

Principles of Clinical Pharmacology Research
PHAR 5230 Principles of Clinical Pharmacology Research
2 Credits

Fall Semester 2019

Location/Time: WDH 7-193/Life Sci 160; Mondays 10:10 – 12:05 pm

Course Delivery Director: Mark Kirstein, Pharm.D.
 Associate Professor
 Experimental and Clinical Pharmacology
 717 Delaware Room 459
 Phone : 612-624-5689
 E-mail : kirst002@umn.edu

Participating Faculty:

<p>Swayam Prabha, Ph.D., M.S., MBA Assistant Professor Experimental and Clinical Pharmacology Phone: 612-626-3545- Email: prabh025@umn.edu</p>	<p>L'Aurette Johnson, Ph.D. Assistant Professor Experimental and Clinical Pharmacology 7-115C Weaver-Densford Hall Phone: 612-624-5430 Fax: 612-625-3927 Email: joh02745@umn.edu</p>
<p>Jeff Bishop, Pharm.D. Associate Professor Experimental and Clinical Pharmacology 14-271 Moos T Phone : 612-625-5435 Email : jrbishop@umn.edu</p>	<p>Ling Li, Ph.D. Professor and VFW Endowed Chair Experimental and Clinical Pharmacology 4-208 MTRF Phone: 612-626-2359 Email: lil@umn.edu</p>
<p>Scott Chapman, Pharm.D. Associate Professor Experimental and Clinical Pharmacology 7-115E Weaver-Densford Hall Chapm004@umn.edu</p>	<p>Debra Skaar, Pharm.D. Associate Professor Experimental and Clinical Pharmacology 7-109 Weaver-Densford Hall Phone: 612-626-3005 E-mail: skaar006@umn.edu</p>
<p>Ramaiah Muthyala, Ph.D., FRSC Research Associate Professor Experimental & Clinical Pharmacology 717 Delaware Rm 519 University of Minnesota Minneapolis, MN muthy003@umn.edu</p>	<p>Mahmoud Al Kofahi, D.D.S., Ph.D. Assistant Professor Experimental and Clinical Pharmacology 717 Delaware Room 464 Phone : 612-624-1161 Email : malkofah@umn.edu</p>
<p>Pamala Jacobson, Pharm.D. Professor Experimental and Clinical Pharmacology 7-151 Weaver-Densford Hall Phone: 612-624-6118 Email: jacob117@umn.edu</p>	<p>Wendy St Peter, Pharm.D. Professor Pharmaceutical Care and Health Systems 7-176 Weaver-Densford Hall Phone: 612-625-5848 Email: stpet002@umn.edu</p>

Michael Walters, Ph.D. Director, Lead Probe and Discovery Institute for Therapeutics Discovery and Development 717 Delaware Room 102 Phone: 612-626-6864 Email: walte294@umn.edu	Angela Birnbaum, Ph.D. Professor Experimental & Clinical Pharmacology 717 Delaware Room 463 Email: birnb002@umn.edu
--	---

Teaching Assistant: Gerrit Vreeman (Canvas TA), (vreem012@umn.edu)

Course Overview: This course is taught by guest lecturers, depending on topic. Students on Duluth campus would listen and participate in lecture/discussion via ITV. It is designed to teach the student about research principles in clinical pharmacology. This is not a basic pharmacology course. Instead, topics related to drug therapy investigation are emphasized. Topics include experimental design of drug studies in human research subject volunteers (e.g., exposure-response relationships, to learn appropriate dose, interval, drug-drug interactions, study endpoints, adverse events etc.). In the era of Personalized or Precision Medicine, this course will address topics related to individualization of therapy including effects of genetic polymorphisms, demographic variables, physiologic variables, and age on drug disposition and treatment outcomes. Topics will also include preclinical models of human disease states, drug-based literature interpretation of experimental design and results, and pharmaceutical industry.

Technology Requirements: This class will meet in a physical classroom setting and transmit via ITV. The student is expected to have electronic devices such as iPad or laptop computer with capabilities to view powerpoint slides, PDF versions of journal articles, word docs, e- text books, etc. Lectures and discussions are not recorded, so classroom attendance is highly encouraged.

Prerequisites: Third year pharmacy program students, or consent of instructor. The students would be expected to have some concurrent/prior pharmacokinetics, pharmacology, and pharmacotherapy instruction.

Learning Objectives: This course would be classified under Competency Domain 6: Knowledge, Scientific Inquiry, and Scholarly Thinking.
 The course is designed to explore (related to scientific investigation):

- Factors Determining Drug Exposure
- Drug-Receptor Pharmacology
- Factors Affecting Drug Response & Personalized Medicine
- Drug Interactions
- Obesity
- Age – Pediatrics
- Critically Ill
- Therapeutic Evaluation
- Drug Development
- Pre-clinical/Translational
- Phase I/II

At the conclusion of the course, the student will be able to:

1. **Describe** and **apply** the fundamental principles of pharmacologic investigation.
2. **Describe** the factors that affect drug systemic exposure and response; and **explain** the utility of this information in advancing scientific knowledge (related to improving drug therapy).
3. **Recognize** primary and secondary objectives in a research article.
4. **Identify** and **Understand** factors of consideration in personalized medicine (e.g., pharmacogenetics, physiologic, demographic covariates).
5. **Describe** the process of drug development.
6. **Develop** presentations based upon work done for projects completed outside of class time.

Attendance Policy:

Classes are not recorded. The learning process is highly enriched through classroom discussions; therefore, it is highly important the students attend all meetings. Course grade will in part, be determined from the student's participation in classroom discussion.

Course Materials:

Recommended (but not required):
Principles of Clinical Pharmacology, Arthur J Atkinson, et al. 3rd ed. 2012.
ISBN: 978-0-12-385471-1

Handouts will be provided by instructors. Journal articles will also be distributed, often with the expectation of reading them prior to the class for which they pertain.

The National Institutes of Health has historically offered Clinical Pharmacology lectures online. These might be available for viewing on line.

Guidance Documents posted by Food and Drug Administration

Course Requirements:

Two (2) take-home exams consisting of short answer/essay questions (one at approximately mid-term and the second at semester end). Each exam will be worth 35% of the final grade, and students will have one week to complete them. Exams will be open book, open internet, but no collaborations with other students or other experts, and no plagiarism. Remaining 30% of the course grade will be determined from written assignments and in-class presentations. These might either be individual projects or as groups (to be determined once enrollment confirmed). Possible topics include hepatic assessment & effects on drug disposition and outcomes, bioequivalence, adherence/compliance, drug candidates for therapeutic drug monitoring, drug-drug interaction study design, etc. Class participation will be taken into account when determining final grade. Students must come prepared to discuss and ask questions.

In order for the exam turn in time to be changed, a 100% positive vote by students in the class will be required.

Graded Assessments:

Two (2) exams (35% each) + classroom presentation + discussion and other assignments such as reviewing articles or identifying study objectives

(remaining 30% of grade). No extra credit projects will be offered/accepted. Assignments turned in late will be graded, but will be reduced by two letter grades (e.g., A to C in best case scenario). Any student who has not completed their assignments by the time grades must be posted will receive "I" (incomplete).

Exam Policy: Please refer to Course Requirements listed above.

Grading Information: A total of 100 points can be obtained on exams and presentation. A percentage will be calculated based on the number of points each student earns over the semester. Grades will be assigned as follows:

Grade	Percentage
A	93.0 - 100
A-	90.0 - 92.9
B+	87.0 - 89.9
B	83.0 - 86.9
B-	80.0 - 82.9
C+	77.0 - 79.9
C	73.0 - 76.9
C-	70.0 - 72.9
D	60.0 - 69.9
F	0 - 59.9

Course Schedule: Please refer to separate attachment and moodle site.

College of Pharmacy central syllabus site: [College of Pharmacy Central Syllabus](#)

Academic Misconduct: Academic misconduct is any unauthorized act which may give a student an unfair advantage over other students, including but not limited to: falsification, plagiarism, misuse of test materials, receiving unauthorized assistance and giving unauthorized assistance. Each student will be required to do their own work on all take-home exams and the presentation. Each student will be asked to sign a cover sheet on each exam stating that these guidelines have been followed.

Make-up Policy: A make-up exam or rescheduling of a presentation will be allowed only under one of the following circumstances: illness, verified by a note from a doctor; a family emergency, verified by a note from the professional person in attendance; a University-sponsored event, verified by a note from the leader of the sponsoring organization.

Disability Accommodations: Any student with a documented disability (eg. physical, learning, psychiatric, vision, hearing, etc.) who needs to arrange reasonable accommodations must contact the course director as well as each section director for the course. Documentation of the need for

accommodations should be received within the first week of the course and at least 7 days prior to any exam for which you are seeking an accommodation. It is the student's responsibility to contact Disability Services (TC: <http://ds.umn.edu/>, 612-626-1333, Duluth: Access Center, <http://www.d.umn.edu/access/>, 218-726-8217) to document the disability and quantify the necessary accommodations before the beginning of the Semester. All discussions concerning this issue will remain confidential. As a lack of proficiency with the English language is not considered a disability by the College of Pharmacy, this course will not accommodate any requests for additional time for assessments based on this criterion.

Workload and Expectations: For undergraduate courses, one credit is defined as equivalent to an average of three hours of learning effort per week (over a full semester) necessary for an average student to achieve an average grade in the course. We expect at least that much effort from our professional students. In this 2 credit course, you should expect to spend at least an additional six hours a week on coursework outside the classroom.

Class Etiquette: The instructors expect all students to conduct themselves in a professional manner consistent with the University of Minnesota Pharmacy Student Code of Ethical Responsibility and Professional Behavior. Students will not engage in disruptive classroom conduct. This refers to behavior that substantially or repeatedly interrupts either the instructor's ability to teach or student learning. The classroom extends to any setting where a student is engaged in work toward academic credit or satisfaction of program-based requirements or related activities.

Honor Code and Classroom Etiquette: Each student is bound by the honor code which defines academic misconduct as any unauthorized act which may give a student an unfair advantage over other students, including but not limited to: falsification, plagiarism, misuse of test materials, receiving unauthorized assistance and giving unauthorized assistance. Specifically, each student will be required to do their own work on all written exams and assignments unless otherwise advised by the course instructors. For exams or other assessments that are not returned to students by the instructors, it will be considered a "misuse of test materials" and therefore a violation of the honor code to copy, scan, photograph or otherwise re-construct such assessment content.

You signed the following statement upon accepting placement in the University of Minnesota College of Pharmacy:

I hereby affirm that I have read and understood the provisions and stipulations of the University of Minnesota Pharmacy Student Code of Ethical Responsibility and Professional Behavior.

The Code was established in the belief that central to any intellectual and professional endeavor is an atmosphere of mutual trust and respect, based on individual maintenance of community standards. Your professional community starts here...at the College of Pharmacy with your peers, faculty, preceptors, staff and administration. It is our expectation that you will exhibit professional behavior towards other students and to faculty in the classroom at all times. In turn, we will treat you with the professional respect you deserve.

Course/Instructor Evaluation: Students will have an opportunity to complete online course evaluations for instructors. An overall course evaluation and/or key lecturers will also be administered at an appropriate time.

Recording Policy: For information relevant to the recording policy for this course, please refer to the following link.

<https://www.pharmacy.umn.edu/sites/pharmacy.umn.edu/files/classroom-lecture-recording-policy.pdf>

Problems/Office Hours: Any problems concerning the presentation of this curriculum or any problems related to this course should be directed to the lecturer or course director. Dr. Kirstein will have office hours by appointment. Please call or e-mail to make arrangements; he will be more than happy to get together with you.

Technology help Duluth: 218-726-8847 itsshelp@d.umn.edu

Technology help Twin Cities: 612-301-4357 help@umn.edu