PHM425: PHARMACY PRACTICE RESEARCH

FALL 2011

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Personal web: http://individual.utoronto.ca/grootendorst/index.htm

Course Hours and Location: Tuesdays 3:00-5:00 pm. PB B150.

Office Hours: Fridays 1:30-3:00 and by appointment.

Teaching Assistants: Ivana Todorovic, MSc
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Office Hours: TBA

Ethar Ismail, BSc
Email: ethar.ismail@gmail.com
Office Hours: TBA

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.

GERSTEIN CALL NUMBER RS122 .S65 2002

GERSTEIN CALL NUMBER RS122 .S645 2005

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 2007 (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>item</th>
<th>% of final grade</th>
<th>due date</th>
</tr>
</thead>
<tbody>
<tr>
<td>literature review*</td>
<td>10</td>
<td>4:00pm Friday, October 7, 2011</td>
</tr>
<tr>
<td>Midterm</td>
<td>35</td>
<td>Friday, October 28 from 2:00-3:30pm</td>
</tr>
<tr>
<td>Methods*</td>
<td>15</td>
<td>4:00pm Friday, November 4, 2011</td>
</tr>
<tr>
<td>Presentation</td>
<td>5</td>
<td>Tuesday, 15 November, 11</td>
</tr>
<tr>
<td>Protocol*</td>
<td>35</td>
<td>4:00pm Tuesday, 29 November, 11</td>
</tr>
<tr>
<td>total</td>
<td>100</td>
<td></td>
</tr>
</tbody>
</table>

*Please drop off your assignment at PB 671; also please sign the registry indicating that you have done so. E-mailed or faxed assignments will not be accepted. Students are advised to retain a backup copy of all assignments.

Questions/complaints about grades should be directed initially to the appropriate TA. This is done to ensure consistency in grading. 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 describing 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.

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:

http://epe.lac-bac.gc.ca/100/201/300/cdn_medical_association/publications/mwc/uniform.htm

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 innocuous.
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

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

The following writing resources may be useful:

Taylor D. Hit Parade of Errors in Style, Grammar and Punctuation
http://hswriting.library.utoronto.ca/index.php/hswriting/article/view/3089/1234

Helpful suggestions on critical argument and logical connectors:
Assignment 2: Methods for your research protocol

Describe, motivate and justify the methods that you propose to use to address your research question. Include the following:

- PHM 425 Assignment 2
- 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 (5 marks)
- Description and justification of the methods you propose to you to address research question. (25 marks)
- Reference List: References cited need to be formatted according to the guidelines described earlier. (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).

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 (5 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/](http://www.hswriting.ca/). The Pharmacy Writing Centre is located in PB 426. 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 use the primary headings described above (i.e. Abstract, Introduction, The research question, Methods, Ethical considerations, Discussion, References, Appendices) and will reference articles correctly.

**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 Jan-03 Mar-03 Apr-03 May-03 Jun-03 Jul-03 Aug-03 Sep-03 Oct-03 Nov-03 Dec-03 Jan-04</td>
</tr>
<tr>
<td>something else</td>
<td></td>
</tr>
<tr>
<td>…</td>
<td></td>
</tr>
<tr>
<td>win nobel prize</td>
<td></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>Stata 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 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 written assignment (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 per day.

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, the final exam will count for 40% of the final grade and the midterm exam 0%.

6 SCHEDULE OF CLASSES

<table>
<thead>
<tr>
<th>Date</th>
<th>Session #</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tuesday, 6 September, 11</td>
<td>1</td>
<td>Overview of Pharmacy Practice Research (PPR)</td>
</tr>
<tr>
<td>Monday, 12 September, 11</td>
<td>2</td>
<td>Examples of PPR*</td>
</tr>
<tr>
<td>Tuesday, 13 September, 11</td>
<td>3</td>
<td>Prediction and forecasting</td>
</tr>
<tr>
<td>Tuesday, 20 September, 11</td>
<td>4</td>
<td>Estimating treatment effects using RCTs</td>
</tr>
<tr>
<td>Tuesday, 27 September, 11</td>
<td>5</td>
<td>Qualitative methods</td>
</tr>
<tr>
<td>Tuesday, 4 October, 11</td>
<td>6</td>
<td>Estimating treatment effects using regression and matching</td>
</tr>
<tr>
<td>Tuesday, 11 October, 11</td>
<td>7</td>
<td>Estimating treatment effects using IV and time series methods</td>
</tr>
<tr>
<td>Tuesday, 18 October, 11</td>
<td>8</td>
<td>Measuring variables and collecting data</td>
</tr>
<tr>
<td>Tuesday, 25 October, 11</td>
<td>9</td>
<td>Student presentations of protocols</td>
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<tr>
<td>Tuesday, 1 November, 11</td>
<td>10</td>
<td>Ethical issues in PPR</td>
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<td>Tuesday, 8 November, 11</td>
<td>11</td>
<td>Assessing estimator precision</td>
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<td>Tuesday, 15 November, 11</td>
<td>12</td>
<td>Student presentations of protocols</td>
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</table>
Tuesday, 22 November, 11  13  Wrap-up
Tuesday, 29 November, 11  Protocols due

Tuesday classes are held 3:00-5:00 pm in PB B150
*Class on Monday, September 12 will be held from 10:00am to 12:00pm in the Medical Sciences Building Room 3154.
** Students working together on the same protocol will be assigned to one of 13 different meeting rooms.

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: Examples of PPR

Objectives:
Practitioners of PPR will describe their research and its relevance.

Session 3: Prediction and Forecasting

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

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

Session 4: Estimating treatment effects using randomized controlled trials (RCTs)

Objectives:
Review what many call the “gold standard” method for estimating treatment effects (i.e. estimating effect of x on y); show off its nice properties. Review the differences between experimental and observational research approaches.
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

Sessions 6 and 7: Estimating treatment effects using observational data.

Objectives:
Review the different approaches, including matching, regression, instrumental variables 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: Student presentations of draft research protocols.

This session you and your colleagues will present your preliminary protocols to your classmates in small groups to get constructive feedback.

Session 10: 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 11: 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 12: Student presentations of draft research protocols.

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 this presentation is worth 5% of your grade.

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
distractions 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.
  o tell the audience what you are going to tell them
  o tell it to them
  o 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.