## PHM 425H1: PHARMACY PRACTICE RESEARCH
### FALL 2013

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Email: paul.grootendorst@utoronto.ca; Phone: 416 946-3994  
Personal web: http://individual.utoronto.ca/grootendorst/index.htm |
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td><strong>Course Hours and Location:</strong></td>
<td>Wednesdays 9:30am-11.30am. PB B250.</td>
</tr>
</tbody>
</table>
| **Teaching Assistants:** | Mosa Alhamami, MSc  
mosa.alhamami@gmail.com  
Matt Machina, MSc  
mattmachina@gmail.com  
David Rudoler, MSc  
drudoler@gmail.com |
| **Office Hours:** | Grootendorst office hours: Wednesdays 11:30am-12:30pm and by appointment. I have an open door policy; if my door is open feel free to drop by.  
Teaching Assistant office hours: 3:30-4:30pm Wednesdays in PB 671 until Oct 2; thereafter 3:30-5:30pm Wednesdays in PB 671. |
| **Prerequisites:** | PHM 122 (Biostatistics), PHM 328S (Prof. Practice III). |
| **Co-requisites:** | PHM 428F (Prof. Practice IV). |
| **Required Readings:** | Students are expected to have read the required readings prior to each session. These readings consist of lecture notes and other instructional materials that will be made available for download on the course website: https://portal.utoronto.ca/webapps/portal/frameset.jsp at least one week prior to the class.  
Supplemental instructional materials for each session (such as overhead presentations by guest speakers, additional notes that I will provide) will be made available on the course website. |
Course Website Administrator:

Please email Blackboard technical support portal.help@utoronto.ca or contact 416 978-4357 if you are experiencing technical difficulties with the course website.

Optional Readings:

There are two books on pharmacy practice research that might be useful. Hardcopies of these books are available for short-term loan in the Gerstein Library.


Information on the Gerstein Library is available at: http://main.library.utoronto.ca/guide/libraryMap.cfm?ID=111&detail=111

Software to view the instructional materials

Some handouts will be in Microsoft Office (Word, Excel, PowerPoint) format. If you do not have this software you can download software to view and print these files:


Some handouts will be in Adobe PDF format. You can download the Acrobat PDF Reader software at:

http://www.adobe.com/products/acrobat/readstep2.html

1 COURSE DESCRIPTION FROM CALENDAR

“This course introduces the student to research methods and design relevant to pharmacy practice. Drawing on what they learn in class, as well as their knowledge of, and experiences with pharmacy practice, the health system, bioethics and biostatistics, students will develop a proposal for a small practice research project applicable to pharmacy practice.”

This course is designed to enable the student to meet the Faculty’s expectation that graduating students be able to apply the principles of the scientific method to pharmacy practice problems.
2 COURSE GOALS & OBJECTIVES

The main goals of the course are for students:

a) to gain familiarity with, and understanding of, research methods applicable to the pharmacy practice setting;

b) to be able to apply this learning in the development of research projects;

c) to be able to critically evaluate the research literature pertinent to pharmacy practice.

The learning objectives include:

a) the ability to recognize research problems in the practice setting;

b) knowing what questions to ask to address these problems;

c) the ability to search the literature appropriately;

d) the ability to choose research methods appropriate to the problem;

e) knowing what data analyses are appropriate for the research design;

f) the ability to identify relevant ethical issues which might apply;

g) the ability to critically evaluate the research design, data analyses and conclusions presented in the research literature.

3 TEACHING METHOD

The course material will be presented in class sessions. The class sessions will include lectures and group discussion, as well as presentations by guest speakers. In addition, students are encouraged to consult with the coordinator, teaching assistants, and/or practicing pharmacists in the development of their research projects.

4 STUDENT EVALUATION

<table>
<thead>
<tr>
<th>Assignment</th>
<th>Group or solo work?</th>
<th>Percent of final grade</th>
<th>Due date</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>literature review</td>
<td>Group</td>
<td>10</td>
<td>4:00pm Friday October 4, 2013</td>
<td>PB 670*</td>
</tr>
<tr>
<td>methods assignment</td>
<td>solo</td>
<td>15</td>
<td>4:00pm Monday October 28, 2013</td>
<td>PB 670</td>
</tr>
<tr>
<td>midterm</td>
<td>solo</td>
<td>40</td>
<td>10:30am-noon, Monday November 4, 2013</td>
<td>EX 300, 310 &amp; 320</td>
</tr>
<tr>
<td>presentation</td>
<td>group</td>
<td>0</td>
<td>9:00-11:00 Wednesday November 13, 2013</td>
<td>various locations on campus</td>
</tr>
<tr>
<td>research protocol</td>
<td>solo</td>
<td>35</td>
<td>4:00pm Wednesday December 4, 2013</td>
<td>PB 670</td>
</tr>
</tbody>
</table>

Only one literature review per research group is required

*Please drop off your assignment at PB 670. PB 670 is the reception desk on the 6th floor of the pharmacy building. You will see it once you exit the elevators. Please sign the registry after handing in your assignment. E-mailed or faxed assignments will not be accepted. Students are advised to retain a backup copy of all assignments.
To ensure consistency in grading, questions/complaints about grades should be directed initially to the appropriate TA. (The TA will put his initials on the cover page of the marked assignment.) If that does not yield satisfaction, please see me.

**Description of evaluation components:**

**Assignment 1: Motivate your research question**

This assignment provides you with the opportunity to address how your research topic will contribute to the existing literature. This includes a review of the existing literature; its limitations (if any); how you plan to contribute to the literature; and the anticipated value of your contribution.

**Guidelines –**

*Statement of the research question.* Describe the research question and its relevance. What is to be gained by addressing the study question?

*Review of existing literature.* The goal here is to synthesize the literature. I am not interested in a detailed study-by-study description. I am interested in a description of the common elements and important differences in the studies that you have uncovered. For instance, do all the studies report the same results? What methods do the studies use? What kinds of patients/subjects were used in the studies? What are the problems or limitations with the studies?

Note: if your research question has not been addressed previously, select the literature that is most closely associated with your question. Suppose that you propose to assess the effect of an in-pharmacy video presentation on the appropriate use of medications for the management of *Weil’s disease* on the health outcomes of patients with this disease. While there are likely no studies in the literature on this exact topic, you could review the evidence on the effects of educational videos on the medication compliance and/or health outcomes of patients with other types of disease, or even look more generally at theories and/or empirical evidence on the impact of educational interventions on self care. The same applies to research questions for which the existing literature is sparse.

*Your contribution to the literature.* Given the gaps in the literature that you have identified, how do you intend to fill the gap? For example, the existing literature might have all been conducted outside of Canada, and you might expect the results to be different in the Canadian context for such and such a reason and you are therefore going to repeat the study using Canadian subjects. Or perhaps the last time the study was conducted was in 1975 and since then the context has changed dramatically and you might expect results to differ for the following reasons. Or perhaps there are methodological flaws with the existing studies and you have an idea as to how to improve them. Or perhaps the intervention you are evaluating was conducted on patients with a certain set of characteristics (health problems, age, sex, language …) and for such and such reasons you expect that the impact of the intervention to differ in a population of patients with different characteristics that you intend to study. Or perhaps the intervention that you are planning has never been conducted before. Or perhaps previous studies have been conducted
using a very small sample size and results might therefore be unreliable. You intend to repeat the study on a larger sample size.

**Other guidelines.** It may be helpful to consult published studies in the pharmacy practice research literature to get a sense of how others have synthesized the literature and identified their contributions. Students are permitted to work alone or in groups. Only one assignment per group is required.

Include the following:

- PHM 425 Assignment 1
- Date
- Title of Research Protocol
- Student Name and Student Number
- Student Name and Student Number of your partners, if applicable
- Brief statement of the research topic you are pursuing and why it is important (10 marks)
- Review of the existing literature in the area and its limitations, if any. Identification of your contribution to the literature. (30 marks)
- Reference List: A list of research articles relevant to your topic, formatted according to the guidelines described below. (5 marks)
- An additional 5 marks will be awarded for presentation (grammar, syntax, coherent organization and development of ideas).

There are no firm page limits, but you should be able to complete the assignment in a maximum of 4 pages (double spaced) and should aim for 10-20 references. Please number your pages.

**References** – The references in the paper should be written according to the style guidelines described in the “Uniform requirements for manuscripts submitted to biomedical journals”. These guidelines are available on-line at:


Note the one exception to the guidelines: Students are not required to abbreviate journal names.

References should be numbered consecutively in the order in which they are first mentioned in the text. Identify references in text by arabic numerals in parentheses. Example: Jones et al [5] report that smoking causes cancer, while Smith and Fleming [6] find that smoking is harmless. As a more complete example, check out any research article published in the CMAJ, such as: [http://www.cmaj.ca/cgi/reprint/175/2/155](http://www.cmaj.ca/cgi/reprint/175/2/155)

The following writing resources may be useful:

Taylor D. Hit Parade of Errors in Style, Grammar and Punctuation

Helpful suggestions on critical argument and logical connectors:
Link to a website which provides links to the major pharmacy-related literature databases:
http://main.library.utoronto.ca/eir/articlesbytopic.cfm?subject=96

Link to the ‘refworks’ website – this online service allows you to manage your references on line and generate reference lists

Taylor D. Writing a Literature Review in Health Sciences
http://www.writing.utoronto.ca/advice/specific-types-of-writing/literature-review

Link to a website which provides instruction on the use of the major health-related literature databases:
http://gerstein.library.utoronto.ca/research/database-help

Assignment 2: Methods assignment

In this assignment you will use R, the open source statistical software, (or your favorite statistical software) to load a data set, and analyze these data using the methods presented in the course. The assignment will be available in the final week of September.

Assignment 3: Presentation of your research protocol

This is your opportunity to present your draft research protocols to your peers and a tutorial leader and hopefully get some useful feedback that could improve it. Don’t be afraid to discuss the parts of your protocol that you are having difficulty with; use the presentation to your advantage.

In order to provide sufficient time per group, we will be meeting in 10 separate locations around campus. You will be informed of your tutorial meeting room later on.

Assignment 4: The research protocol

Purpose – The purpose of this project is to provide you with the opportunity to demonstrate your understanding of the goals and objectives of the course; namely, to design a research proposal to examine a clearly defined, delimited research question in pharmacy practice. You need not actually carry out the study.

Task – You will be required to: choose a topic; provide appropriate background and rationale; review relevant research literature; propose a hypothesis, if appropriate; describe your design
(methods) with supporting documentation; identify relevant ethical issues; describe how you will analyze your data; present a project time line and prepare a budget.

**Length** – the resulting paper should not exceed ten (10) pages, double-spaced (about 2,500 words 12pt font with 1” margins) plus abstract, references, appendices and any figures and tables.

**Marks allocation for the research protocol:**

**Title page:** be sure to list the name and student number of you and those in your research team

**Abstract:** (no more than 250 words) (5 marks)

**Body:** (10 pages, double-spaced: 2,500 words)

*Introduction (10 marks)*
- Problem/background/rationale;
- Review of the literature and your contribution to it.

*The research question (5 marks)*
- Explicit research question or hypothesis that you will address
- Conceptual framework (including path diagram where appropriate)

**Methods**
- research design (15 marks);
- sampling from the target population (5 marks);
- measurement of outcome variables and other variables (10 marks);
- sample size justification (5 marks);
- statistical or other procedures to estimate parameters and precision of parameter estimates (5 marks);

**Ethical considerations (10 marks)**

**Discussion (5 marks)**
- Recap the significance of research contribution to pharmacy practice,
- Limitations of proposed research,
- Recommendations for further research.

**References:** (5 marks)
- New page, no limit. Use only those identified in text.

**Appendices** (each beginning on a new page):
- Include copies of all documents referred to in text, e.g., instruments used; consent forms; tables; figures; time line with explanation (5 marks); itemized budget w/expense justification (5 marks).
Clarity of presentation (15 marks)

Criteria for evaluation – The project will be evaluated on the following:

- *its contribution to the body of knowledge in pharmacy practice research*. For maximum marks, the study will add to the literature: it will address a novel research question using appropriate methods. In particular, the research design, and statistical methods and formulae (if appropriate) are clearly described and motivated. If you propose to evaluate an intervention (such as the effect on some outcome of new vs old care), for maximum marks, you need to provide some justification that the proposed new care might actually work better than old care.

- *the clarity of presentation*. For maximum marks, the study will use appropriate grammar and syntax, and express ideas coherently and succinctly. Note that the University offers both in-person and on-line writing assistance. Check out the University of Toronto Health Sciences Writing Centre: http://www.hswriting.ca/. Because demand for this service is high, you are advised to book appointments well in advance of assignment due dates.

- *the ability to follow instructions*. For maximum marks, the study: will observe the 10 page limit and use the primary headings described above (i.e. Abstract, Introduction, The Research Question, Methods, Ethical considerations, Discussion, References, Appendices), will reference articles correctly, and will add page numbers.

Marks allocation for different types of research protocols

For full marks, research protocols need to use the primary headings described above. The content of each of these sections, however, will depend largely on the type of research protocol. For instance, if you are proposing to conduct research using secondary data (such as anonymized drug claims data) then you would indicate in the Ethical Considerations section that, because the research is not being conducted on identifiable individuals, no informed consent is required. That will earn you full marks for that section. Similarly, if you are proposing to conduct qualitative research, then you would not conduct any statistical procedures. Instead you would need to synthesize the results of the interviews or other ‘data’ collected. If you are proposing to estimate a mean of some outcome variable (such as the proportion of some target population with undiagnosed hypertension) then the usual sample size formulae are not applicable. In particular, you don’t need to power your study to be able to detect a treatment effect of size $d$ with probability $1 - \beta$. 


Explanation of the different sections

Abstract: this is a succinct summary of your research protocol. It very briefly describes the importance of the research topic, the gap in the literature that you intend to address, and how you intend to address it.

Introduction: this section describes the importance of the research topic to pharmacy practice, and identifies the gap in the literature that you intend to address. Given that you and your teammates have joint ownership over the introduction and literature review that you have previously submitted in term assignment 1, you do not necessarily need to rephrase these portions “in your own words” when writing up the research protocol. On the other hand, you might very well wish to condense these sections for the protocol.

The research question: be sure that you are explicit about the questions that you propose to investigate. Also, if you are evaluating an intervention, include in this section a detailed description of your intervention and an explanation of how you think your intervention will affect intermediate and/or final outcomes of interest. In this section you would describe:

1. the intervention and study populations: what is being done to whom, by whom, where and how often? What is the intervention being compared against?
2. the outcome variable(s) that you will be monitoring
3. a path diagram relating the intervention to intermediate and final outcome variables. If you are targeting an intermediate outcome, what evidence is there that changes in an intermediate outcome would affect the final outcome. The path diagram would also indicate the amount of time that you think would be required for the hypothesized effects to occur and how long you think that the effects will last. For instance, suppose that you are proposing to mount a one-time educational intervention designed to increase patient compliance with prescribed diuretic medication regimens. Do you expect compliance to be permanently affected by the intervention or will the effect of the intervention wear off after a while?

For further details, see the lecture notes.

Methods

Research design: outline how you propose to address your research question(s). For instance, you might propose to conduct a randomized controlled trial, whereby half of the subjects in your sample are randomly assigned to receive the new intervention and the other half receives standard care. Or perhaps you need to cluster randomize. Or perhaps you plan to use one of the methods for observational data. If you use an RCT, how will you overcome any limitations (blinding etc). If you use observational methods, how will you overcome the limitations of those methods (controls for confounders etc)? If you plan on conducting qualitative research, justify why qualitative methods are required and identify what type of qualitative research you will use (e.g. semi-structured interviews, document review, etc.).
**Sampling from the population of interest:** if you are sampling, describe how you will select and recruit members of the target population for inclusion into the study. If you are conducting quantitative research, how will you ensure maximum generalizability of your study results and avoid selection bias? If you are conducting qualitative research, how will you ensure that you will capture the diversity of perspectives on the phenomenon of interest?

**Measurement instruments:** how will you measure outcome variables and other variables? What evidence is there that the measurement instrument(s) are valid and reliable? How do you intend to collect this information? For instance, will it be a survey or will you use administrative data?

- If possible, use a validated instrument – HAPI is a good source of information
- If no validated instruments are available, search the literature for validated instruments which are similar to the one you need and adapt those for your own purposes.
- You might then budget for a small pilot study to assess the measurement instrument prior to commencing the main study

If you are using a qualitative approach, ensure that you provide copies of any interview guides or other instruments used to collect information.

**Sample size justification:** Justify your choice of sample size using sample size calculation formulae where appropriate.

**Statistical analyses:** Suppose that the goal of your research protocol is to estimate an unknown parameter (such as a treatment effect parameter or the mean of some outcome variable). The statistical analysis section of your protocol indicates to the reader how you will go about estimating the parameter(s) and estimating the precision of your estimates using the data that you have collected. Once you have both of these pieces of information, you can estimate a confidence interval (CI) around your parameter estimate. The CI is a convenient way to presenting your results. Once you have estimated a CI, normally there is no need to conduct hypothesis tests.

How you go about estimating the unknown quantities depends a lot on your research design. For instance, if you are conducting an RCT to generate data, then you can estimate the treatment effect as the difference in means of the outcome variable in the group of subjects assigned to new care and the group of subjects assigned to standard care. The outcome variable can be continuous (such as mean HBA1C) or binary (such as the mean of the binary indicator equal to one if a person is hospitalized; this mean is simply the fraction of individuals hospitalized). You can also take baseline measurements on the outcome variable of each subject and compute the pre-post baseline difference in health outcomes; this will reduce the variability of the error terms. The estimator of the precision of your treatment effect estimate (assuming a continuous outcome) can be estimated with the analytic formula given in the lecture notes for session 10.

Alternatively you can use the bootstrap procedure to estimate the precision of any parameter estimate. (Resample with replacement from your original data and re-estimate the parameter. Repeat this a large number (say 1,000) times and estimate the standard error of your parameter estimate as the 2.5th and 97.5th percentiles of the distribution of the 1000 parameter estimates.)
To estimate unknown parameters you can alternatively use regression methods.

<table>
<thead>
<tr>
<th>Nature of outcome variable</th>
<th>Estimation method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuous: interval or ratio scale. E.g. Blood pressure, INR, HBA1C level.</td>
<td>Linear regression</td>
</tr>
<tr>
<td>Binary (0,1). E.g. High blood pressure or not. Compliant or not.</td>
<td>Logit regression</td>
</tr>
<tr>
<td>Unordered categorical. E.g. Patient’s choice of treatment: self care using natural health product, self care using OTC drug, professional care from pharmacist or physician</td>
<td>Multinomial logit regression</td>
</tr>
<tr>
<td>Ordered categorical. E.g. Patient’s self assessed health status: excellent, very good, good, fair, poor. Level of activity limitation due to arthritis: severe, somewhat, none.</td>
<td>Ordered logit regression</td>
</tr>
</tbody>
</table>

These methods can be used for both RCT and observational data. Moreover these methods will produce analytic estimates of the standard error of your parameter estimates which, in combination with the parameter estimates, can be used to estimate a confidence interval.

If you are proposing to use qualitative methods, how will you analyze the interview or other data that you will collect?

*Ethical considerations:* if you research involves human subjects, explain how you will obtain subjects’ informed consent by individuals other than subject’s usual health care provider. If the research involves ‘vulnerable’ subjects (such as those with HIV-AIDs), or exposes subjects to possible harm, explain how the anticipated benefits of the proposed research outweigh the foreseeable risks.

If your research involves interviews or interventions conducted on human subjects, include copies of informed consent forms in the Appendix. There are numerous informed consent form templates available on-line, including those provided by the World Health Organization:

http://www.who.int/rpc/research_ethics/informed_consent/en/

**References:** A list of research articles relevant to your topic, formatted according to the guidelines set out in:
http://epe.lac-bac.gc.ca/100/201/300/cdn_medical_association/publications/mwc/uniform.htm
(Note the one exception to the guidelines: Students are not required to abbreviate journal names.)

References should be numbered consecutively in the order in which they are first mentioned in the text. Identify references in text by Arabic numerals in parentheses. Example:
Jones et al [5] were the first to provide evidence that nicotine is addictive. Numerous studies conducted since then have provided confirmatory evidence [6-14,17].

**Clarity of presentation.** 15 marks will be awarded for syntax, grammar and organization (i.e. your ability to structure a logical sequence of arguments). When writing the protocol it is useful to first identify the points you want to make in “point format”. Then organize the sequence in which you want to make these points. Then write up the protocol, paying attention to syntax and grammar.

**Appendices:** There are several components of the Appendix section that we have not discussed in class. These are the Time Line and Itemized Budget.

The **time line** enumerates all of the separate tasks that are involved in the execution of the research protocol and provides an estimate of how long each task will take.

You can create a timeline easily using a spreadsheet program or word processor. Suppose your study will take 13 months from start (patient recruitment) to finish (writing up of the final report). Simply enumerate all of the major activities in your study in the order in which they will commence in a column. These activities might include recruitment of patients or health care providers, interviews or data collection, call backs to follow up patients who haven’t responded, data analysis (clean up, description, statistical analysis), report write-up. Then create a column for each of the 13 months of your study and shade in the months during which each activity will take place. Keep in mind the logical order of activities – e.g. you can’t begin statistical analysis until your data is ready for analysis. See the example on the next page.
Sample timeline

<table>
<thead>
<tr>
<th>Activity</th>
<th>Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>recruit patients</td>
<td>Jan-03</td>
</tr>
<tr>
<td>something else</td>
<td>Feb-03, Mar-03, Apr-03, May-03</td>
</tr>
<tr>
<td>win nobel prize</td>
<td>Jun-03, Jul-03, Aug-03, Sep-03, Oct-03, Nov-03, Dec-03, Jan-04</td>
</tr>
</tbody>
</table>
Part of the reason that you are preparing the research protocol is to convince a granting agency to fund your study. The *itemized budget* indicates what resources are required to conduct your study and the cost of these resources.

Notes on preparing an itemized research budget:

- In Canada, the study investigators normally cannot get paid for their time

- Be sure to include all costs of research – e.g. data, software licenses, licenses to use measurement instruments, reprints, travel costs for investigators, travel to scientific meeting (possibly somewhere warm) to present results, research assistants, additional costs to deliver the intervention (such as cost of pharmacists’ time spent counseling patients), secretarial support

- If you can get costs covered elsewhere, say so! This makes it seem that the funder is getting a good deal  Examples:
  - Get a consultant to be a co-investigator (and work for free!)
  - If you can get free data, include a line item for this in the budget, but indicate “no charge”

- Don’t obviously inflate budget requirements. Provide several quotes for large expenditure items.

- Justify your expenditures (e.g. provide description of roles of personnel, explain why you need a specific piece of lab. equipment)

- For the purposes of the preparing the research budget for your protocol, because you will not be actually submitting this for funding, it is not necessary to provide accurate estimates of the cost of the resources you are using. You can provide reasonable guesses. You should, however, enumerate the resources that you require for your study.

- Students working in the same research group can share all appendix materials (if you are all proposing the same research, there is no need to devise separate budgets, timelines, etc.). Students are reminded that they have to write up the body of the research protocol independently so as to conform to Faculty of Pharmacy regulations.

I have posted to the course website an MS Excel spreadsheet to facilitate the creation of the study budget and timelines.
### Sample itemized budget

<table>
<thead>
<tr>
<th>Item</th>
<th>Rationale</th>
<th>Cost</th>
<th>Amount Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research Assistant</td>
<td>recruit subjects from our community pharmacy to join our study; obtain informed consent; remind subjects of upcoming appointments; data entry</td>
<td>250 hours @ $25/hour including benefits</td>
<td>6,250</td>
</tr>
<tr>
<td>Computer</td>
<td>data analysis</td>
<td>computing facilities have been provided by pharmacy</td>
<td>0</td>
</tr>
<tr>
<td>Statistical Software</td>
<td><em>Stata</em> software required for statistical computations and database management</td>
<td>$750</td>
<td>750</td>
</tr>
<tr>
<td>Statistical analysis services</td>
<td>Conduct sample size calculations, model estimation and other statistical analyses</td>
<td>35 hours @ $55/hour – services donated by Dr. Mitch Finkelstein</td>
<td>0</td>
</tr>
<tr>
<td>License fees for health outcome measurement instrument</td>
<td>Fees for use of SF-36 self administered health measurement tool</td>
<td>$1,250</td>
<td>1,250</td>
</tr>
<tr>
<td>Travel</td>
<td>travel for study PI to world pharmacists symposium in Nice, France to present results</td>
<td>$3,000</td>
<td>3,000</td>
</tr>
<tr>
<td><strong>Total Requested</strong></td>
<td></td>
<td></td>
<td><strong>11,250</strong></td>
</tr>
</tbody>
</table>

**Guidelines for Collaborative and Independent Work in PHM 425**

Students are permitted to develop research protocols for the major research project either alone or in groups. Students working in groups need only submit one copy of the literature review but are required to prepare the methods assignment and the final research protocol (due at the end of term) independently. Specifically, in conformity with Faculty policy, students must write up the body of the text independently in order to develop critical thinking and writing skills. For the final research protocol, students working in groups may, however, submit identical copies of the
abstract and appendix materials, such as instruments used; consent forms; tables; figures; time line with explanation; itemized budget w/expense justification. Students working in groups are also allowed to submit identical literature review sections in their research protocols (because this material was previously generated from a group assignment).

Students are advised to review the handout “How Not to Plagiarize”; this is available on-line at: http://www.writing.utoronto.ca/advice/using-sources/how-not-to-plagiarize

Additional information is available on-line at: http://www.utoronto.ca/academicintegrity/

5 LATE ASSIGNMENT AND MISSED EXAM POLICY

Late Assignments will be penalized at 5 percent for each 24 hour period (or portion thereof) past the deadline.

Missed Exams

Students who have missed an examination or assignment must follow the Faculty policy as outlined in the Calendar. Failure to do so will result in a grade of zero for that exam or assignment. In the event that a student is unable to write the midterm exam, and has provided a valid reason to the Faculty Registrar, a make-up exam will be provided. The instructor reserves the right to choose the format (written or oral) of the make up exam.

6 SCHEDULE OF CLASSES

<table>
<thead>
<tr>
<th>session</th>
<th>date</th>
<th>topic</th>
<th>speaker</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>4-Sep-2013</td>
<td>Overview of Pharmacy Practice Research (PPR)</td>
<td>paul grootendorst</td>
</tr>
<tr>
<td>2</td>
<td>11-Sep-2013</td>
<td>Prediction and forecasting</td>
<td>paul grootendorst</td>
</tr>
<tr>
<td>3</td>
<td>18-Sep-2013</td>
<td>Using R to estimate regression models. Literature Search Skills.</td>
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7 SESSION OVERVIEWS AND READINGS

Session 1: Introduction

Objectives:
Motivate pharmacy practice research (PPR) as a worthwhile thing to do, describe how you do it, and finally, what you will be required to do in this course to get a good mark.

Readings:
My lecture notes (downloadable from the course website).

Session 2: Prediction and Forecasting

Objectives:
Review methods to forecast future/unknown values of outcome variables.

Readings:
My lecture notes (downloadable from the course website).

Session 3: Using R to estimate regression models. Literature Search Skills

Objectives:
Hour 1: Understand how to load the open source software R on your computer, and how to use R to read a data set and estimate a regression model using these data.
Hour 2: Understand how to use the literature databases available through the University of Toronto Libraries to find literature related to your research topic.

Readings:
Notes on how to use the R software will be posted to the course website.
The R software is described at: http://www.r-project.org/

Session 4: Examples of PPR. Estimating treatment effects

Objectives:
Hour 1: A PPR practitioner, Lisa Dolovich, will describe her research and its relevance.
Hour 2: Most PPR attempts to estimate treatment effects, the impact of a change in some treatment variable on some outcome variable. We will use the “path diagram” to assess which outcome variable to focus on and discuss the different ways that you can estimate treatment effects.

Readings:
My lecture notes.
Session 5: Overview of qualitative research.

Objectives:
In this session, Prof. Heather Boon, a qualitative methods expert and practitioner at the Faculty of Pharmacy, will speak to the uses of qualitative research in pharmacy practice research.

Readings:
Sofaer S. Qualitative methods: what are they and why use them? Health Services Research 1999; 34(5) Part II: 1101-1118.
http://simplelink.library.utoronto.ca/url.cfm/114389

One other TBA.

Optional:
http://symptomresearch.nih.gov/chapter_7/sec2/cmss2pg1.htm

Giacomini MK, Cook DJ. Users’ guides to the medical literature XXIII. Qualitative research in health care A. Are the results of the study valid? JAMA 2000 Jul 19;284(3):357-362.
http://simplelink.library.utoronto.ca/url.cfm/114390

Giacomini MK, Cook DJ. Users’ guides to the medical literature XXIII. Qualitative research in health care B. What are the results and how do they help me care for my patients? JAMA 2000 Jul 26;284(4):478-482.
http://simplelink.library.utoronto.ca/url.cfm/114391

Session 6: Estimating treatment effects using randomized controlled trials and the instrumental variables estimator.

Objectives:
Review the randomized controlled trial (RCT), what many call the “gold standard” method for estimating treatment effects; show off its nice properties. Show how the RCT can be thought of as a special case of a more general method of treatment effects estimation known as the instrumental variables approach.

Readings:
My lecture notes.

Optional:
Jadad A. Randomised controlled trials: a users guide.
Sessions 7: Estimating treatment effects commonly used with non-experimental data.

Objectives:
Review the different approaches, including matching, regression and time series methods.

Readings:
My lecture notes.

Session 8: Measuring variables and collecting data on them.

Objectives:
Suppose that you wish to investigate the effect of some intervention on patient health. How do you measure health? It could be a clinical, disease-specific measurement (such as blood pressure), it could be a measure of overall health as subjectively experienced by the subject(s) of your study (such as: In general, would you rate your health as: Excellent, Very Good, Good, Fair of Poor) or it could be a measure of functional capacity in a health attributes (for example, capacity in one health attribute, hearing, could be rated on a scale from ‘completely deaf’ to ‘able to hear what is being said in a conversation in a noisy room’; other health attributes might include: hearing, speech, vision, pain, manual dexterity, ambulation, cognition, and emotional health). In this session we will review the desirable features of a measurement instrument (namely ‘reliability’ and ‘validity’) and how to ascertain whether your instrument satisfies these.

Once you have settled on a measurement instrument, you need to collect data. But the form of the data collection – an in-person interview survey, a self-completed mail survey, or a telephone interview – could affect both the accuracy of the response you get and whether you get a response at all. Moreover, whether you ask the subject directly, or a person answering on his/her behalf (known as a proxy) might also make a difference. Finally, the length of the survey and the wording of the questions might make a difference. We will review the evidence on the mode of survey administration and survey design on response patterns.

Readings:
My lecture notes.

Session 9: Research ethics.

Objectives:
Research conducted on human subjects must conform to ethical standards. Daniel Gyewu from the Office of Research Ethics will identify and explain the rationale for these ethical standards in the context of pharmacy practice research.
Readings:
- TBA.

Optional:
The Office of Research Ethics website has sample consent forms and other useful resources
http://www.research.utoronto.ca/for-researchers-administrators/ethics/human/

Session 10: Assessing estimator precision.

Objectives:
- Derive your estimator’s sampling distribution and its variance. Estimating your estimator’s variance. Sample size measurement, p-values, hypothesis tests and confidence intervals.

Readings:
- My lecture notes.

Session 11: Student presentations of draft research protocols.

In this session you and your colleagues will present your preliminary protocols to your classmates and a tutorial leader in small groups to get constructive feedback.

Note that the tutorial takes place from 9:00 – 11:00 am in one of the following locations: PB 850, PB B250, Hautain Building, Room 316 (HA 316); Earth Sciences Building, Room B142 (ES B142); University College, Room 85 (UC 85); UC 330; Sidney Smith, Room 1078 (SS 1078); SS 1085; McLennan Physics, Room 134 (MP 134); Lash Miller, Room 157 (LM 157)

I will assign you and the rest of your research team to one of these rooms.

Session 12: Review of some applied PPR studies.

Objectives:
- Work through some PPR studies published in the literature to get a sense of how the methods discussed in class are actually implemented.

Readings:
- PPR studies to be reviewed TBA.

Session 13: Wrap-up.

Objectives:
- Review progress on your research protocol. Review any materials covered in class.
General Suggestions on making Presentations

(with contributions from Thomas Crossley, Cambridge University)

OVERHEADS (the most likely approach given the time constraints)

- When possible, prepare your overheads ahead of time.
- Do not put overheads on the screen before you plan to refer to them.
- When you put them on the screen, make sure you do refer to them.
- When referring to overheads, you should usually point to the screen, not the overhead on the projector (exception: drawing on the slide).
- Leave overheads up long enough for people to read and understand them.
- If you are running out of time and you still have overheads you had planned to put up on the screen, it is better not to put them up at all than to put them up and then immediately remove them. (Think ahead of time what can be cut)
- Make sure the overheads are aligned and focussed.
- Take care not to cast your shadow on the overhead screen.
- Use larger font sizes when transferring to overheads. For a small classroom or seminar room, about 16 point type with a Times Roman font usually works reasonably well. For a classroom of 100 you will want 20-22 point type.
- Do not try to cram too much onto one overhead; include only what can reasonably be fitted onto an overhead, and be prepared to omit some material altogether.
- Come with a marking pen in case you need to make corrections or annotations on the overhead.

HANDOUTS

- Only distribute what you plan to refer to, and only do so when you plan to refer to it. Anything else will distract members of your audience, who will read it when they should be listening to you.
- Most material on overheads does not also need to be handed out. However, sometimes it is useful to hand out detailed tables that you will be referring back to.

TIME CONSTRAINTS

- Practise your presentation to make sure you don't have too much material. The most common mistake is to prepare too much, rather than too little, material.
- If you have to leave material out, omit detail.

POWERPOINT PRESENTATIONS (or other computer presentation software).

- If you wish to use this software, talk to me ahead of time.
- Be prepared to set up ahead of time.
- Make sure you can do the presentation at least as well as you could by some other method.
GENERAL

- If you wish to use the blackboard or if there is material on the blackboard that might be distracting, clean the board before you start.
- When you are presenting, talk to, and look at, the audience. In particular, do not talk to the blackboard (or white screen).
- Try not to read from a prepared text.
- Try to use some aids (overheads, blackboard, props, etc.); a talking head, even one that isn’t reading, is often difficult to follow.
- If you draw graphs, label the axes.
- Define all your terms: by reading and rereading your protocol, you have become much more knowledgeable about its subject matter than your audience; don't assume members of your audience have a level of familiarity that they obviously haven't got.
- Provide context: link the subject matter to something familiar to the group (where possible), such as a theme from your other pharmacy classes.
- If you have not made a presentation before (and even if you have) a good approach to use as a model is the ‘three-prong’ approach.
  - tell the audience what you are going to tell them
  - tell it to them
  - tell them what you have told them
- If you use a lectern, the sight lines of someone sitting at the desk on the other side may be impaired (especially if you are using overheads). Consider where you can stand so you don’t block the view.
- Stand up straight when talking, and speak slowly, articulating your words clearly.