Course Purpose:
This course provides an introduction to the principles and applications of personalized medicine. The National Institutes of Health defines Personalized Medicine as “an emerging practice of medicine that uses an individual's genetic profile to guide decisions made in regard to the prevention, diagnosis, and treatment of disease”. Indeed, knowledge of a patient’s genetic profile in the context of other clinical information can be used by pharmacists and other health care providers to design optimal drug therapy. Thus, the goal of this course is to prepare students to develop rational drug therapy plans based on a patient's unique clinical, genetic, and other information. The concepts are discussed in the context of applications to patient care.

Course Faculty and Office Hours
Course Coordinator:
Reginald F. Frye, Pharm.D., Ph.D.
Professor, Pharmacotherapy and Translational Research
Email: frye@cop.ufl.edu Office: HPNP 3333
Phone: 352-273-5453

Contact information for other faculty and lecturers in this course is included in Appendix A.

Office Hours: By appointment only. Please e-mail to schedule.

Place and Time of Class Sessions
All lectures are recorded and available through the course website. Two exams will be administered simultaneously at each campus during the semester.

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:

1. Provide Patient-centered Care – Specifically: Design, implement, monitor, evaluate, and adjust pharmacy care plans that are patient-specific; address health literacy, cultural diversity, and behavioral psychosocial issues; are evidence-based and accomplished in collaboration with other health professionals. (SLOs 1.1 and 1.2)
2. Perform pharmacist responsibilities within the medication use system and relate to the larger health care systems to assure safe and quality patient care. (SLO 3.1)
3. Use pharmacy knowledge in the care of patients and resolution of practice problems. (SLO 6.1 and 6.2)
4. Demonstrate ethical behaviors and adhere to legal requirements in pharmacy practice. (SLO 7.1)
5. Solve complex practice problems (both patient-specific and general practice) using an evidence-based approach, other aspects of good clinical science, and informatics. (SLO 8.2)

**Course Objectives**

Upon completion of this course, the student will:

1. Explain the nomenclature that is used to describe genotype and phenotype.
2. Understand how to use available pharmacogenomics databases.
3. Explain how genotype tests work.
4. Discuss how pharmacogenetics contributes to variability in drug metabolism.
5. Discuss the role of pharmacogenomics in drug therapy for the following therapeutic areas:
   a. CNS
   b. Transplantation
   c. Hepatitis C
   d. Oncology
   e. Pain Management
   f. Cardiovascular disease
   g. Asthma
6. Discuss how genotype can be used to identify patients at risk for Adverse Drug Reactions (ADRs).
7. Describe ethical, economic, legal, and social issues that frequently arise with pharmacogenomics.
8. Discuss the evolving role of the pharmacist in pharmacogenomics.

**Pre-Requisite Knowledge and Skills**

Successful completion of 1PD and 2PD coursework in the PharmD program is required to take this course.

**Course Structure & Outline**

**Course Structure.** Multiple self-directed learning activities are required (e.g., prerecorded lecture videos and readings that involve critical thinking). Students must come to campus for exams. Lectures will be pre-recorded prior to the lecture date on the course schedule. Lecture materials and videos will be available on the Canvas PHA5113 course website, which will be maintained through e-Learning (http://elearning.ufl.edu/). You will be able to access course announcements, course information, supplemental documents and grades through this website. Students are expected to check the course website regularly for updated information.

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

**Textbook**

Active Learning Requirements

For all learning experiences in this course, including lectures and reading assignments, students are expected to actively engage in the learning process, striving to grasp 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 course instructors and fellow students.

1. Lecture Viewing – Watching and listening to lectures are considered active processes in this course. As with other audiovisual-based forms of communication, students are expected to actively strive to understand the material and integrate it with their existing knowledge base.

2. Reading Assignments – As with lectures, students are expected to actively engage in their understanding of the ideas communicated in reading assignments.

3. Self-Assessments and Discussion Boards in ELS – It is recommended that students take advantage of the voluntary self-assessments and communication boards to help actively discover and resolve knowledge deficiencies.

4. Completing an individual critical literature appraisal (optional Pharmacogenomics project).

Student Evaluation & Grading

Evaluation Methods

There will be two exams administered during the course; the exams will cover only new material.

*Exams will take place on the following dates and times:*

<table>
<thead>
<tr>
<th>Material Covered</th>
<th>Date and Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exam 1: Weeks 1 through 5</td>
<td>September 27, 4:30 – 6:30 PM</td>
</tr>
<tr>
<td>Exam 2: Weeks 6 through 10</td>
<td>November 1, 4:30 – 6:30 PM</td>
</tr>
</tbody>
</table>

Each examination will cover material presented in class as well as from any required reading materials. Questions for each exam will be prepared by lecturers and the course coordinator and will reflect the goals and objectives that accompany each lecture topic.

Grading Scale

The course grade will be determined as follows:

<table>
<thead>
<tr>
<th>Pgx Project NOT Completed</th>
<th>Pgx Project Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percent of final grade</td>
<td>Percent of final grade</td>
</tr>
<tr>
<td>Exam 1</td>
<td>40%</td>
</tr>
<tr>
<td>Exam 2</td>
<td>40%</td>
</tr>
<tr>
<td>Quizzes (4 x 5% each)</td>
<td>20%</td>
</tr>
<tr>
<td>Pharmacogenomics project</td>
<td>0%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>100%</td>
</tr>
</tbody>
</table>
Quiz Schedule

The timed quizzes will be released by 4PM on the Friday of the designated week, and must be completed by Sunday at 12pm.

- Quiz 1 (9/9)  Week 3  Material: Weeks 1-2
- Quiz 2 (9/23)  Week 5  Material: Weeks 3-4
- Quiz 3 (10/7)  Week 7  Material: Weeks 5-6
- Quiz 4 (10/21)  Week 9  Material: Weeks 7-8

Pharmacogenomics project: Students may complete an optional pharmacogenomics project, which must be completed individually. Specific instructions regarding the project will be provided. The project is optional and will affect the final grade as shown in the preceding section.

A final percentage grade will be calculated and letter grades assigned as follows:

<table>
<thead>
<tr>
<th>Percentage Grade</th>
<th>Letter Grade</th>
<th>Percentage Grade</th>
<th>Letter Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥ 92%</td>
<td>A</td>
<td>72 - &lt; 77%</td>
<td>C</td>
</tr>
<tr>
<td>90 - &lt; 92%</td>
<td>A-</td>
<td>70 - &lt; 72%</td>
<td>C-</td>
</tr>
<tr>
<td>87 - &lt; 90%</td>
<td>B+</td>
<td>67 - &lt; 70%</td>
<td>D+</td>
</tr>
<tr>
<td>82 - &lt; 87%</td>
<td>B</td>
<td>62 - &lt; 67%</td>
<td>D</td>
</tr>
<tr>
<td>80 - &lt; 82%</td>
<td>B-</td>
<td>60 - &lt; 62%</td>
<td>D-</td>
</tr>
<tr>
<td>77 - &lt; 80%</td>
<td>C+</td>
<td>&lt; 60%</td>
<td>E</td>
</tr>
</tbody>
</table>

Information on current UF grading policies for assigning grade points can be found here: [https://catalog.ufl.edu/ugrad/current/regulations/info/grades.aspx](https://catalog.ufl.edu/ugrad/current/regulations/info/grades.aspx)

Class Attendance Policy: Attendance is not required for lectures.

Quiz Policy: Makeup quizzes will not be given. If a student misses a quiz, then they will receive a “0” grade for that quiz.

Exam Policy: Grades will be based on two examinations (September 27 and November 1), the four quizzes, and the optional Pharmacogenomics project (if completed). Exams will cover the material presented and discussed in recorded videos (and assigned readings if applicable). The format of the exams may be a combination of true/false and/or multiple-choice questions.

Exam rebuttals: There is no formal rebuttal process in this course. The validity of each exam question will be determined from a statistical analysis of each question. The Course Coordinator and instructors will carefully review the exam statistics to decide whether to throw out a question or accept additional answers. After these determinations have been made, a final announcement will be posted to the Canvas course site summarizing any changes that will occur in the exam scoring process.

During any Exam:
1. The following items are not allowed to be accessed during the exam: calculators, cell phones, other electronic or digital devices including smart watches, pagers, photographic devices, and recording devices. Any watches must be placed on the top of the desk for proctor review.
2. All backbacks, purses or other bags should be kept away from the student’s designated testing space.
and must not be accessed during the exam. Nonessential materials are NOT allowed at the student's desk during examination periods. Please leave all nonessential materials outside of or in the front of the examination room.

3. **Students must arrive and be seated promptly to be eligible to take the exam.** To maintain exam security, students who arrive late for the exam will not be allowed to start the exam if they are more than 30 minutes late or if another student has left the room after seeing the exam. Students who have valid reasons for arriving late at the exam may request a makeup exam as outlined below.

4. There must be no talking or other disruptive behavior during the distribution or taking of the exam.

5. Calculators must meet the following requirements: Only nonprogrammable calculators are allowed unless the course has a specific policy.

6. If you encounter calculator problems (e.g., dead battery), contact the Proctor.

7. Other exam rules may be instituted during the progression of the course.

8. **Once the exam commences, students may not leave the room without first turning in the exam.** Once the exam is turned in, the examination period for the student is considered complete and the student must leave the examination room.

9. If there is urgent need to use the restroom, the Proctor will provide guidance.

*Failure to follow exam rules may be considered as evidence of academic dishonesty.*

**Make-up Exam Policy:** Students who must miss a scheduled exam due to illness, family emergency or death in the family should personally report this to the course coordinator prior to administration of the exam (note: this information cannot be transmitted to the course coordinator by a friend). Documentation of the need to miss an exam will be required (e.g. physician’s note for illness). A make-up exam will be scheduled for the student at a reasonable time established by the course coordinator. Only in extreme circumstances would the make-up exam be administered more than two weeks after the scheduled exam. The format of the makeup exam will be at the discretion of the course coordinator and may include multiple choice and/or short answer (essay) questions. Unexcused absences from a scheduled examination or failure to notify the course coordinator of an absence will result in the student receiving a zero for that exam.

**Policy on Old Exams:** Selected exams from a previous academic year are posted on the course website.

**Assignment Deadline:** The deadline for the optional Pharmacogenomics project will be Monday, November 7, by 11:59PM.

**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

Please see the following URL for this information:

Faculty and Course Evaluations
Students are expected to provide feedback on the quality of instruction in every course based on 10 criteria. These evaluations are conducted online at https://evaluations.ufl.edu. Evaluations are typically open around mid-semester and need to be completed by the established deadline. Summary results of these assessments are available to students at https://evaluations.ufl.edu.

Computer and Other Technology Requirements
Students are required to meet the following computer and technology requirements:
http://pharmacy.ufl.edu/education/student-affairs/admissions/student-computer-requirements/

ExamSoft® is used for administration of exams and students are required to follow the procedures that are established for exam administration. The exam must be downloaded prior to the start of the exam. Extra time will not be given if the exam has not been downloaded. The exam must be uploaded by the stated deadline of the student will be penalized 5 points off the final grade for each 24 hours the exam is not uploaded to the ExamSoft® server. Students must bring a laptop (or iPad tablet) to class to complete exams and this laptop must meet the computer and technology requirements established by the College. These technology requirements require a backup battery with at least 2 hours of life. Students are encouraged to complete mock exams prior to the actual exam to ensure that all computer features are supported by ExamSoft®.

Complaints: Should you have any complaints with your experience in this course please contact Dr. Frye. If unresolved, contact the COP Associate Dean-Student Affairs, Dr. Shauna Buring. For unresolved issues, see: http://www.distancelearning.ufl.edu/student-complaints to submit a complaint.
Appendix A: Directions for Contacting Faculty & Course Faculty List

Directions for Contacting Course Faculty
Questions regarding lecture content should be posted on the discussion board.

Please keep in mind the following guidelines regarding discussion board postings:

- Strive to exhibit professionalism through this mechanism of communication
- Please keep all communication and requests professional. Avoid sarcastic, negative, or insulting postings, or judging others questions.
- Please check recent discussion board posts and announcements before posting your message to ensure that someone else has not already asked the same question, or that it has not been addressed in an announcement.
- Anonymous postings will not be permitted.
- Also avoid unnecessary posts such as “thank you”, “me too”, etc.

Questions regarding the course or other personal matters should be sent to Dr. Frye.

Course Coordinator
Reginald F. Frye, Pharm.D., Ph.D.
Professor, Pharmacotherapy and Translational Research
frye@cop.ufl.edu

Instructors
Larissa Cavallari, Pharm.D., lcavallari@cop.ufl.edu
Nihal El Rouby, Pharm.D., nihalelrouby@ufl.edu
Reginald F. Frye, Pharm.D., Ph.D., frye@cop.ufl.edu
Caitrin McDonough, Ph.D., caitrinctodonough@ufl.edu
Jatinder Lamba, Ph.D., jlambee@cop.ufl.edu
Taimour Langaee, Ph.D., langaee@cop.ufl.edu
John Markowitz, Pharm.D., markowitz@cop.ufl.edu
Anne Schentrup, Pharm.D., Ph.D., schena@shands.ufl.edu
# Appendix B. Schedule of Course Activities/Topics

<table>
<thead>
<tr>
<th>Week</th>
<th>Date</th>
<th>Module</th>
<th>Topic</th>
<th>Instructor</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>8/22</td>
<td>1</td>
<td>Principles of genetic medicine – Part 1</td>
<td>McDonough</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Principles of genetic medicine – Part 2</td>
<td>McDonough</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Principles of genetic medicine – Part 3</td>
<td>McDonough</td>
</tr>
<tr>
<td>2</td>
<td>8/29</td>
<td>2</td>
<td>Database tools for pharmacogenomics</td>
<td>McDonough</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3</td>
<td>Methods in Pharmacogenomics</td>
<td>Langaee</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4</td>
<td>Introduction to Personalized Medicine</td>
<td>Frye</td>
</tr>
<tr>
<td>3</td>
<td>9/5</td>
<td>5</td>
<td>Pharmacogenomics of drug metabolizing enzymes – Part 1</td>
<td>Frye</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Quiz 1 – Wks 1-2</strong> Pharmacogenomics of drug metabolizing enzymes – Part 2</td>
<td>Frye</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Pharmacogenomics of drug metabolizing enzymes – Part 2</td>
<td>Frye</td>
</tr>
<tr>
<td>4</td>
<td>9/12</td>
<td>6</td>
<td>Pharmacogenomics of drug transporters</td>
<td>Frye</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7</td>
<td>“Omens” and Personalized Medicine – Metabolomics and Proteomics</td>
<td>Frye</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>“Omens” and Personalized Medicine – Transcriptomics and Epigenomics</td>
<td>Frye</td>
</tr>
<tr>
<td>5</td>
<td>9/19</td>
<td>8</td>
<td>CPIC Guidelines</td>
<td>Frye</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Quiz 2 – Wks 3-4</strong> Pharmacogenomics and G6PD deficiency</td>
<td>Frye</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Pharmacogenomic applications in Hepatitis C</td>
<td>Frye</td>
</tr>
<tr>
<td>6</td>
<td>9/26</td>
<td>10</td>
<td>Pharmacogenomic applications in transplantation</td>
<td>Frye</td>
</tr>
<tr>
<td></td>
<td></td>
<td>11</td>
<td>Pharmacogenomic applications in asthma</td>
<td>El Rouby</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>9/27 – EXAM 1 (material from weeks 1 – 5) 4:30–6:30PM.</strong></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>10/3</td>
<td>12</td>
<td>Pharmacogenomic applications in pain management</td>
<td>Markowitz</td>
</tr>
<tr>
<td></td>
<td></td>
<td>13</td>
<td>Pharmacogenomic applications in CNS disorders – Part 1</td>
<td>Markowitz</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Pharmacogenomic applications in CNS disorders – Part 2</td>
<td>Markowitz</td>
</tr>
<tr>
<td>8</td>
<td>10/10</td>
<td>14</td>
<td>Pharmacogenomic applications in cardiovascular disease I</td>
<td>Cavallari</td>
</tr>
<tr>
<td></td>
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<td>15</td>
<td>Pharmacogenomic applications in cardiovascular disease II</td>
<td>Cavallari</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Pharmacogenomics in drug discovery and development</td>
<td>Frye</td>
</tr>
<tr>
<td>9</td>
<td>10/17</td>
<td>16</td>
<td>Pharmacogenomic applications in oncology – Solid tumors</td>
<td>J. Lamba</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Quiz 4 – Wks 7-8</strong> Pharmacogenomic applications in oncology – hematological malignancies</td>
<td>J. Lamba</td>
</tr>
<tr>
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<td>Ethical, economic, legal, and social (EELS) issues in pharmacogenomics</td>
<td>Schentrup</td>
</tr>
<tr>
<td>10</td>
<td>10/24</td>
<td>19</td>
<td>Pharmacogenomics of adverse drug reactions</td>
<td>Frye</td>
</tr>
<tr>
<td></td>
<td></td>
<td>20</td>
<td>Personalized Medicine and the Pharmacist’s role</td>
<td>Cavallari</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>11/1 – EXAM 2 (material from weeks 6 – 10) 4:30–6:30PM.</strong></td>
<td></td>
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</tbody>
</table>