

Course and Contact Information:

Course: Department of Pharmacology and Physiology, PHAR 6116 – Pharmacogenomics and Personalized Medicine (3 Credits)

Semester: Spring, 2020

Meeting time: Wednesdays, 3:00-6:00 PM

Location: Ross Hall, Room 237

Instructor:

Travis J. O'Brien, MEd, PhD

Department of Pharmacology and Physiology

Ross Hall, 660

202-994-3373

phmtjo@gwu.edu

Course Description:

Relationships between human genetic variability and drug responsiveness, susceptibility to disease, and disease severity. Scientific, clinical, legal, and ethical challenges in applying pharmacogenomics to drug discovery and clinical development. Professionals from such disciplines as human genetics, pharmacology, pharmaceutical sciences, genomic medicine, clinical and translational sciences, law, and regulatory affairs provide an integrative view of the application of pharmacogenomics to personalized medicine.

Course prerequisites:

Instructor permission required. Prerequisites: PHAR 6205 or permission of the instructor (all IBS/PhD students are permitted to enroll in the course).

Learning outcomes that state descriptions of behaviors or skills that students will be able to demonstrate at the end of the class or unit:

At the end of the course the student will be able to:

1. Describe the basic principles of genetic inheritance and variability in humans.
2. Explain the major techniques for investigating human genetic variability
3. Describe how human genetic variability can impact drug action
4. Define genetic biomarkers and explain how they are incorporated into drug development and monitoring
5. Explain the ethical, social and legal implications surrounding the clinical application of pharmacogenomic biomarkers
6. Critically analyze data from a genetic study.

Required textbooks, materials, and recommended readings:

There is no required textbook for this course. The major content of the course will be presented in lecture and/or handouts. Each handout will provide a list of learning objectives as well as a drug list of the specific pharmacologic agents that students are expected to know. There are many textbooks of pharmacology available. We recommend either "Basic and Clinical Pharmacology" by Katzung (13th edition, 2014) and/or Goodman and Gilman's the "Pharmacological Basis of Therapeutics" (11th edition, 2011) as suitable texts for the pharmacological concepts covered in this course. The books are available on the GWUMC library website (<http://libguides.gwumc.edu/content.php?pid=60105&sid=441899>).

Session Schedule

Date	Topic(s)	Lecturer	Room
1/15	Introduction to Human Variability in Drug Response	Dr. O'Brien	602
1/22	Human Genetic Variability: P450 Enzymes & Drug Transporters	Drs. Harralson and O'Brien	602
1/29	PGx Application: Cancer Chemotherapy	Dr. Lee	602
2/5	PGx Resources/Guidelines	Dr. O'Brien and/or Harralson	602
2/12	Exam 1 (1/15-2/5)*		602
2/19	Introduction to Drug Development	Dr. Huber or Dr. Chiappinelli	116
2/26	Population Genomics and Pharmacology	Dr. Goodsaid (video webinar)	
3/4	Biomarker Development and Validation	Dr. Goodsaid (video webinar)	602
3/11	Toxicogenomics	Dr. Harrouk – US FDA	602
3/18	Spring Break!!!		Beach
3/25	Exam 2 (2/19-3/11)		602
4/1	Genetic Counseling and Ethics	Dr. Schwartz and Prof. Callier	602
4/8	PGx-Assisted Prescribing	Dr. O'Brien and/or Harralson	602
4/15	Personalized Medicine and Policy I	Dr. Pritchard – Personalized Medicine Coalition	602
4/22	Personalized Medicine and Policy II	Dr. Prichard and/or O'Brien	602
5/6	Exam 3 (4/1-4/22)		602

Calculation of the final grade

Task	Worth
Examinations	90%
Paper	10%
Total	100%

Blackboard

Pharmacology 6116 materials are also available through the Blackboard portal. Lecture notes and slides for each week's material will be posted as soon as possible. To log onto Blackboard, you must have registered for the course and have a gwu email address.

Examinations

Students must seek approval for any planned missed examinations within the first week of class.

A student who misses an exam and provides an excuse acceptable to the course coordinator will be allowed to take a make-up exam at a time designated by the course coordinator. Missing an exam without an accepted excuse will result in a grade of zero for that exam.

Paper

Part of your grade will be based on a concise position paper. The paper will be based on the following scenario: You work for a regional health care network that includes several hospitals and satellite clinics. The administration has decided that the organization needs to be a local leader in precision medicine, in general, and in the implementation of FDA pharmacogenomic biomarkers into clinical care, specifically. You are tasked with developing a **1-page single-spaced (references on a second page)** paper that identifies 2-3 major obstacles to implementing this plan on possible ways to overcome these issues. Alternatively, you may write a paper against the implementation of this plan providing 2-3 concrete reasons for your dissent. In either case, you **MUST** provide specific, peer-reviewed information to support your argument. You should send the paper to Dr. O'Brien via e-mail (phmtjo@gwu.edu) by 11:59 PM on April 29th. You will be graded on:

- a) Did you provide 2-3 discussion points in your paper?
- b) Do you have adequate literature to support your points? (i.e. should be recently published)
- c) Did you keep your paper to 1-page in length?
- d) The quality of your references and citations
- e) Your grammar and spelling (i.e. use spell/grammar check)

Honor Policy Academic Misconduct

Academic Dishonesty will not be tolerated. Faculty is obligated to report suspicions of violations to the Student honor code to the appropriate Academic Committees. Academic dishonesty is defined as cheating of any kind, including misrepresenting one's own work, taking credit for the work of others without crediting them and without appropriate authorization, and fabrication of information. Academic dishonesty includes giving, receiving, or using unauthorized aid on academic work. Again any student suspected of cheating or plagiarism will be reported. For a review of the University's code of misconduct please go to <http://www.gwu.edu/~ntegrity/code.html>.

University policies:

University policy on observance of religious holidays

In accordance with University policy, students should notify faculty during the first week of the semester of their intention to be absent from class on their day(s) of religious observance. For details and policy,

see: students.gwu.edu/accommodations-religious-holidays.

Academic integrity code

Academic dishonesty is defined as cheating of any kind, including misrepresenting one's own work, taking credit for the work of others without crediting them and without appropriate authorization, and the fabrication of information. For details and complete code, see: studentconduct.gwu.edu/code-academic-integrity

Safety and security

In the case of an emergency, if at all possible, the class should shelter in place. If the building that the class is in is affected, follow the evacuation procedures for the building. After evacuation, seek shelter at a predetermined rendezvous location.

Support for students outside the classroom

Disability Support Services (DSS)

Any student who may need an accommodation based on the potential impact of a disability should contact the Disability Support Services office at 202-994-8250 in the Rome Hall, Suite 102, to establish eligibility and to coordinate reasonable accommodations. For additional information see: disabilitysupport.gwu.edu/

Mental Health Services 202-994-5300

The University's Mental Health Services offers 24/7 assistance and referral to address students' personal, social, career, and study skills problems. Services for students include: crisis and emergency mental health consultations confidential assessment, counseling services (individual and small group), and referrals. For additional information see: counselingcenter.gwu.edu/