you attain a mark of 70% or greater on the make-up assignment you will be given the 5 points for that assignment.

The assignments will be as follows:  
Clinical research design choice  
Reflective piece after visiting a statistician

The Research Grant Proposal project will be worth 25 points. Marking of the project and both exams will be criterion-based.

### **Schedule**

Sep 14 – Dec 2: Tues. 1:30-2:50, Thurs 1:30-2:50, unfortunately rooms will vary a fair bit. Please refer to class schedule on final page for details and exceptions.

### **Important dates (Fall '10)**

- Certain classes (10) – submit a brief written piece documenting you have done the preparatory work for that class session
- F Sep 17 Add period for fall semester classes ends
- Tu Sep 14 First day of class
- Th Oct 23 TBA
- Tu Nov 2 Midterm Exam (tentative date)
- Th Nov 4 40<sup>th</sup> class day – last day to drop one semester classes
- Th Dec 2 Last day of class
- Th Dec 9 Cumulative final exam – Date to be Confirmed!

### **Course structure – Tentative Sequence of topics (sequence may vary)**

#### **September**

Introduction

Formulating good research questions (Hulley)

Clinical research design choices (Hulley)

Clinical trial design (Hulley)

- subject recruitment
- outcome measurement
- hypotheses statements
- sample size calculations

#### **October**

Clinical trial design (cont.)

- randomization and blinding
- maximizing follow-up & adherence to protocol

Grant proposals (Friedland)

- writing and funding a research proposal
- starting & authorship - *Chap 1, 2 Friedland*

#### **October (cont.)**

Grant proposals (cont.)

- organization - *Chap 3 Friedland*
- titles & significance statement – *Chap 4-5 Friedland*
- hypotheses and objectives – *Chap 6-7 Friedland*
- plan of work – *Chaps 8-10 Friedland*

- timeline – *Chap 11 Friedland*
- references – *Chap 12 Friedland*
- budget – *Chap 13 Friedland*
- follow-up - *Chaps 14-15 Friedland*
- ethics – *Chap 16 Friedland*

#### Statistical Analysis

- framework for choosing statistical tests - *handouts*

#### **November**

##### Statistical Analysis (cont.)

- framework for choosing statistical tests - *handouts*
- practice using statistical tests - *handouts*
- data management

##### Implementation of the clinical trial (Hulley)

##### Summary

- reflection and assessment

#### **Office hours**

Given the varied schedules for students and course instructors, there are few common times that are well suited for office hours. As such, we will not have formal regular office hours. However, we want you to succeed in the course and we are here to help you do just that. If you want to meet with one of the instructors or the teaching assistant, please take the time to come to see us individually whenever you determine it will help your learning. Contact us by phone or email and we will make an appointment to meet with you.

## Dates, Times and Rooms for POPM\*6230 – Fall 2010

**NOTE: Rooms and Instructors are tentative.....some will change....**

<b>Day</b>	<b>Date</b>	<b>Time</b>	<b>Room</b>	<b>Instructor</b>
Tuesday	14-Sep-10	1:30 - 3:00	1715 LLC	Kelton
Thursday	16-Sep-10	1:30 - 3:00	1713 LLC	Kelton
Tuesday	21-Sep-10	1:30 - 3:00	1715 LLC	Kelton
Thursday	23-Sep-10	1:30 - 3:00	1438 CS	Kelton
Tuesday	28-Sep-10	1:30 - 3:00	1715 LLC	Sorge
Thursday	30-Sep-10	1:30 - 3:00	1434 CS	Sorge
Tuesday	5-Oct-10	1:30 - 3:00	1715 LLC	Kelton
Thursday	7-Oct-10	1:30 - 3:00	1642 BioMed	Kelton
Tuesday	12-Oct-10	1:30 - 3:00	1715 LLC	Kelton
Thursday	14-Oct-10	1:30 - 3:00	1642 BioMed	Kelton
Tuesday	19-Oct-10	1:30 - 3:00	1715 LLC	Kelton
Thursday	21-Oct-10	1:30 - 3:00	1642 BioMed	Kelton
Tuesday	26-Oct-10	1:30 - 3:00	1715 LLC	Kelton
Thursday	28-Oct-10	1:30 - 3:00	1713 LLC	Kelton
Tuesday	2-Nov-10	1:30 - 3:00	1713 LLC	Sorge
Thursday	4-Nov-10	1:30 - 3:00	1713 LLC	Sorge
Tuesday	9-Nov-10	1:30 - 3:00	1438 CS	Sorge
Thursday	11-Nov-10	1:30 - 3:00	1438 CS	Sorge
Tuesday	16-Nov-10	1:30 - 3:00	1438 CS	Sorge
Thursday	18-Nov-10	1:30 - 3:00	1434 CS	Sorge
Tuesday	23-Nov-10	1:30 - 3:00	1715 LLC	Sorge
Thursday	25-Nov-10	1:30 - 3:00	1714 LLC	Sorge
Tuesday	30-Nov-10	1:30 - 3:00	TBA	Kelton
Thursday	2-Dec-10	1:30 - 3:00	1434 CS	Kelton
Thursday	9-Dec-10	1:00 - 4:00	1642 BioMed	Kelton