Cover Sheet: Request 10137

PHA5XXX - Clinical Applications of Personalized Medicine

Info

Process	Course|New|Ugrad/Pro
Status	Pending
Submitter	Barker, Sarah K skbarker@ufl.edu
Created	3/11/2015 12:12:26 PM
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Description	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.

Actions

Step	Status	Group	User	Comment	Updated
Department	Approved	COP - Pharmacotherapy and Translational Research 313206000	Frye, Reginald F		3/11/2015
College	Approved	COP - College of Pharmacy	Beck, Diane Elizabeth		3/12/2015
University Curriculum Committee	Pending	PV - University Curriculum Committee (UCC)			3/12/2015
Statewide Course Numbering System					
Office of the Registrar					
Student Academic Support System					
Catalog					
College Notified					

UCC1: New Course Transmittal Form

Recommended SCNS Course Identification

1. Prefix PHA 2. Level 5 3. Number XXX 4. Lab Code None

5. Course Title Clinical Applications of Personalized Medicine

6. Transcript Title (21 character maximum) Clin App Personal Med

7. Effective Term Earliest Available 8. Effective Year Earliest Available 9. Rotating Topic? No

10. Amount of Credit 3 11. If variable, # minimum and # maximum credits per semester.

12. Repeatable credit? No 13. If yes, total repeatable credit allowed #

14. S/U Only? No 15. Contact Type Regularly Scheduled [base hr]

16. Degree Type Professional 17. If other, please specify: Click here to enter text.

18. Category of Instruction Introductory

19. Course Description (50 words maximum)

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.

20. Prerequisites

Departmental approval is required.

21. Co-requisites

none

22. Rationale and Placement in Curriculum

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.

23. Complete the syllabus checklist on the next page of this form.

Syllabus Requirements Checklist

The University's complete Syllabus Policy can be found at:
http://www.aa.ufl.edu/Data/Sites/18/media/policies/syllabi_policy.pdf

The syllabus of the proposed course **must** include the following:

- ☒ Course title
- ☒ Instructor contact information (if applicable, TA information may be listed as TBA)
- ☒ Office hours during which students may meet with the instructor and TA (if applicable)
- ☒ Course objectives and/or goals
- ☒ A weekly course schedule of topics and assignments.
- ☒ Methods by which students will be evaluated and their grades determined
- ☒ Information on current UF grading policies for assigning grade points. This may be achieved by including a link to the appropriate undergraduate catalog web page: https://catalog.ufl.edu/ugrad/current/regulations/info/grades.aspx.
- ☒ List of all required and recommended textbooks
- ☒ Materials and Supplies Fees, if any
- ☒ A statement related to class attendance, make-up exams and other work such as: *"Requirements for class attendance and make-up exams, assignments, and other work in this course are consistent with university policies that can be found in the online catalog at: https://catalog.ufl.edu/ugrad/current/regulations/info/attendance.aspx."*
- ☒ A statement related to accommodations for students with disabilities such as: *"Students requesting classroom accommodation must first register with the Dean of Students Office. The Dean of Students Office will provide documentation to the student who must then provide this documentation to the Instructor when requesting accommodation."*
- ☒ A statement informing students of the online course evaluation process such as: *"Students are expected to provide feedback on the quality of instruction in this course based on 10 criteria. These evaluations are conducted online 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."*

It is **recommended** that the syllabus contain the following:

- ☐ Critical dates for exams or other work
- ☐ Class demeanor expected by the professor (e.g. tardiness, cell phone usage)
- ☐ The university's honesty policy regarding cheating, plagiarism, etc.

  Suggested wording: UF students are bound by The Honor Pledge which states, "We, the members of the University of Florida community, pledge to hold ourselves and our peers to the highest standards of honor and integrity by abiding by the Honor Code. On all work submitted for credit by students at the University of Florida, the following pledge is either required or implied: "On my honor, I have neither given nor received unauthorized aid in doing this assignment." The Honor Code (http://www.dso.ufl.edu/sccr/process/student-conduct-honor-code/) specifies a number of behaviors that are in violation of this code and the possible sanctions. Furthermore, you are obligated to report any condition that facilitates academic misconduct to appropriate personnel. If you have any questions or concerns, please consult with the instructor or TAs in this class.

- ☐ Contact information for the Counseling and Wellness Center: http://www.counseling.ufl.edu/cwc/, 392-1575; and the University Police Department: 392-1111 or 9-1-1 for emergencies

PHA 5XXX Clinical Applications of Personalized Medicine

Summer C 2015 3 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:
Kristin Weitzel, PharmD, CDE, FAPhA
Associate Director, UF Health Personalized Medicine Program
Clinical Associate Professor, Pharmacotherapy and Translational Research
Email: Kweitzel@cop.ufl.edu Office: MSB PG-21
Phone: 352-273-5114

Co-Coordinator:
Caitrin McDonough, PhD
Research Assistant Professor, Pharmacotherapy and Translational Research
Email: cmcdonough@cop.ufl.edu Office: MSB PG-05B
Phone: 352-273-6435

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 1.5 hour live online learning sessions. Live sessions are conducted via Adobe Connect, with meeting time depending on the assigned section. 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:
    a. CYP2D6 and codeine
    b. Clopidogrel & CYP2C19
    c. SLCO1B1 and simvastatin
    d. CYP2C9, VKORC1 and warfarin
    e. TPMT and thiopurines
    f. IL28B (IFNL3) and PEG-IFN
4. Apply family history and pedigree information to clinical decision-making and disease risk prediction.
5. 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
6. Demonstrate best practices for returning genetic and pharmacogenetic test results to a patient, including legal and ethical concerns and communication strategies.
7. Explain circumstances in which a patient should be referred to a genetic counselor or other specialist.
8. Demonstrate the contributions and roles of other health care professionals in the clinical application of genomic information to patient care.
9. 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 Permission is 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 (6)
2. Adobe Connect Sessions (9). 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 Evaluations (2)

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 – 6% (1% each)
- Adobe Connect Sessions – 18% (2% each)
- Survey/Reflections – 6% (3% each)

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 adobe connect sessions is mandatory and participation in the group discussion is required. Because there are 2 opportunities to attend the adobe connect sessions, students who know that they will miss an Adobe Connect session should contact the facilitator as soon as possible and arrange to attend another adobe connect session. Upon approval of the facilitator only, students may make up a missed session by completing a brief written assignment for a maximum of 3 out of the 9 sessions. Failure to get approval for the missed session prior to the session will result in a mark of zero for the adobe session. Written documentation of the session content 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/) 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: *Schedule of Course Activities/Topics*

Week	Instructor(s)	Lecture Topic/Activity	Assessment/Activity
1 (2 hours)*	Weitzel Cooper-Dehoff	Course Overview Role of Bioethics and Informed Consent	Survey/Reflection 1
2 (3 hours)*	McDonough McDonough McDonough	Principles of Genetic Medicine 1 Principles of Genetic Medicine 2 Principles of Genetic Medicine 3	DNA Kit Return Discussion Board 1
3 (2 hours)*	Weitzel Weitzel	Introduction to Personalized Medicine Electronic Health Record: Storing and using pharmacogenomic and genomic data	Discussion Board 2
4 (4 hours)*	McDonough Weitzel	Medical evidence in Genomic Medicine and Pharmacogenomics Evidence-Based Approach to PGx	Journal Eval 1 Adobe 1: Databases for Clinical Questions
5 (3 hours)*	McDonough	Direct-to-consumer genetic testing	Adobe 2: DTC genetic testing **EXAM 1**
6 (4 hours)*	Orlando McDonough	Family History Cardiology (GM): 9p21, 4Q25	Discussion Board 3 Adobe 3: Family history and CV risk assessment
7 (4 hours)*	Cavallari Cooper-Dehoff	Cardiology 1 (PGx): CYP2C19-clopidogrel Cardiology 2 (PGx): SLC01B1-simvastatin	Adobe 3: CYP2C19/SLC01B1
8 (4 hours)*	Cavallari Weitzel	Cardiology 3 (PGx): CYP2C9/VK0RC1-warfarin Personalized medicine in cardiology	Adobe 4: warfarin/ clinical implementation **EXAM 2**
9 (3 hours)*	TBD Weitzel	Personalized Medicine in Oncology Oncology 1 (PGx): TPMT	Discussion Board 4 Journal Eval 2
10 (3 hours)*	Lamba	Oncology 2 (PGx): DPYD, G6PD, UGT1A1	Adobe 5: Oncology PGx
11 (3 hours)*	McDonough Lamba	Oncology 3 (GM, risk assessment): BRCA Oncology 4 Tumor) testing/CDTs: (e.g., KRAS/BRAF)	Discussion Board 5 Adobe 6: Oncology genomics
12 (3 hours)*	Weitzel	Pain Management (PGx): CYP2D6	Adobe 7: codeine, tramadol-CYP2D6 **EXAM 3**
13 (3 hours)*	Markowitz Weitzel	Pyschiatry 1 (PGx) Psychiatry 2 (PGx)	Discussion Board 6 Adobe 8: CYP2D6/CYP2C19 testing with SSRIs and TCAs
14 (4 hours)*	Hamadeh Weitzel Weitzel	ID 1: CYP2C19-voriconazole ID 2: hepatitis C/INFL3 Clinical Implementation Summary	Adobe 9: Infectious Diseases Survey/Reflection 2
			EXAM 4 (Final)

*Contribution to course credit assignment

UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and

AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

Please read this form which describes the study in some detail. A member of the research team will describe the study to you and answer all of your questions. Your participation is entirely voluntary. If you choose to participate you can change your mind at any time and withdraw from the study. You will not be penalized in any way or lose any benefits to which you would otherwise be entitled if you choose not to participate in this study or to withdraw. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the Title of this research study?

Genomic Medicine Implementation: The Personalized Medicine Program Education Protocol

3. Who do you call if you have questions about this research study?

Study Coordinator: Amanda Elsey (352) 273-6257

4. Who is paying for this research study?

The sponsor of this study is the National Institutes of Health (NIH).

5. Why is this research study being done?

The purpose of this study is to determine whether health care professional students' use of their own pharmacogenetic data, as compared with anonymous data, to solve patient cases affects their knowledge, attitudes, and beliefs surrounding pharmacogenomics in clinical practice.

You are being asked to participate in this research study because you are enrolled in Clinical Applications in Pharmacogenomics.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal participation in this course (even if you did not participate in this research study)?

As part of your normal participation in this course, all students will receive a DNA test kit, informed consent for DNA testing, and a 4-digit identification number in the mail before the course starts.

Throughout the course, all students will complete patient cases using genetic data to answer clinical questions. You will have the option to use an anonymous DNA dataset for these assignments or to participate in the research study and have your DNA analyzed with the test kit you received and use your own results for the patient cases. These options will be reviewed during the first live, web-based class session that will occur during the first week of class.

<u>If you choose NOT to have your DNA tested</u>, you will be required to mail the unopened kit back to the study coordinator using the enclosed pre-paid envelope. All DNA test kits will be due back to the study coordinator by the beginning of Week 2, whether you decide to participate in the study or not.

Successful return of the DNA test kit packet (with or without a saliva sample) by the due date will be incorporated into your participation grade for the course. However, your course instructors will not know whether you are using your own data or an anonymous dataset. The study coordinator will communicate only yes/no completion of the return of the DNA test kit to course faculty for this portion of the class participation grade. The study coordinator is not a faculty member in the course and has no influence on, or awareness of, student grading processes for the course.

Once the DNA test kit package is returned to the study coordinator, students opting not to use their genetic data will receive an anonymous DNA dataset by email to use for completing the cases.

All students will also be given the option to complete a survey before and after the course to provide information on their knowledge, attitudes, and beliefs surrounding clinical pharmacogenomics.

If you have any questions now or at any time during the study, please contact the study coordinator listed in question 3 of this form.

7. What will be done only because you are in this research study?

As part of your normal participation in this course, all students will receive a DNA test kit, informed consent for DNA testing, and a 4-digit identification number in the mail before the course starts.

Throughout the course, all students will complete patient cases using genetic data to answer clinical questions. You will have the option to use an anonymous DNA dataset for these assignments or to participate in the research study and have your DNA analyzed with the test kit you received and use your own results for the patient cases. These options will be reviewed during the first live, web-based class session that will occur during the first week of class.

If you choose to have your DNA tested, you will complete the saliva-based DNA test kit that was mailed to you according to the test instructions and then mail the completed test and signed informed consent form back to the study coordinator in the enclosed pre-paid envelope as instructed. You will also be given the option to sign and return an addendum to the consent form allowing your genetic data to be shared with the National Institutes of Health's database of genotypes and phenotypes (dbGaP). You are NOT required to share your genetic data with dbGaP in order to participate in the DNA testing.

The study coordinator will explain this consent form to you during the first live, web-based class session, in which you will also have the opportunity to ask questions and voice any concerns. All DNA test kits will be due back to the study coordinator by the beginning of Week 2, whether you decide to participate in the study or not.

Successful return of the DNA test kit packet (with or without a saliva sample) by the due date will be incorporated into your participation grade for the course. However, the course instructors will not know whether you are using an anonymous dataset, using your own genetic data, or if you share your data with dbGaP. The study coordinator will communicate only yes/no completion of the return of the DNA test kit to course faculty for this portion of the class participation grade.

Once the study coordinator receives your DNA test kit, the saliva sample will be delivered to the laboratory, identified only by your 4-digit identification number. After the test is processed, laboratory personnel will communicate your genotype results to the study coordinator, identified only by your 4-digit identification number. The study coordinator will then communicate the genotype test results to you via an encrypted, password-protected document attached to an email.

For research activities and all documentation related to the study, you will be identified only by the assigned 4-digit number to all investigators, course faculty, study personnel, and laboratory personnel, except the study coordinator, who will maintain the only identification key. The study coordinator is not a faculty member in the course and has no influence on, or awareness of, student grading processes for the course.

At the end of the course, if you consented to share your de-identified genotype data with dbGaP by signing the addendum attached to the informed consent, the study coordinator will notify the laboratory of your 4-digit identification code and the laboratory will submit your de-identified data to dbGaP. All laboratory samples and any documentation or data related to your DNA test, whether you consented to share your data with dbGaP or not, will be destroyed by laboratory personnel once this step is complete.

All students will also be given the option to complete a survey before and after the course to provide information on their knowledge, attitudes, and beliefs surrounding clinical pharmacogenomics.

If you have any questions now or at any time during the study, please contact the study coordinator listed in question 3 of this form.

8. How long will you be in this research study?

8 weeks

9. How many people are expected to take part in this research study?

No more than 90 students

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

10. What are the possible discomforts and risks from taking part in this research study?

There are minimal risks to participating in this research study and having your DNA tested.

You could potentially feel coerced to use your own genetic data, and/or have your genotype data submitted to dbGaP.

Although currently there are no risks of ancillary findings that impact future disease risk with the very limited pharmacogenetic data that is included in the DNA testing being done in this research study, it is theoretically possible (although highly unlikely) that future research will reveal disease risk associations with these data. The possibility of such information becoming available in the future may create psychological stress for you (and potentially your family members).

You could theoretically be at risk for future negative insurance or other consequences when receiving results of personal genotype evaluation (e.g., potential risk of decreased patient insurability secondary to increased disease risk or risk of stress from ancillary findings).

No potential social, economic (no cost to you), or physical (DNA obtained through saliva instead of blood sample) risks or discomforts are anticipated with this research study.

A number of safeguards will be used to minimize any risks to you:

1. To address confidentiality, course faculty will be fully unaware of which students consent to participate in the research study. All study-related communication and identification will be conducted and maintained by the study coordinator, who is not associated with course grading or administration.

2. To support informed student decision-making, there will be substantial time spent prior to students making the decision about using their own genetic data in which ethicists and genetic counselors will review the issues/risks associated with genetic information, in addition to review of the informed consent documents. Students will have multiple opportunities to opt out of participating in the research study, even after they have consented to do so, including after their sample is submitted but before results are received.

3. To address the theoretical risk of psychological stress from participating in this study, students experiencing stress or with questions about their test results will be given the opportunity to meet with a counselor or pharmacogenetic expert confidentially and at no charge to discuss any questions they might have.

4. To address the theoretical risk of loss of insurability or other consequences of participating in this study, students will get only very limited pharmacogenetic single nucleotide polymorphism (SNP) data, which are low risk in nature. Additionally, these data will be provided in a completely confidential manner directly to the student. Pharmacogenetic information will not be returned to the participant's medical record or otherwise be stored.

5. To further address the theoretical risk of a negative impact of ancillary findings, only SNPs associated with pharmacogenetics (not disease risk) will be genotyped. An analysis of genetic association data from the National Human Genome Research Institutes' genome-wide association study data and dbGaP will also be conducted prior to returning SNP data to students. If this analysis reveals that any of the SNPs that will be genotyped have recently been associated with any common disease, these SNPs will NOT be returned to the students. These precautionary steps greatly minimize any possible risk of decreased future eligibility for insurance or other purposes.

If you wish to discuss the information above, please ask questions by email or call the study coordinator listed in question 3 in this form.

11a. What are the potential benefits to you for taking part in this research study?

There is an anticipated educational benefit to participating in this research study. Preliminary data support the effectiveness of teaching strategies which incorporate personal DNA testing in in improving students' knowledge and ability to use pharmacogenetic and genetic data in the clinical care of patients. As a health care professional student, you may receive this benefit with no or minimal theoretical risk by participating in this study.

Your DNA test results are for research purposes only and should not be used for health information or clinical use. If you have questions about your health or medical conditions, you should discuss these with your medical provider.

11b. How could others possibly benefit from this study?

Results of this study may be used to inform and support the development of similar educational strategies that incorporate personal DNA testing in educating health care professional students about pharmacogenomics and genomic medicine.

Additionally, if you agree to share your data with dbGaP, your de-identified genotype information could be used in research studies related to pharmacogenomics.

11c. How could the researchers benefit from this study?

The researchers will not benefit from your participation in this study. The researchers are not conducting any research on your DNA test results, and will not present any of the data from your DNA test results at scientific meetings or in scientific journals.

12. What other choices do you have if you do not want to be in this study?

If you decide not to participate in this study, you will be provided with an anonymous DNA dataset to complete the assigned patient cases in the course. To ensure similar information is provided to you if you have opted not to participate in the study, laboratory personnel will conduct the same DNA tests on anonymous donor samples obtained a tissue repository prior to study enrollment, or will obtain anonymous genotypes from publically available databases (e.g. 1,000 Genomes, HapMap). If necessary, theoretical datasets may be used in place of anonymous or de-identified SNP data.

Your participation in this study is voluntary and any decision to take part or not to participate in the study will in no way affect your grade or class standing.

If you believe that your participation in this study or your decision to withdraw from or to not participate in this study has improperly affected your grade(s), you should discuss this with the dean of your college or you may contact the Institutional Review Board (IRB) office at (352) 273-9600.

13. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in the genotyping at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled.

If you decide to withdraw your consent to participate in this study for any reason, please contact the study coordinator listed in question 3 of this form. The study coordinator will tell you how to stop your participation and obtain an anonymous dataset to complete the patient case assignments.

If you have any questions regarding your rights, please call the Institutional Review Board (IRB) office at (352) 273-9600.

SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this course; the alternative to being in the study; and how the participant's information will be collected, used, and shared with others:

Signature of Person Obtaining Consent and Authorization

Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You voluntarily agree to participate in this study. By signing this form, you are not waiving any of your legal rights.

Signature of Person Consenting and Authorizing

Date

ADDENDUM: Consent to Collect and Store Your Genetic Data for Future Research

As part of the research project University Of Florida Health Personalized Medicine Program Dr. Kristin Weitzel is seeking your consent to store your genetic data.

Reason for Storing Your Data:

You have recently agreed to participate in the research study listed above, which is funded by the National Institute for Health (NIH). That research study involves determining certain genetic information about you. The NIH has a policy of sharing genetic information with other researchers to help further new discoveries on disease treatment and cures. Genetic factors are those that people are born with and that can affect other family members. What is included in the genetic information of yours that will be stored in this federal data bank, will be determined by the research study you have already agreed to.

The person in charge of the research project you agreed to (also known as the Principal Investigator) or a representative of the Principal Investigator will describe this data sharing to you and answer all of your questions. Your participation in allowing your data to be shared and stored in this NIH data bank is entirely voluntary. Before you decide whether or not to take part, read the information below and ask questions about anything you do not understand. If you choose not to participate in this data banking and data sharing study you will not be penalized or lose any benefits that you would otherwise be entitled to.

What will Happen to Your Genetic Data:

If you agree to this data banking and data sharing study, your genetic data and any other data that is collected in the study will be placed into a secure location(a large computer) at the University of Florida (UF). Once the other study you agreed to (listed above) is completed, your genetic data and other data collected on you during that study will have all identifiable information removed and then be sent to the NIH data bank. Your de-identified data that is sent will be given a unique ID number, but only those at UF will be able to match this unique ID number to identify you.

Who Can Use Your Stored Data:

At the NIH, de-identified genetic data that has been collected from you and other participants may be given to researcher from around the country who apply to the NIH to receive de-identified data to use in their research projects. This request will first have to be approved by an NIH committee that oversees the release of the data. Once the NIH committee approves the release of the de-identified data, the researcher will have to get local Institutional Review Board (IRB - an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research) approval before they can start their study.

At the NIH, since your data is de-identified in the data bank, neither you nor UF will receive any information when data is used in future research or receive any results from that future research.

Benefits to You in Storing Your Data:

There is no direct benefit to you for participating in this data bank.

Risks to You in Storing Your Data:

At NIH:

- Risk of Identification: The genetic data being sent to the NIH Data Bank is de-identified, however there is a slight chance that identifiable information may be mistakenly sent.

- Risk Associated with the Freedom of Information Act: Your information that is sent to the NIH will be kept in an NIH data bank and will, thereby, become U.S. government records that are subject to the Federal Freedom of Information Act (FOIA). As an agency of the Federal government, the NIH is required to release government records in response to requests under the federal Freedom of Information Act (FOIA), unless the records are exempt from release under one of the FOIA exemptions. The NIH believes that the only release of your data under such a request would be your data with the unique ID number removed.

- Risks Associated with Law Enforcement Access: It is possible that law enforcement agencies could request access to the de-identified genetic data within the NIH data bank and, for example, search for matches to DNA data collected as part of some criminal activity. While this is expected to be rare, such requests may be granted by the NIH. Law enforcement officials might then try to identify you by requiring your study doctor to release the key to the unique ID number which could identify you. However, the release of identifiable information by your study doctor may be protected by the Certificate of Confidentiality.

  In order to better protect access to your genetic information, both UF and the NIH have obtained a Certificate of Confidentiality. Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect researchers from being forced to release research records, which in this case is your genetic information. These Certificates allow the researchers and others who have access to research information to refuse to release information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

- Risks to Specific Populations, Groups, and Communities: Medical research has already shown that some populations demonstrate a higher likelihood to develop certain medical diseases than others. It is possible that if you have some rare condition or rare physical characteristics, that someone could identify you based on the de-identified data in the NIH data bank.

Can You Withdraw Your Consent to Store Your Data?

If you decide that your genetic data can be kept for research but you later change your mind, tell the UF Health Personalized Medicine Program's Dr. Kristin Weitzel at 352-273-5114 who will remove your data from the UF databank, and inform the Federal Data bank to remove your de-identified data from the data bank. There will be no cost to you for this storage of your de-identified genetic data.

Do You Agree to Participate?

Please review statement below and initial by your choice:

I agree to have my de-identified genetic data shared with the NIH databank to be used for future unknown research.

Initials _____ YES Initials _____ NO