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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Co-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 1-hour live online learning sessions that meet in select weeks on Mondays from 11:45-12:35. Instructions for accessing the meetings and when they will occur will be provided in the course website.

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:
    a. CYP2D6 and codeine
    b. Clopidogrel & CYP2C19
    c. CYP2C9, VKORC1 and warfarin
    d. TPMT and thiopurines
    e. IL28B (IFNL3) and PEG-IFN
    f. CYP2D6 and CYP2C19 and TCAs
    g. CYP2D6 and atomoxetine
    h. CYP2D6 and CYP2C19 and SSRIs
    i. CYP2C19 and voriconazole
4. Apply theoretical genetic information to clinical decision-making and disease risk prediction for the following types of diseases:
    a. Complex Diseases: Cardiovascular Disease Risk
    b. 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 web-based lectures, readings, and/or assignments and lectures, and live, web-based interactions with instructors and students.

Students will be periodically assigned to present and discuss content individually 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. 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. Exams are open book and are administered over a 2-day period as indicated in the Course Schedule (Appendix A). Specific instructions and open and closing times for exams will be provided on the course website prior to administration.

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/) 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: Course Topics and Activities					
Wk	Dates	Instructor(s)	Topic	Live Session*	Assessment/Activity+
1	8/24 - 8/28	Weitzel Cooper-DeHoff	Course Overview Bioethics and Informed Consent	Orientation (8/24: 11:45-12:35)	Survey or Reflection 1
2	8/31 - 9/4	McDonough	Genotype-Phenotype Relations in PGx and GM Evidence analysis in PGx and GM	--	DNA Kit Return
3	9/7 – 9/11 (Labor Day)	Weitzel	Evidence-Based Approach to Clinical Pharmacogenetics	--	Journal Evaluation 1 Discussion Board 1
4	9/14 –9 /18	McDonough Orlando	Direct-to-Consumer Genetics Family History	--	**EXAM 1: Sept 16-18** *Bioethics/Informed Consent through Family History*
5	9/21 – 9/25	McDonough	Cardiovascular Complex Diseases: 9p21, 4q25	Cardiovascular Cases (9/21: 11:45-12:35)	--
6	9/28 – 10/2	Cavallari	PGx Cardiology 1: *CYP2C19* and clopidogrel	*CYP2C19* Cases (9/28: 11:45-12:35)	--
7	10/5 – 10/9	Cavallari	PGx Cardiology 2: *CYP2C9/VKORC1* and warfarin	Warfarin Cases (10/5: 11:45-12:35)	Discussion Board 2
8	10/12 – 10/16	Mosley	Personalized Medicine in Oncology	--	**EXAM 2: Oct 12-14** *Complex Disease and Cardiology through Warfarin PGx*
9	10/19 – 10/23	Lamba	Oncology 2: PGx Applications in Oncology	Oncology PGx Cases (10/19: 11:45-12:35)	--
10	10/26 – 10/30	McDonough	Oncology 3: Genomic Testing for Risk Assessment and Somatic Testing in Oncology	Oncology GM Cases (10/26: 11:45-12:35)	--
11	11/2 – 11/6 (Homecoming)	Mosley	Pain Management PGx: *CYP2D6* and Codeine and Tramadol	Codeine, Tramadol Cases (11/2: 11:45-12:35)	Discussion Board 3
12	11/9 – 11/13 (Veterans Day)	Markowitz	Pyschiatry Pharmacogenomics 1: Intro to psychiatry, TCAs, and atomoxetine	--	**EXAM 3: Nov 12-14** *Oncology through Pain Management*
13	11/16 – 11/20	Wake	Pyschiatry Pharmacogenomics 2: SSRIs	SSRI and TCA Cases (11/16: 11:45-12:35)	
14	11/23 -11/27 (Thanksgiving)	Hamadeh	Infectious Diseases PGx 1: CYP2C19 and voriconazole	--	Journal Evaluation 2
15	11/30 – 12/4	Trinh	Infectious Diseases PGx 2: Hepatitis C and IFNL3	ID Cases (11/30: 11:45-12:35)	Survey or Reflection 2
16	12/7 – 12/11 (ASHP)	--	--	--	**EXAM 4: Dec 7-9** *Psychiatry through Infectious Diseases*

*Live class sessions will be conducted via Big Blue Button. Complete instructions for accessing the live sessions is available on the course website.
+Instructions for all course assignments and activities will be posted to the course website.