New Course Outline

- The [PharmD Approval Process for New Course Outlines](#) document provides for more information on next steps and approval timelines.
- The [Course Outline Submission Overview](#) document provides more detailed guidelines on course learning objectives, topic outlines/scheduling requirements, and assessment methods.
- The [AFPC Educational Outcomes for Professional Programs](#) document provides complete information on roles and key competencies for Pharmacy Degree Programs.

**Course Number:** PHM212H1

**Course Title:** Research Methods for Pharmacy

**Outline Version Code:**

**Course Description:**

Pharmacists are required to apply research evidence in practice. As health care providers, pharmacists discern and translate both the quality and relevance of health information with the goal of optimizing patient outcomes. This course introduces students to clinical trial designs typically used in health care. The course will explore core principles in experimental and non-experimental research designs. The focus will be on randomized controlled trials as they are the primary method of generating evidence for therapeutic interventions. Students will learn how various research approaches are selected, designed, executed, analyzed, published and applied (including critical appraisal). The course covers a broad range of research topics at the introductory to intermediate level. Students will develop foundational knowledge and skills in research methods, statistics and ethics that will be applied in pharmacotherapy modules.

**Semester:** ☒ Fall ☐ Winter ☐ Summer

**Course Type:** ☐ Elective ☐ Selective ☒ Mandatory

1. **Course Learning Objectives:**
   Upon completion of this course, students will have achieved the following level of learning objectives:
   - Introductory = knowledge and comprehension of concepts, definitions
   - Intermediate = application of concepts to simple situations
   - Advanced = application of concepts to more complex situations with ability to synthesize and evaluate
**Knowledge**

**Introductory Level:**

- Explain the process of research and the role of ethics in research
- Describe common experimental and non-experimental research designs in pharmacy research and discuss their strengths and weaknesses; Identify and describe the critical elements of study design for therapeutic interventions
- Define validity and reliability, explain how they are measured and interpret results
- Define bias, chance and confounding, describe common methods to control for confounding/reduce bias and interpret results
- Calculate common descriptive (e.g., rates) and effect (e.g., relative risk, number needed to treat) measures and interpret results
- Identify the appropriate statistical test(s) to analyze a given set of data that employ common research designs, and interpret results
- Consider the strengths of different types of study designs to answer different clinical and research questions

**Intermediate Level:**

- Explain the process of research and the role of ethics in research
- Describe common experimental and non-experimental research designs in pharmacy research and discuss their strengths and weaknesses; Identify and describe the critical elements of study design for therapeutic interventions
- Define validity and reliability, explain how they are measured and interpret results
- Define bias, chance and confounding, describe common methods to control for confounding/reduce bias and interpret results
- Calculate common descriptive (e.g., rates) and effect (e.g., relative risk, number needed to treat) measures and interpret results
- Identify the appropriate statistical test(s) to analyze a given set of data that employ common research designs, and interpret results
- Consider the strengths of different types of study designs to answer different clinical and research questions

**Advanced Level:**

- Identify and describe the critical elements of study design for therapeutic interventions
- Define validity and reliability, explain how they are measured and interpret results
- Define bias, chance and confounding, describe common methods to control for confounding/reduce bias and interpret results

**Skills**

**Introductory Level:**

- Identify and describe the critical elements of study design for therapeutic interventions
- Define validity and reliability, explain how they are measured and interpret results
- Define bias, chance and confounding, describe common methods to control for confounding/reduce bias and interpret results
- Calculate common descriptive (e.g., rates) and effect (e.g., relative risk, number needed to treat) measures and interpret results
- Identify the appropriate statistical test(s) to analyze a given set of data that employ common research designs, and interpret results
- Apply critical appraisal skills. This may include, but is not limited to assessing:
  a. the research design and statistical techniques,
  b. the outcome and control measures,
  c. internal and external validity, and
  d. presentation of material.
- Consider the strengths of different types of study designs to answer different clinical and research questions

**Intermediate Level:**

- Define validity and reliability, explain how they are measured and interpret results
- Define bias, chance and confounding, describe common methods to control for confounding/reduce bias and interpret results
- Calculate common descriptive (e.g., rates) and effect (e.g., relative risk, number needed to treat) measures and interpret results
- Identify the appropriate statistical test(s) to analyze a given set of data that employ common research designs, and interpret results
- Apply critical appraisal skills. This may include, but is not limited to assessing:
  a. the research design and statistical techniques,
  b. the outcome and control measures,
  c. internal and external validity, and
  d. presentation of material.
- Consider the strengths of different types of study designs to answer different clinical and research questions

**Advanced Level:**

**Attitudes/Values:**

**Introductory Level:**

- Value the need to create and evaluate health research knowledge

**Intermediate Level:**

- Value the need to create and evaluate health research knowledge
Advanced Level:

2. Rationale for Inclusion in the Curriculum:

As scholars, pharmacy graduates are able to master, generate, interpret and disseminate pharmaceutical and pharmacy practice knowledge. This course is designed to provide pharmacy students with strong foundational skills in research design, statistics and ethics for use in the pharmacotherapy modules and for a career in advanced pharmacy practice.

3. Pre-requisites:

All first year courses

4. Co-requisites:

5. Course Contact Hours and Teaching Methodologies:

| Didactic (lecture)                        | Hours: 16          |
| Large group problem-based/ case-based learning (group size: 20-140) | Hours: 10         |
| Laboratory or Simulation                  | Hours:             |
| Tutorial/Seminar/Workshop/Small Group     | Hours:             |
| Experiential                              | Hours:             |
| On-line                                   | Hours:             |
| Other (please specify):                   | Hours:             |
| **Total Course Contact Hours**            | **Hours: 26**      |

6. Estimate and description of student’s weekly out-of-class preparation time excluding exam preparation:

2 hours per week: readings and practice

7. Topics Covered and Lecture Specific Learning Objectives

   **Week 1**
   **Lecture Topic:** Introduction

   **Lecture Learning Objectives:**

   1) describe role of research in evidence-based practice;
2) describe different study designs and research evidence,
3) describe the hierarchy of research evidence

**Week 2**
**Lecture Topic:** Introduction to reading scientific literature and critical appraisal

**Lecture Learning Objectives:**
1) describe anatomy of a paper,
2) understand and identify reporting guideline tools,
3) describe qualities of a good and bad trial,
4) describe critical appraisal methods with a focus on RCTs

**Week 3**
**Lecture Topic:** Measurement and analysis

**Lecture Learning Objectives:**
1) describe concepts of measurement (data, reliability, validity),
2) describe concepts related to inferential statistics, reporting treatment effects, sample size considerations

**Week 4**
**Lecture Topic:** Randomized controlled trials

**Lecture Learning Objectives:**
1) define and discuss various features of RCT design (using PICO framework)

**Week 5**
**Lecture Topic:** Randomized controlled trials

**Lecture Learning Objectives:**
1) continue from week 4,
2) describe reporting and appraisal tools,
3) practice critical appraisal (with focus on internal validity)

**Week 6**
**Lecture Topic:** Rules and regulations

**Lecture Learning Objectives:**
1) understand the conduct and regulation of clinical trials in Canada (focus on ethical and responsible research)
Week 7
Lecture Topic: Cohort studies

Lecture Learning Objectives:

1) describe design features of cohort studies,
2) describe reporting and appraisal tools,
3) practice critical appraisal

Week 8
Lecture Topic: Case control studies

Lecture Learning Objectives:

1) describe design features of case-control studies,
2) describe reporting and appraisal tools,
3) practice critical appraisal

Week 9
Lecture Topic: Systematic reviews

Lecture Learning Objectives:

1) describe systematic reviews and why they are needed,
2) describe steps in a systematic review,
3) describe reporting and appraisal tools,
4) practice critical appraisal

Week 10
Lecture Topic: Qualitative research

Lecture Learning Objectives:

1) describe the design features of qualitative studies,
2) describe reporting and appraisal tools,
3) practice critical appraisal

Week 11
Lecture Topic: Clinical practice guidelines

Lecture Learning Objectives:

1) describe clinical practice guidelines and why they are needed,
2) describe steps in a clinical practice guideline,
3) describe reporting and appraisal tools,
4) practice critical appraisal
Week 12
Lecture Topic: GRADE

Lecture Learning Objectives:
1) describe the role of GRADE in systematic reviews and clinical practice guidelines,
2) explain GRADE quality of evidence and strength of recommendations,
3) understand GRADE tools and resources

Week 13
Lecture Topic: Review

Lecture Learning Objectives:
1) define case reports and case series,
2) refresh important concepts in course

8. Assessment Methodologies Used:

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Course Learning Objectives Addressed</th>
<th>Assessment Method Used</th>
<th>Percent of Course Grade</th>
<th>For Group Work: Individualized or same mark for all group members</th>
</tr>
</thead>
<tbody>
<tr>
<td>☒ Assignment ☐ Presentation ☐ Participation ☐ Mid-term ☐ Final Exam</td>
<td>1-9</td>
<td>Critical appraisal assignments</td>
<td>10% Graded (5 x 2% of grade)</td>
<td></td>
</tr>
<tr>
<td>☐ Assignment ☐ Presentation ☐ Participation ☒ Mid-term ☐ Final Exam</td>
<td>1-9</td>
<td>Mid-term 1 of 2 Written test 1.5 hour each</td>
<td>20%</td>
<td></td>
</tr>
<tr>
<td>☒ Assignment ☐ Presentation ☐ Participation ☒ Mid-term ☐ Final Exam</td>
<td>1-9</td>
<td>Mid-term 2 of 2 Written test 1.5 hour each</td>
<td>20%</td>
<td></td>
</tr>
<tr>
<td>☐ Assignment ☐ Presentation ☐ Participation ☐ Mid-term ☐ Final Exam</td>
<td>1-9</td>
<td>One final written test, 2.5 hour ▶ may include multiple-choice, ranking, calculations and short answer ▶ applied, cumulative and integrated</td>
<td>50%</td>
<td></td>
</tr>
</tbody>
</table>

Expectation for pass grades for all Pharmacy courses is 60%
9. Policy and procedure regarding late assignments/examinations/laboratories:

Missed Exam/Test Policy: If either mid-term test is missed with a valid petition filed with the Registrar’s office, weighting will be added to the final examination (i.e., the final examination will be worth 70%). If the first and second mid-term tests are both missed with a valid petition filed with the Registrar’s office, then students will be eligible to complete a makeup mid-term test worth 40%. The format of this examination will be at the discretion of the course coordinator, and may include, for example, an oral examination.

Missed Quiz/Test Policy: If any quizzes are missed with a valid petition filed with the Registrar’s office, weighting will be added to the remaining quizzes. If all quizzes are missed with a valid petition filed with the Registrar’s office, then students will be eligible to complete a makeup quiz worth the equivalent of all quizzes combined. The format of this make-up quiz will be at the discretion of the course coordinator, and may include, for example, an oral quiz.

10. Policy and procedure regarding missed assignments/examinations/laboratories:

Missed Assignment Policy: Students who fail to submit an assignment by the specified due date, and who have a valid petition filed with the Registrar’s office will be eligible to submit the completed assignment or an alternative assignment at the discretion of the course coordinator with no academic penalty. The format of the alternative assignment will be at the discretion of the course coordinator, and may include for example, an oral examination or the development of a webinar.

Late Assignment Policy: Students who fail to submit a homework assignment by the specified due date will receive a deduction of 50% for the first working day beyond the due date. Assignments will not be accepted for grading if they are late by more than 1 working day.

11. AFPC Education Outcomes addressed (check all those that apply):

- Refer to AFPC Educational Outcomes for Professional Programs for further information about the role and key competencies.

As Care Providers, pharmacy graduates:

**CP1 – Practice within the pharmacist scope of practice and expertise**

☐ CP1.1 Apply knowledge from the foundational sciences to make decisions relevant to the contemporary and evolving scope of pharmacist practice;

☐ CP1.2 Integrate AFPC Communicator, Collaborator, Leader-Manager, Health Advocate, Scholar, and Professional roles in their practice of pharmacy;

☐ CP1.3 Recognize and respond to the complexity, uncertainty and ambiguity inherent in pharmacy practice;

☐ CP1.4 Explain the benefits, risks and rationale associated with pharmacist-provided care as an important step in obtaining and documenting consent to pharmacist care;

☐ CP1.5 Recognize and take appropriate action when signs, symptoms and risk factors that relate to medical or health problems that fall into the scope of practice of other health professionals are encountered.
CP2 – Provide patient-centred care

☐ CP2.1 Collect, interpret, and assess relevant, necessary information about a patient’s health-related care needs;

☐ CP2.2 Formulate assessments of actual and potential issues and in collaboration with the patient and other health team members as appropriate, prioritize issues to be addressed in a given patient encounter;

☐ CP2.3 Create and document plans in collaboration with the patient and other health team members as appropriate, and make recommendations to prevent, improve or resolve issues;

☐ CP2.4 Implement plans in collaboration with the patient and other health team members as appropriate, including:
  - CP2.4.1 obtaining consent
  - CP2.4.2 making a referral or consulting others
  - CP2.4.3 adapting, initiating, renewing/continuing, discontinuing or administering medication as authorized
  - CP2.4.4 dispensing and/or
  - CP2.4.4a dispensing and/or
  - CP2.4.4b compounding and/or
  - CP2.4.4c delegating/authorizing such tasks to others appropriately
  - CP2.4.5 engaging the patient or care-giver through education, empowerment and self-management, and
  - CP2.4.6 negotiating the role of pharmacy and non-pharmacy team members in continuity and transitions of care.

☐ CP2.5 Follow-up by monitoring, evaluating progress toward achievement of the patient’s goals of therapy, adjusting plans in collaboration with the patient and health team members across the care continuum.

CP3 – Actively contribute, as an individual and as a member of a team providing care, to the continuous improvement of health care quality and patient safety

☐ CP3.1 Recognize and respond to harm and potential harm from health care delivery, including patient safety incidents;

☐ CP3.2 Adopt strategies that promote patient safety and address human and system factors;

As Communicators, pharmacy graduates:

CM1 – Communicate in a responsible and responsive manner that encourages trust and confidence

☐ CM1.1 Select and use oral, non-verbal and written communication strategies (tools, techniques, technologies, etc.) effectively so that the patient’s best interests are foremost;

☐ CM1.2 Provide timely, clear responses that are tailored to the context and audience;
CM1 – Express facts, evidence, opinions and positions accurately and effectively, with clarity and confidence;

CM1.4 Listen, actively solicit and respond appropriately to ideas, opinions and feedback from others;

CM1.5 Use language, pace, tone, and non-verbal communication that is suitable for:
   a) the intended outcomes of the communication, and
   b) the complexity, ambiguity, urgency and/or difficulty of a situation, conversation or conflict

CM1.6 Seek and synthesize relevant information from others in a manner that ensures common understanding and where applicable, clarifies and secures agreement and/or consent;

CM1.7 Compose and share oral, written, and electronic information in a manner that optimizes patient safety, dignity, confidentiality, and privacy.

CM2 – Communicate in a manner that supports a team approach to health promotion and health care

CM2.1 Engage in respectful, empathetic, compassionate, non-judgmental, culturally safe, tactful conversations with patients, communities, populations, and health team members;

CM2.2 Demonstrate awareness of the impact of one’s own experience level, professional culture, biases and power and hierarchy within the health team on effective working relationships, communication and conflict resolution with health team members and adapt the approach to the situation appropriately;

CM2.3 Demonstrate accuracy and appropriateness of communication as well as respect for the role of other health team members when disclosing information about harmful or potentially harmful situations;

CM2.4 In word and in action, convey the importance of teamwork in patient-centred care, patient safety, health care quality improvement and health program delivery.

As Collaborators, pharmacy graduates:

CL1 – Work effectively with members of the health team including patients, pharmacy colleagues and individuals from other professions

CL1.1 Establish and maintain positive relationships;

CL1.2 Recognize, respect and negotiate the roles and shared/overlapping responsibilities of team members;

CL1.3 Join with others in respectful, effective shared decision-making.

CL2 – Hand over the care of the patient to other pharmacy team members and non-pharmacy team members to facilitate continuity of safe patient care
☐ CL2.1 Determine when and how care should be handed over to another team member;
☐ CL2.2 Recognize, respect and honour the negotiate shared and overlapping responsibilities of patients, pharmacy team members and other health members when handovers occur;
☐ CL2.3 Demonstrate safe handover of care, using oral, written, and electronic communication, during a patient transition to a different care provider or setting.

As Leader-Managers, pharmacy graduates:

**LM1 – Contribute to optimizing health care delivery and pharmacy services**

☐ LM1.1 Work with others to apply quality improvement strategies and techniques to optimize pharmacy care;
☐ LM1.2 Contribute to a culture of patient safety;
☐ LM1.3 Confirm the quality, safety, and integrity of products;
☐ LM1.4 Use health informatics to improve the quality of care, manage resources and optimize patient safety.

**LM2 – Contribute to the stewardship of resources in health care systems**

☐ LM2.1 Apply evidence and management processes to achieve cost appropriate care;
☐ LM2.2 Allocate health care resources for optimal patient care;
☐ LM2.3 Contribute to the management of finances and health human resources in pharmacy practice settings;

**LM3 – Demonstrate leadership skills**

☐ LM3.1 Demonstrate leadership skills to enhance pharmacy practice and health care.

**LM4 – Demonstrate management skills**

☐ LM4.1 Work with others to apply the principles of effective management and supervision of health human resources and medication use systems;
☐ LM4.2 Use effective strategies to manage and improve their own practice of pharmacy.

As Health Advocates, pharmacy graduates:

**HA1 – Respond to an individual patient’s health needs by advocating with the patient within and beyond the patient care environment**
HA1.1 Work with patients to address determinants of health that affect them and their access to needed health services or resources;

HA1.2 Work with patients to increase opportunities to adopt healthy behaviours;

HA1.3 Incorporate disease prevention, health promotion and health surveillance into interactions with individual patients.

HA2 – Respond to needs of communities or populations they serve by advocating with them for system-level change in a socially accountable manner

HA2.1 Work with community or population to identify the determinants of health that affect them;

HA2.2 Participate in health promotion and disease prevention programs.

As Scholars, pharmacy graduates:

SC1 – Apply medication therapy expertise to optimize pharmacy care, pharmacy services and health care delivery

SC1.1 Use knowledge and problem-solving to arrive at recommendations and decisions that are appropriate, accurate, and practical;

SC1.2 Use professional experience to solve routine, previously encountered problems;

SC1.3 Use established decision-making frameworks and apply learning required to manage new situations and problems.

SC2 – Integrate best available evidence into pharmacy practice

SC2.1 Generate focused questions related to needs for information, recommendations and decisions in practice;

SC2.2 Use systematic approaches in the search for best available evidence;

SC2.3 Critically appraise health-related research and literature;

SC2.4 Incorporate best available evidence in the decision-making process.

SC3 – Contribute to the creation of knowledge or practices in the field of pharmacy

SC3.1 Apply scientific principles of research and scholarly inquiry;

SC3.2 Apply ethical principles that underlie research and scholarly inquiry.

SC4 – Teach other pharmacy team members, the public and other health care professionals including students

SC4.1 Provide effective education to others;
SC4.2 Employ appropriate teaching roles when teaching others;

SC4.3 Deliver effective feedback in teaching and learning situations;

SC4.4 Use appropriate learning assessment and evaluation strategies when working with patients, team members, students and teachers.

As Professionals, pharmacy graduates:

PR1 – Committed to apply best practices and adhere to high ethical standards in the delivery of pharmacy care

PR1.1 Exhibit professional behaviour whether face-to-face, in writing, or via technology-enabled communication. Professional; behaviour includes, but is not limited to:

a) demonstrating honesty, integrity, humility, commitment, altruism, compassion, respect for diversity and patient autonomy;
b) being accessible, diligent, timely and reliable in service to others;
c) abiding by the principle of non-abandonment;
d) maintaining appropriate interpersonal boundaries;
e) maintaining professional composure, demeanor, and language even in difficult situations, and;
f) maintaining privacy and confidentiality;

PR1.2 Use ethical frameworks as one component of professional judgment;

PR1.3 Recognize and respond to situations presenting ethical dilemmas, including conflicts of interest;

PR1.4 Engage in activities that:

a) protect the public, and;
b) advance the practice of pharmacy.

PR2 – Able to recognize and respond to societal expectations of regulated health care professionals

PR2.1 Take responsibility and accountability for actions and inactions;

PR2.2 Demonstrate a commitment to patient safety and quality improvement;

PR2.3 Honour the laws, ethical codes, and regulatory requirements (by-laws, standards, policies) that govern the self-regulated profession of pharmacy;

PR2.4 Demonstrate an understanding of federal, provincial/territorial, and municipal laws, policies and standards that apply to pharmacy workplaces;
☐ PR2.5 Demonstrate an ability to maintain competence to practice through evaluating areas for improvement and planning, undertaking learning activities to address limitations in competence and/or performance and incorporating learning into practice;

☐ PR2.6 Identify and respond to unprofessional, unethical, and illegal behaviours in pharmacists, other pharmacy team members, and other health professionals.

PR3 – Committed to self-awareness in the management of personal and professional well being

☐ PR3.1 Set professional and personal goals, priorities, and manage their time to balance patient care, workflow, and practice requirements;

☐ PR3.2 Examine, reflect upon, and manage personal attributes (knowledge, skills, beliefs, biases, motivations, emotions, etc.) that could influence self-development and professional performance;

☐ PR3.3 Adapt their practice of pharmacy to fulfill evolving professional roles;

☐ PR3.4 Recognize and respond to self and colleagues in need.