**PHA 5933 Clinical Applications of Personalized Medicine
2 Credit Hours**

**Course Purpose:**Personalized medicine involves the use an individual's genetic profile to guide decisions made in regard to the prevention, diagnosis, and treatment of disease. This course will focus on how pharmacogenomic and genomic medicine data can be used in patient care. Students will be given the opportunity to have their personal DNA genotyped on a custom chip, and utilize this information for the class assignments. Alternatively students may work with a de-identified genotype dataset. This course will use a combination of interprofessional lectures, and case-based discussions of clinical pharmacogenetic guidelines and primary literature. The goal of this course is to provide health professional students with the knowledge and skills to use a personalized medicine approach in their future clinical practice in an interprofessional learning environment.

Course Faculty and Office Hours

Course Coordinator:
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Office Hours

By appointment only.

**Place and Time of Class Sessions**

Online course material (e.g., recorded lectures, readings) will be made available on the course website, along with instructions for each topic discussion. Lectures, readings, and pre-discussion assignments must be completed prior to the live web-based session. The course has weekly 1-hour live online learning sessions. Meeting times will be provided at the start of the course.

**How This Course Relates to the Learning Outcomes You Will Achieve in the Pharm.D. Program:**

This course prepares the Pharm.D. student to accomplish the following abilities and the related Student Learning Outcomes (SLOs) upon graduation:

* **2.1. Patient-centered care (Caregiver)** - Provide patient-centered care as the medication expert (collect and interpret evidence, prioritize patient needs, formulate assessments and recommendations, implement, monitor and adjust plans, and document activities).
* **3.1. Problem Solving (Problem Solver) –** Identify and assess problems; explore and prioritize potential strategies; and design, implement, and evaluate the most viable solution.
* **3.4. Interprofessional collaboration (Collaborator) –** Actively participate and engage as a healthcare team member by demonstrating mutual respect, understanding, and values to meet patient care needs.

**Course Objectives**

Upon completion of this course, the student will:

1. Explain risks involved with pharmacogenetic testing.
2. Interpret and apply evidence for pharmacogenomics and genomic medicine from the medical literature to patient care.
3. Apply personal or de-identified genetic information to clinical decision-making for representative cases using the following pharmacogenomic drug-gene pairs:
	1. CYP2D6 and codeine
	2. Clopidogrel & CYP2C19
	3. SLCO1B1 and simvastatin
	4. CYP2C9, VKORC1 and warfarin
	5. TPMT and thiopurines
	6. IL28B (IFNL3) and PEG-IFN
4. Apply theoretical genetic information to clinical decision-making and disease risk prediction for the following types of diseases:
	1. Complex Diseases: Cardiovascular Disease Risk
	2. Somatic Genomics: Genomic Medicine in Breast Cancer
5. Demonstrate best practices for returning genetic and pharmacogenetic test results to a patient, including legal and ethical concerns and communication strategies.
6. Demonstrate the contributions and roles of other health care professionals in the clinical application of genomic information to patient care.
7. Summarize the challenges and opportunities in integrating genomic medicine and pharmacogenomics data into the clinical process of patient care.

**Pre-Requisite Knowledge and Skills**

Departmental approval required.

**Course Structure & Outline**

**Course Structure.** The course consists of weekly web-based lectures, readings, and/or assignments and lectures, and weekly live, web-based interactions with instructors and students (via Adobe Connect).

Students will be periodically assigned to present and discuss content individual or in groups during live sessions (e.g. answers to cases or questions). These assignments will occur in such a way as to give an equal number of opportunities for students to present and participate.

**Course Outline/Activities.** The outline of course activities is listed in **Appendix** **A**.

Textbooks

There is no required text. The instructor will provide required reading for each topic.

Active Learning Requirements

For all learning experiences in this course, including lectures, reading assignments, cases and discussions, students are expected to actively engage in the learning process, striving to comprehend the meaning and relevance of all transmitted concepts and facts. Students should strive to discover deficiencies in their understanding, and attempt to resolve those deficiencies by any of several means, including through their own research (a recommended first step) and through consultation with fellow students and course instructors.

1. Discussion board postings
2. Live web-based sessions. Attending and participating in cases and discussions are active learning processes in this course. Students are expected to actively participate in discussions and case-based learning, and communicate the concepts and ideas that they have learned in the lectures and are applying in this class.
3. Journal Evaluation

Feedback to Students

Feedback will be provided through written feedback on assignments via the eLearning system. Feedback on exams will be available via the eLearning system within 24 hours following the exam. In addition, students may schedule an appointment with the instructor if they wish to obtain more detailed verbal feedback.

Student Evaluation & Grading

**Course Evaluation Methods**

Each student’s grade will be based on individual performance according to the following:

Class Participation 30%

* Discussion board postings – 5%
* Live web-based sessions – 20%
* Survey/Reflections – 5%

Exams 60%

* Exam 1 – 15%
* Exam 2 – 15%
* Exam 3 – 15%
* Exam 4 – 15%

Assignments 10%

* Journal evaluation 1 – 5%
* Journal evaluation 2 – 5%

**Grading Scale**

Information on current UF grading policies can be found here:

<https://catalog.ufl.edu/ugrad/current/regulations/info/grades.aspxl>.

95-100 = A 90-94 = A-

86-89 = B+ 83-85 = B

80-82 = B- 76-79 = C+

73-75 = C 70-72 = C-

66-69 = D+ 63-68 = D

60-62 = D- <60 = E

**Class Attendance Policy**

Attendance at live web-based sessions is mandatory and participation in the group discussion is required. Upon approval of the course coordinator, students may make up a missed session by completing a brief written assignment for a maximum of 4 sessions. Failure to get approval for the missed session prior to the session will result in a mark of zero for that session. The written makeup assignment must be submitted to the facilitator no later than 1 week past the missed session.

Requirements for class attendance, assignments, and other work in this course are consistent with university policies that can be found at:

<https://catalog.ufl.edu/ugrad/current/regulations/info/attendance.aspx>.

**Exam Policy**

**Online Examinations**

Exams will be administered online. Online examinations may consist of multiple choice, short answer and/or case-based questions. To maintain the highest standards of academic integrity, high stakes online examinations may require the use of a proctoring system. More information on the proctoring system may be found at: http://www.proctoru.com/

**Missing Exams and Make-Up Exam Policy**

Students with an excused absence may be allowed to take a make-up exam. Make-up exams should be arranged with the course coordinator and administered within two weeks of the original exam date. Requirements for make-up exams are consistent with university policies that can be found at:

<https://catalog.ufl.edu/ugrad/current/regulations/info/attendance.aspx>.

**Posting of Exam Grades**

Exam grades will be posted within one week of the exam. Notice will be provided to the students if there will be a delay in posting of exam grades.

**Exam Rebuttals**

Students have one week after posting of the exam grades to challenge any exam question. No appeals will be accepted after one week. Written appeals must include the following: **the question number and an evidence-based rationale for why the student feels their response is accurate**. The exam will be re-graded, in full, by a third party. Note: the score of a fully re-graded exam may increase, decrease, or stay the same. The re-graded score will be considered final.

**Policy on Old Assignments and Exams**

Students are not provided old assignments or exams.

**Assignment Deadlines**

Please submit online assignments early to avert last minute issues with technology. Late submission of assignments will result in a 20% point deduction without adequate explanation and may result in a zero grade, depending on the assignment. Students who experience technical difficulty when submitting assignments electronically must notify the course coordinator as soon as possible.

**Course Evaluation**

Students are expected to provide feedback on the quality of instruction in this course by completing online evaluations at https://evaluations.ufl.edu. Evaluations are typically open during the last two or three weeks of the semester, but students will be given specific times when they are open. Summary results of these assessments are available to students at <https://evaluations.ufl.edu/results/>.

**Complaints**

Should you have any complaints with your experience in this course please contact your course coordinator. If unresolved, contact the COP Senior Associate Dean-Professional Affairs. For unresolved issues, see: <http://www.distancelearning.ufl.edu/student-complaints> to submit a complaint.

**Accommodations for Students with Disabilities**

The University of Florida is committed to providing academic accommodations for students with disabilities. Students with disabilities requesting accommodations should first register with the Disability Resource Center (352-392-8565, [www.dso.ufl.edu/drc/](http://www.dso.ufl.edu/drc/)) by providing appropriate documentation. Once registered, a student should present his/her accommodation letter to me supporting a request for accommodations. The University encourages students with disabilities to follow these procedures as early as possible within the semester.

**General College of Pharmacy Course Policies**

The College of Pharmacy has a website that lists course policies that are common to all courses. This website covers the following:

1. University Grading Policies
2. Academic Integrity Policy
3. How to request learning accommodations
4. Faculty and course evaluations
5. Student expectations in class
6. Discussion board policy
7. Email communications
8. Religious holidays
9. Counseling & student health
10. How to access services for student success
11. Faculty Lectures/Presentations Download Policy

Please see the following URL for this information:
<http://www.cop.ufl.edu/wp-content/uploads/dept/studaff/policies/General%20COP%20Course%20Policies.pdf>

**Appendix A: *Tentative******Schedule of Course Activities/Topics***

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| --- | --- | --- | --- |
| **Week** | **Instructor(s)** | **Lecture Topic/Activity** | **Assessment/Activity** |
| 1 | WeitzelCooper-Dehoff | Course OverviewBioethics and Informed Consent | Survey/Reflection 1In-Class Session 1: Orientation |
| 2 | McDonough | Genotype-Phenotype RelationsEvidence analysis in Pharmacogenomics and Genomic Medicine | DNA Kit ReturnDiscussion Board 1 |
| 3 | Weitzel   | Evidence-Based Approach to PGx | Discussion Board 2Journal Eval 1 |
| 4  | McDonoughOrlando | Direct-to-consumer genetic testingFamily History | Discussion Board 3**EXAM 1** |
| 5 | McDonough  | Cardiology (GM): 9p21, 4Q25 | In-Class Session 2: Cardiology genomic medicine patient cases  |
| 6 | Cavallari | Cardiology 1 (PGx): CYP2C19-clopidogrel  | In-Class Session 3: CYP2C19 patient cases |
| 7 | Cavallari | Cardiology 3 (PGx): CYP2C9/VKORC1-warfarin | In-Class Session 4: Warfarin patient cases/ clinical implementation**EXAM 2** |
| 8 | Weitzel | Personalized Medicine in Oncology | Discussion Board 4Journal Eval 2 |
| 9 | Lamba | Oncology 2 (PGx/GM): PGx Applications in Oncology | In-Class Session 5: Oncology PGx patient cases |
| 10 | McDonough | Oncology 3 (GM): Genomic Testing for Oncology Risk Assessment | Discussion Board 5In-Class Session 6: Oncology genomics patient case |
| 11 | Weitzel | Pain Management (PGx): Codeine, tramadol | In-Class Session 7: Codeine, tramadol-CYP2D6**EXAM 3** |
| 12 | Markowitz | Pyschiatry 1 (PGx): Intro to psychiatry, TCAs, atomoxetine  | Discussion Board 6 |
| 13 | Weitzel  | Psychiatry 2 (PGx): SSRIs | In-Class Session 8: SSRIs and TCAs |
| 14 | Hamadeh | ID 1: CYP2C19-voriconazole | N/A |
| 15 | Trinh | ID 2: hepatitis C/IFNL3 | In-Class Session 9: Infectious DiseasesSurvey/Reflection 2 |
| 16 |  |  | **EXAM 4 (Final)** |