PHM389/PHM589 Research Project

August 20, 2021 (DRAFT)

DESCRIPTION

This elective course is designed to introduce pharmacy students to the philosophy, methodology and performance of research in scientific fields offered by faculty members who hold SGS appointments in the *Graduate Department of Pharmaceutical Sciences*. Thus fields of study are wide ranging and may include as examples: bioethics, clinical pharmacy, drug delivery, drug metabolism, drug policy, drug safety, global health and corruption, health services research, medicinal chemistry, pharmaceutical diagnostics and imaging, neuroscience, pharmaceutics, pharmacoeconomics, pharmacoepidemiology, pharmacokinetics, pharmacology, pharmacy administration, radiopharmacy, receptor biology, therapeutics, toxicology.

Research methods across the fields of pharmaceutical sciences are broad ranging and may include, as examples: cohort studies, case-control studies, chart review, clinical studies, costing studies, cross-sectional studies, documentary data analysis, drug utilization studies, experimentation in the lab, focus groups, time series analysis, interviews, literature synthesis*, qualitative methods, self-controlled studies, survey methods.

*All types of systematic literature synthesis are eligible, e.g., scoping review, meta-analysis, network meta-analysis. However, a <u>traditional narrative review that does not include replicable</u> <u>study methods</u> (e.g., databases and search terms identified as well as study flow of results) <u>are</u> <u>not eligible</u> for this course. Regardless of the type of research, all students are required to review pertinent scientific literature to inform the background, rationale, methods, and discussion.

Course Coordinator:

Suzanne Cadarette, PhD s.cadarette@utoronto.ca* 416-978-2993 PB 602 (first office left off the main elevators on the 6th floor)

**if sending email to the course coordinator, please include PHM389/PHM589 in the subject heading*

APPLICATION AND ENROLMENT PROCEDURES

If the professor agrees to supervise the student research project, the **Research Project** -**Supervisor Form** (see Appendix), must be completed and **submitted to the course coordinator by the** <u>first day of the term</u>. The PHM389/PHM589 Course Coordinator must also sign this form. Submission of the **Research Project** – **Supervisor Form** does not in itself complete your registration in the course. You <u>must also complete a course add form</u> (PHM389: contact Linda Chung - <u>l.chung@utoronto.ca</u>, PHM589: contact Cecilia Sumi - <u>cecelia.sumi@utoronto.ca</u>).

RESPONSIBILITIES OF THE STUDENT

1. Identify a Supervisor

- Students may identify a supervisor from among the faculty that hold an <u>unrestricted</u> School of Graduate Studies (SGS) appointment with the Graduate Department of Pharmaceutical Sciences, i.e., at minimum able to serve as sole supervisor for MSc students.
- Students are encouraged to meet with several professors to discuss potential research projects. The decision to enroll in the course is a joint decision of the student and faculty member.
- Faculty members can supervise a maximum of 2 students (primary or co-supervisor) per term in PHM389 and PHM589 combined (i.e., 2 PharmD research projects total per term).

NB: The sooner you reach out to potential faculty members, the better. Students typically reach out and secure a supervisor one or two terms before enrolment in the course.

2. Course Enrolment

- Once a supervisor is secured, students are required to complete the course enrolment form with their supervisor and submit to the course coordinator by the first day of the term. NB: *Ethics approval is required BEFORE course approval by the course coordinator.*
- Once course enrolment is approved, students are required to complete and submit a course add form (PHM389: contact Linda Chung <u>l.chung@utoronto.ca</u>, PHM589: contact Cecilia Sumi <u>cecelia.sumi@utoronto.ca</u>).

3. Course Orientation

All students are expected to attend the course orientation (typically 1st Monday of the term). Please contact the course coordinator if there is an unavoidable conflict.

4. Write and Submit Proposal

Students will submit a preliminary report/protocol by the end of the third week of the term that outlines the background and rationale, the type of question(s) or hypotheses asked, methods, significance and feasibility of the project.

- Max: 3 double-spaced, typed pages (Times New Roman, 12-point font) + up to 10 pages supplemental material for references, tables and figures. References are imperative!
- Please refer to rubric for more detail.

5. Meet with Course Coordinator

Students will meet with the course coordinator (typically in the 4th week of the term) to discuss their research project, including feasibility.

6. Execution of Project

Depending on the project and supervisor, the research may be completed in a number of settings, e.g., laboratory or office at the Faculty, hospital, community pharmacy or pharmaceutical company. Students are expected to spend a <u>minimum of 78 hours on the course project</u>. This typically includes:

- searching for, reading, and critically appraising pertinent literature;
- preparing a detailed proposal to guide the project;
- execution of a research project (e.g., data collection, analysis); and
- communication of research findings (oral presentation and written paper).

The actual time distribution will be flexible and determined by the nature of the research conditions and any timetable conflicts.

7. Complete and submit mid-term report

Students will meet with their supervisor(s) to discuss progress for the mid-term assessment, and submit the **PHM389H1 Research Project Mid-term Review Form** through Quercus by the deadline.

• The purpose of this assessment is to identify any deficiencies or problems at the mid-point, determine if the project is progressing well, and identify changes as needed to support student success in the course.

8. Meet with course coordinator briefly (touchpoint) to discuss progress/mid-term report

9. Complete and submit abstract and secondary reviewer suggestions

• Submit the final abstract and list of 3 potential secondary reviewers with rationale based on the faculty members' areas of research expertise in Quercus.

10. Complete and submit final report

- Prepare a final, double-spaced, type-written (Times New Roman, 12-point font) report of maximum 3500 words, excluding abstract, references, tables and figures. The report must follow the format of a scientific journal with sections on Introduction, Materials and Methods, Results, Discussion, Acknowledgement, References, Tables and Figures.
- Please see Appendix for detail and Template/Checklist in Quercus.

11. Presentation

• Present their research in a 10-minute "PowerPoint" presentation with an additional 5-minute question and answer period. Supervisors and peers will be invited.

SUPERVISOR(S)' RESPONSIBILITIES:

- 1. define the research project (topic must be different from prior PHM389/PHM589 projects);
- 2. complete the course enrolment form with the student;
- 3. attend course orientation meeting for supervisors
- 4. ensure progress of the student through guidance and encouragement;
- 5. provide resources and support for conduct of the project;
- 6. stimulate and evaluate the student in the laboratory (or other relevant setting) on their aptitude to think and learn;
- 7. oversee the progress of the student and meet with the student at mid-term to document progress;
- 8. ensure successful write-up of the project for submission of a grade; and
- 9. grade the final report and "industry, originality and creativity" of the student.

COURSE COORDINATOR'S RESPONSIBILITIES:

- 1. oversee project students;*
- 2. approve enrolment in the course;
- 3. remind supervisors of course requirements and deadlines throughout the term;
- 4. meet with each student to discuss their proposal and assign a grade;
- 5. review mid-term reports and identify potential issues for remedy;
- 6. meet with each student to discuss progress in the course at the mid-point;
- 7. reach-out to students and supervisor(s) with any concerns (e.g., progress in the course)
- 8. coordinate presentations and assign a grade;
- 9. grade the abstract and suggested secondary reviewers for the final paper
- 10. secure a secondary reviewer to evaluate the final report; and
- 11. assign the final grade.

*if the course coordinator also supervises the student, the Director or one of the Graduate Field Coordinators in the Graduate Department of Pharmaceutical Sciences will serve these roles.

Course orientation	No grade, yet required
Proposal (write-up and meeting with course coordinator)	10%
Mid-term review form + touchpoint with coordinator	No grade, yet required
Presentation	10%
Abstract & suggested reviewers	5%
 Industry, originality and creativity over the entire term graded by supervisor(s) at the end of the term / submitted to coordinator with the grading for the final paper 	15%
 Research paper Supervisor, 35% Secondary reviewer, 25% 	60%

SUMMARY OF COURSE REQUIREMENTS

Forms and rubrics are included in the Appendix and will be available through Quercus.

PHM389H1 Research Project – 2021/22 Deadlines			
	2021 Fall Term	2022 Winter Term	
Submit Supervisor Form to Course Coordinator (<u>s.cadarette@utoronto.ca</u> (PHM358 or PHM589 in subject line)	Th September 9 by 5PM (1st week of term, typical start date)	M January 3 @ 5PM (1st week of term, typical start date)	
Safety course (only required for students doing experiments in labs)	contact Graduate Department (<u>phm.grad@utoronto.ca</u>) for detail		
Course Orientation**	M September 13 @ 9AM (typically Monday, 2nd week of term) To add zoom info	TBD - <i>tentative M Jan 3 @ 9AM</i> (typically Monday, 2nd week of term) To add zoom info	
Once approved, Submit Course Add Form to: PHM389: <u>I.chung@utoronto.ca</u> , PHM589: <u>cecelia.sumi@utoronto.ca</u>	T September 14 by 5PM (typically 2nd week of fall term)	T January 4 by 5PM (typically 1 st week of winter term)	
Submit 3-page proposal in Quercus***	F September 24 @ 5PM (3rd week of term)	F January 21 @ 5PM (3rd week of term)	
Meeting with Course Coordinator (sign-up in Quercus)	<i>Tentative: Sept 28 or 29</i> (4th week of term)	TBD* <i>Jan 24-28</i> (4th week of term)	
Submit Mid-term Review Form through Quercus	F October 22 @ 5PM (7th week of term)	F February 18 @ 5PM (7th week of term)	
Touchpoint (brief meeting) with Course Coordinator (sign-up in Quercus)	<i>Tentative: October 25-29</i> (8th week of term)	<i>Tentative: February 28-March 4</i> (8th week of term)	
Submit preliminary abstract & suggested reviewers with rationale through Quercus***	F November 19 @ 5PM (11th week of term)	F March 18 @ 5PM (11th week of term)	
Submit final report to Supervisor, and Quercus*** 	F December 3 @ 5PM (12th week of term)	F April 1 @ 5PM (12th week of term)	
Presentation of work 10 minute presentation 5 minute questions and answer period 	M December 6 @ 9AM (typically first Monday of December)	M April 4 @ 9AM (typically first Monday of April)	

* TBD=to be determined, dates/times will be posted in Quercus once known

** ALL students that enrol in the course are expected to have attended the course orientation. Please contact the course coordinator if there is an unavoidable conflict.

*** LATE PENALTY: Students who fail to submit graded assignments by the specified due date and time will receive a deduction of 5% for each day beyond the due date (including weekends/holidays).

Appendix - Supplemental Material*

- 1. Forms
 - Supervisor Agreement Form (NB: some methodological detail must be provided to support project feasibility within the 1-term time frame)
 - Mid-term Review Form
- 2. Evaluation
 - Proposal and Coordinator Meeting
 - Final Paper
 - Presentation
- 3. Guidance Material
 - Final Report Template

*Word version of forms and templates are available in Quercus

PHM389H1 RESEARCH PROJECT – SUPERVISOR FORM

Submit to Course Coordinator (email - include PHM389 or PHM589 in subject heading) by deadline, NB:

- Max 2 students per supervisor (primary or co-supervisor) per term in PHM389/PHM589 combined
- Ethics approval must be granted BEFORE course enrolment can be approved
- Only faculty members with an <u>unrestricted</u> School of Graduate Studies (SGS) appointment in the Graduate Department of Pharmaceutical Sciences can supervise students in this course.

TO BE COMPLETED BY THE STUDENT (all fields MUST be completed):

Surname

Given Names (as on ACORN)

Student Number

Telephone Number

U of T E-mail Address

Date

Student's Signature

TO BE COMPLETED BY THE SUPERVISOR(S)

Please check to confirm you are eligible to serve as PHM389 / PHM589 supervisor:

- □ I hold an unrestricted Associate SGS appointment in the Graduate Department of Pharmaceutical Sciences that permits at minimum sole supervision of MSc students*, **and**:
 - □ I have supervised or co-supervised PHM389 students in the past (if not, you must identify / list a co-supervisor with experience supervising PHM389 or PHM589 students).
- □ I approve supervision of this student, **and:**
 - □ I select this student as one of my maximum two students per term as primary or co-supervisor
 - Lethics approval has been granted or is not applicable, detail:
 - □ I have attached detail to support project feasibility (title, research question and...), e.g.,
 - □ literature synthesis: search terms finalized and provided;

u qualitative interviews or focus group: interview guide finalized and provided;

Other primary data collection: questionnaire / chart abstraction form finalized and provided;

Other experimental: materials (e.g., animals, cell lines, equipment) are available in-house;

□ ICES or other secondary data analysis: data are available in-house (not waiting for data cut or data access).

Date

Supervisor Name(s) (Please print)

Supervisor Signature(s)

TO BE COMPLETED BY THE COURSE COORDINATOR:

□ I approve this student's enrolment in PHM389/PHM589 with above supervisor(s)

D minimum 1 supervisor holds unrestricted Associate or Full SGS appointment in Pharm Sci

D project appears feasible based on the detail provided by supervisor(s)

Date

PHM389H1 RESEARCH PROJECT – MID-TERM REVIEW FORM

Students to upload in Quercus by the deadline

Student Name: _____

Supervisor Name(s): _____

Meeting Date: _____

1. Brief summary of progress (describe accomplishments during the first half of the course):

2. Are there any problems or difficulties you foresee in completing the project?

- 3. Goals for the remainder of the project course:
- 4. Strengths:
- 5. Areas for improvement:

Mid-point eva	luation of stud	ent performa	nce by superviso	or (please circle ON	E)
Excellent	Very Good	Good	Adequate	Marginal	Inadequate
		For fe	eedback only, no n	narks	
Signatures					
Supervisor(s):				Student:	

Date:_____

PHM389 - Grading Structure for Proposal and Meeting with Course Coordinator 10% of final grade*

Components	Grade Distribution
	Marks
Written	10
Background/Rationale (identification of problem)	2
Supported by well-referenced peer-reviewed literature	
Objectives (what you will accomplish)	1
 Clear, logical (based on background/rationale), measurable Hypotheses (if applicable) 	
Methods – Design and rationale (how data collected)	3
 State the study design (e.g., RCT, cohort, cross-sectional, time series) Identify data sources and/or data collection instruments/ methods Clear, logical (rationale provided), measurable, replicable Sample size or power considerations (if applicable) Supported by well-referenced peer-reviewed literature, e.g., validity of data sources or rationale for variable coding/categorization – use tables if space is limited (include as appendix) 	
Methods - Data analysis (how summarize/analyze data)	2
 Clear, specific, appropriate, replicable Includes mock tables or figures 	
Ethical considerations, feasibility and timeline	2
 Includes statement about ethical considerations (e.g., indicates ethics approval with project number) Includes timeline demonstrating feasibility Identifies possible feasibility issues and contingency plans 	
Formatting, flow, style, grammar	Up to -5
Did student follow formatting guidelines, e.g., title page, max 3 pages in main text, Times New Roman 12 point font, 1 inch margins, includes peer-reviewed references,* max 10 pages supplemental including references + readability, flow and grammar.	
Oral	10
Clearly summarizes background and rationale	2
Clearly articulates objectives/purpose + hypotheses (if applicable)	1
Clearly describes (and defends) methods for data collection and analysis with rationale	2
Clearly discusses ethical considerations, feasibility and timeline	1
Clearly articulates strengths and limitations	1
General ability to respond to questions	3
Total	20

*Students will receive a deduction of 5% for each day beyond the due date (including weekends/holidays). In addition, 10% of the overall grade (-2/10) will be deducted if the written proposal does not adhere to format requirements.

PHM389 - Grading Structure for Final	Paper
75% of final grade*	

Components	Grade Distribution	
	Supervisor	Second Reader
Industry (carefulness, time, punctual), Originality and Creativity, 15%	15%	0%
 Assess student initiative, industry, problem- solving skills, responsiveness to suggestions, attention to detail, comprehension, originality and creativity 	20	n/a
Research Paper, 60%	35%	25%
Background/Rationale (identification of problem)	10	10
Assess thoroughness of literature review and rationale		
Methods / Data Analysis (quality and depth of work)	10	10
 Assess whether student has adequately described the methods with support from the literature (e.g. validity, rationale for sample size calculation) 		
Results	10	10
 Assess whether student has presented and summarized the results in a suitable way 		
Discussion (critical evaluation, interpretation)	10	10
 Assess student's critical evaluation, interpretation and how they fit results into the context of the existing literature Assess discussion of study strengths, limitations and future directions 		
Write-up	10	10
 Assess paper flow, style, grammar 	_	-
(NB: supervisors please consider how well student follows your guidance)		

*Students who fail to submit the final report by the specified due date will receive a deduction of 5% for each day beyond the due date (including weekends/holidays). If a student does not adhere to the formatting guidelines, they will be requested to revise and resubmit; facing any late penalty for the revision based on the final submission date of the paper that follows formatting guidelines.

	Marks
Content, e.g.,	10
Background, study rationale	
Methods	
Results	
Discussion, significance, future	
"written" - quality of slides	2.5
"oral" - clarity, enthusiasm	2.5
Question and Answer	5
Total	20x10%

PHM389 - Grading Structure for Presentations 10% of final grade

PHM389H1 RESEARCH PROJECT – ABSTRACT + SUGGESTED REVIEWERS 5% of final grade

Format Requirements:

- Times New Roman, 12 point font
- Single-spaced
- 1 inch margins
- Page numbers

Title

Student Name: xxxxx xxxxxx

Supervisor Name(s): xxxxx xxxxxx, xxxxx xxxxx

Abstract (max 300 words, excludes title and funding sources)

The abstract is a summary of the story and snapshot of highlights; it is not possible to include all information. However, the abstract should be able to stand alone and be coherent independently of the manuscript.

Abstracts are commonly submitted to conferences for considered presentation based on results that are not yet finalized. It is acceptable to revise the abstract prior to submitting the final paper, however there is no separate grade for the abstract as part of final paper. Rather, content/writing in the abstract will be considered within the separate sections in the overall paper grading rubric.

Format:

Purpose or Background: 1-2 sentences to set the stage Methods: include study design, data source, statistical analysis Results: number of patients studied, main results (only highlights-not all results) Conclusions: The conclusion in an abstract may only refer to what is mentioned in the results section in the abstract

Funding Sources: *if none, indicate: unfunded research* **Word count:** (max 300 words, excludes title and funding sources)

Suggested Secondary Reviewers*

Submit suggested reviewers separately for consideration by the course coordinator (1-page maximum).

Suggested Secondary Reviewers*

- 1. xxxxxxxxxxx + rationale
- 2. xxxxxxxxxxxxx + rationale
- **3.** xxxxxxxxxxxx + rationale

*must have an unrestricted SGS Appointment in the Graduate Department of Pharmaceutical Sciences, i.e., minimum sole supervisor of MSc students – see list of eligible faculty members in Quercus

PHM389H1 RESEARCH PROJECT – FINAL PAPER TEMPLATE

Format Requirements:

- Times New Roman, 12 point font
- Double-spaced
- 1 inch margins
- Page numbers
- Acronyms
 - Use sparingly or not at all
 - Define acronym upon first use in the main text (and abstract if applicable)
- Structured abstract of maximum 300 words
- Maximum 3500 words in **main text** (excludes title page, abstract, references, tables/figures, appendices)
- Maximum 10 pages of supplemental material, including references, tables, figures.

The report must follow the format of a scientific journal – below includes some guidance.

Title Page

Title

Student Name: xxxxx xxxxxx

Supervisor Name(s): xxxxx xxxxxx, xxxxx xxxxx

Manuscript word count: xxxx (Max 3500, excludes title page, abstract, references, tables/figures, appendices) **Number of figures:** x **Number of tables:** x **Number of references:** xx

Funding Sources: if none, indicate: unfunded research

Abstract (max 300 words)

The abstract provides a summary of the research story and snapshot of highlights; it is not possible to include all information. However, the abstract should be able to stand alone and be coherent independently of the manuscript.

Format:

Purpose or Background: 1-2 sentences to set the stage Methods: include study design, data source, statistical analysis Results: number of patients studied, main results (only highlights-not all results) Conclusions: The conclusion in an abstract may only refer to what is mentioned in the results section <u>in the abstract</u>

Abstract word count: xxx (300 max for course, yet typically 250 for peer-reviewed journals)

□ please include on a separate (its own) page(s)

MAIN TEXT (typically 2500 words, maximum 3500 words in PHM389/PHM589)

Introduction

- □ Brief review of the literature that provides enough background / context to understand the rationale for your study. Even a literature synthesis requires background to justify the rationale for the paper.
- □ Include statements of
 - *Problem / significance*
 - o Rationale / purpose
 - *Research objectives, questions and/or hypotheses.*
- □ *References are imperative.*

Methods

- Detailed description of study methods in <u>sufficient detail to replicate</u>, e.g.,
 - Study design
 - Inclusion / exclusion criteria
 - Measurements
 - Data collection (if applicable)
 - Data sources
 - Statistical analysis
- □ Include
 - *Rationale for methods and analyses selected (include references to support)*
 - o Software when applicable (include reference if applicable)
- □ Make sure to only describe methods and NOT report results, e.g., total sample included after inclusion/exclusion criteria applied belongs in the results section. However, sample size estimate to base data collection are to be included in the methods section.
- □ Include an ethics statement even if not applicable (e.g., completing literature synthesis), a statement re: ethics is still required.
- □ *References to justify methods are imperative.*

Results: Present and summarize results efficiently using tables, figures and text

- □ *All tables, figures and appendices must be cited in the main text*
- □ *Mention the most interesting findings in tables and figures rather than repeating all the data summarized in tables/figures*
- □ *Tables and Figures appear AFTER the references section and NOT within the main text of the results section.*

Discussion

- □ Interpret findings within the context of the literature
- □ *Make sure NOT to present new results that were not mentioned in the results section text* - *here you discuss the findings (not report them)*
- □ Include study strengths and limitations
- □ If applicable, discuss any unforeseen disruptions to the course project (e.g., Winter 2020 projects were impacted by COVID-19 disruptions)
- □ Include recommendations for future research (all) and for policy changes (if applicable)
- □ *References are imperative*

Acknowledgements and Student Contributions: PHM389 projects are often completed with support from graduate students, post-doctoral fellows or other research staff (e.g., analyst, lab technician) in addition to supervisor(s).

- □ Acknowledge and specify contributions from others
- □ *Clearly indicate your specific contributions to the project/report submitted*

Maximum 10 pages of supplemental content, including references and result tables / figures

References

□ *Cite references in order (numerical) of appearance in the main text*

Table(s) – single spaced is acceptable

- □ Number tables in order of appearance in the manuscript
- □ *Tables titles go above the table*
- □ Tables should "stand alone" and include enough detail to be interpreted without the detailed methods or results sections, e.g., include sample size, define abbreviations used in table footnotes
- □ If table is too long to fit on a single page, repeat the heading row on subsequent pages

Figure(s)

- □ *Number figures in order of appearance in the manuscript*
- \Box Captions go underneath the image single spaced is acceptable
- □ *Figures should "stand alone" see above under Tables*
- □ Have an adequate legend, e.g., use colour or other features (e.g., symbols, shading) that can be interpreted when printed in black and white

Appendix (uncommon for PHM389/PHM589), e.g., supplemental Tables with statistical code, animations of results