

Cover Sheet: Request 14258

PHA5XXX Oncology Clinical Trial Evaluation

Info

Process	Course New Ugrad/Pro
Status	Pending at PV - University Curriculum Committee (UCC)
Submitter	Karen Whalen whalen@cop.ufl.edu
Created	9/20/2019 10:19:31 AM
Updated	9/20/2019 11:01:17 AM
Description of request	The College of Pharmacy would like to offer a new 2-credit elective course in Oncology Clinical Trial Evaluation. This course is designed to allow student pharmacists with a strong interest in oncology to further develop the skills necessary to make optimal decisions regarding treatment and supportive care pharmacotherapy in patients with cancer. The course will be offered in a condensed 2-week format to students in the third professional year of the PharmD curriculum.

Actions

Step	Status	Group	User	Comment	Updated
Department	Approved	COP - Interdisciplinary Studies	Karen Whalen		9/20/2019
PHA5XXX Oncology Trial Evaluation Elective Syllabus.pdf					9/20/2019
COP Course Policies Approved 2019-08-12 final.pdf					9/20/2019
College	Approved	COP - College of Pharmacy	Shauna Buring		9/20/2019
No document changes					
University Curriculum Committee	Pending	PV - University Curriculum Committee (UCC)			9/20/2019
No document changes					
Statewide Course Numbering System					
No document changes					
Office of the Registrar					
No document changes					
Student Academic Support System					
No document changes					
Catalog					
No document changes					
College Notified					
No document changes					

Course|New for request 14258

Info

Request: PHA5XXX Oncology Clinical Trial Evaluation

Description of request: The College of Pharmacy would like to offer a new 2-credit elective course in Oncology Clinical Trial Evaluation. This course is designed to allow student pharmacists with a strong interest in oncology to further develop the skills necessary to make optimal decisions regarding treatment and supportive care pharmacotherapy in patients with cancer. The course will be offered in a condensed 2-week format to students in the third professional year of the PharmD curriculum.

Submitter: Karen Whalen whalen@cop.ufl.edu

Created: 9/20/2019 9:40:45 AM

Form version: 1

Responses

Recommended Prefix PHA

Course Level 5

Course Number XXX

Category of Instruction Advanced

Lab Code None

Course Title Oncology Trial Evaluation

Transcript Title Oncology Trial Eval

Degree Type Professional

Delivery Method(s) On-Campus, Off-Campus, Online

Co-Listing No

Effective Term Spring

Effective Year 2020

Rotating Topic? No

Repeatable Credit? No

Amount of Credit 2

S/U Only? No

Contact Type Regularly Scheduled

Weekly Contact Hours 15

Course Description This course allows student pharmacists with an interest in oncology to further develop the skills necessary to make optimal decisions regarding treatment and supportive care in cancer patients. Students will evaluate primary oncology literature and engage in discussions of clinical trials and debates on controversies in clinical practice.

Prerequisites Successful completion of Blocks 1-15 of the Doctor of Pharmacy curriculum including milestones

Co-requisites None

Rationale and Placement in Curriculum This is an elective course in the PharmD curriculum. The course requires application of knowledge learned in years 1 through 3 of the curriculum and prepares them for the year 4 advanced pharmacy practice experiences.

Course Objectives

1. Evaluate scientific manuscripts including study design, methodology, biostatistics, and applicability to clinical practice for an oncology patient population.

2. Apply statistical knowledge and skills to interpret the usefulness of clinical drug studies

3. Develop a formalized journal club review document that summarizes essential criteria of assigned oncology based clinical trial

4. Apply applicability of trial outcomes to clinical practice

Course Textbook(s) and/or Other Assigned Reading No required text

Reading from primary oncology literature will be assigned

Weekly Schedule of Topics See syllabus for contact hours and details

Prior to each class session, students will review primary literature and submit a trial assessment. Trials

will be reviewed during the class session. Topics include:

- Biosimilars and their role in cancer therapy
- Vaccines in cancer patients
- Non-small cell lung cancer
- Leukemias
- Multiple myeloma
- Lymphoma

Grading Scheme Online pre-ALS quizzes (5 at 4% each) - 20%

Mock Final Exam - 10%

Trial Assessments (10 at 3% each) - 30%

Participation in active learning sessions (10 at 1% each) - 10%

Team debate - 5%

Final Exam - 25%

Instructor(s) David DeRemer, Pharm.D. BCOP, FCCP, FHOPA

Brooke Adams, Pharm.D., BCOP

Kaitlyn Kowalski, Pharm.D.

Ashley Richards, Pharm.D., BCOP

Sarah Wheeler, Pharm.D., BCOP

Attendance & Make-up Yes

Accommodations Yes

UF Grading Policies for assigning Grade Points Yes

Course Evaluation Policy Yes

Class Attendance

Attendance and punctuality are expected of pharmacists in practice since they are essential elements in maintaining quality patient care and patient safety. The PharmD program has firm attendance policies in order to instill good habits that will be needed in practice. In addition, class participation is vital to developing the knowledge, skills, and attitudes essential for success as a pharmacist. Class attendance is mandatory for active learning sessions such as team-based learning sessions, case discussions, laboratory sessions, and other activities that the instructor designates as required attendance.

Excused/Non-excused Absences

Similar to employment expectations in pharmacy practice, unexcused absences and tardiness are not tolerated.

Attendance may be excused in the following situations: serious illness (3 or more consecutive class days requires a health care provider note/documentation), serious family emergencies, military obligation, severe weather conditions, religious holidays (Please see the [University policy on attendance and religious holidays](#)) and other reasons of that are of serious nature or unexpected. Absences from class for court-imposed legal obligations (e.g., jury duty or subpoena) **will be** excused. Absences due to an infectious illness in the contagious phase will be excused. Students should not come to class if they have a contagious illness.

Consideration for any excused absence will be given to unusual situations communicated to the Academic Coordinator **at least 30 days prior** to the event. Requests made less than 30 days from the event may not be considered.

The PharmD calendar allows for participation in professional development opportunities, including professional meetings. Students should consult the PharmD calendar before making travel plans for professional development opportunities to ensure travel falls within the dates allotted on the PharmD calendar. Absences outside of allotted travel days on the PharmD calendar for professional development opportunities will not be excused.

For excused absences, the grade book will show EX (excused) for the grade of a missed graded activity and the course grade will be calculated without consideration of these missing points unless a makeup is assigned. When the instructor assigns a makeup assignment, the EX grade will be replaced with the grade earned on the makeup assignment.

Both excused and unexcused absences are tracked across the curriculum. Students with three or more absences (excused and unexcused) during a semester or five or more absences during the academic

year may be referred to the Assistant Dean for Student Affairs. The student may be requested to provide a higher level of documentation.

Requests for Excused Absence

A request for an excused absence must be communicated via email **at least 30 minutes prior to the class session**, with the exception of unforeseen emergencies. It is recommended to communicate your absence as soon as you become aware you will not be able to attend class. Students should use the class-appropriate email address to request an excused absence.

- 1PD = absent1PD@cop.ufl.edu
- 2PD = absent2PD@cop.ufl.edu
- 3PD = absent3PD@cop.ufl.edu

If email is not possible, the student should call the Academic Coordinator (352-273-6523).

The email format below is recommended for submitting the request:

To: (insert absent email address for your class year)

Subject: PHA XXXX – Excused Absence request

I would like to request an excused absence from (insert course name, date, and time of sessions you will be missing here). Explain the nature of conflict and rationale for receiving an excused absence. Please be sure to be professional and polite. This is a request and should be phrased as such.

Thank you for your consideration of this special request.

Salutation,

Type in your full name and last 4 digits of UF-ID #, Campus Name, Team number

This email message will be received by the Academic Coordinator, distant campus and Education Coordinator. The Academic Coordinator will communicate the information to the appropriate faculty member. The Academic Coordinator will coordinate all communications about the absence request and therefore, serve as the point of contact about decisions on the request and other information. Students are encouraged to call the Academic Coordinator for assistance with excused absences.

Failing to follow this policy will render the absence unexcused. The expectation of prior notification will be exempted in situations where there was an emergency situation such as an accident or similar serious situation.

A request for an “excused absence” does not guarantee acceptance. No precedence can be drawn from any courses in the College of Pharmacy or any other college within University of Florida.

The student is responsible for follow up and confirming whether the absence is excused or unexcused.

Make Up Assignments

Make-up assignments will be provided for any excused absences when the instructor deems a make-up is indicated. Students shall be permitted a reasonable amount of time to make-up any excused absence(s). Due to the block curriculum model, **students must complete the make-up assignment by the deadline set by the course director**. The time period for this make up will be consistent with the UF attendance policies. If a student misses multiple class sessions and make-up by the end of the course becomes difficult, the student and Teaching Partnership Leader/Course Director will meet with the Assistant Dean of Student Affairs to develop options such as a makeup/remediation plan or withdrawal from the course.

Please refer to the [University Attendance Policy](#) for more details.

Tardiness

Punctuality is expected for all class and laboratory sessions and other educational events. A request for an excused tardy must be communicated via email **prior to the class session**, with the exception of unforeseen emergencies. It is recommended to communicate your tardy as soon as you become aware you will be late to class. Students should use the class-appropriate email address to request an excused tardy.

- 1PD = absent1PD@cop.ufl.edu
- 2PD = absent2PD@cop.ufl.edu
- 3PD = absent3PD@cop.ufl.edu

If email is not possible, the student should call the Academic Coordinator (352 273-6523).

The email format below is recommended for submitting the request:

To: (insert absent email address for your class year)

Subject: PHA XXXX – Excused Tardy request

I would like to request an excused tardy from (insert course name, date, and time of sessions you will be missing here). Explain the nature of conflict and rationale for receiving an excused tardy. Please be sure to be professional and polite. This is a request and should be phrased as such.

Thank you for your consideration of this special request.

Salutation,

Type in your full name and last 4 digits of UF-ID #, Campus Name, Team number

Failing to follow this policy will render the tardy unexcused. The expectation of prior notification will be exempted in situations where there was an emergency situation such as an accident or similar serious situation.

A request for an “excused tardy” does not guarantee acceptance. No precedence can be drawn from any courses in the College of Pharmacy or any other college within University of Florida.

The student is responsible for follow up and confirming whether the tardy is excused or unexcused.

Professionalism Assessments

Professionalism is an educational outcome of the PharmD program and therefore, is continually assessed. Professional behaviors and attitudes are evaluated using the [Professionalism Advisement Plan](#) to determine progression and eventual readiness for graduation.

Unexcused absences are considered unprofessional behavior. Other forms of unprofessional behavior include: lateness to class resulting in missing the start of the application exercises/discussions unless permitted by instructor, classroom behaviors that are distracting or disruptive to others (e.g., loud talking that is off topic, derogatory statements towards faculty or other individuals, off-topic jokes, cat calls, slamming items against furniture), reading emails/messages, use of social media, leaving class early without informing the faculty or staff member, leaving class to purchase or pick-up food or beverage, inappropriate discussion board or social media postings, or other disrespectful behaviors (e.g., culturally insensitive statements, jokes, discussing topics that make others feel uncomfortable) towards faculty, staff, preceptors, career coaches, or other students. Non-adherence to the dress code policy is also considered unprofessional behavior. Students who do not comply with the dress code will be asked to leave class. For more information, see the [Dress Code Policy](#).

Expectations for Behavior During Class and Other Learning Activities

Students are expected to:

- Be diligent and timely in studying the course material.
- Be on time for class sessions, quizzes, and exams. This includes being on time when returning to class after a break.
- Remain in class for the duration of the session (i.e., if food or beverage is needed, these should be prepared ahead of time or obtained on breaks)
- Complete assigned preparation activities.
- Complete work individually or as a team, as assigned by course faculty.
- Dress appropriately for class sessions and clinical activities.
- Silence cell phones and other electronic communication devices. Computers or other electronic devices should only be used for course-related activities and with faculty approval during class.
- Discuss special circumstances that will require use of electronic devices for personal communication during class (i.e., family emergencies, etc) with the class instructor, academic coordinator, or education coordinator at the start of class.
- Be attentive to anyone presenting or contributing to discussions.
- Participate in class or group discussions.
- Be focused and avoid distractive behaviors in class.
- Focus on the course learning activities; it is not respectful to study for other coursework during the class session.
- State your name, campus, and team number when making comments during a class session.
- Be respectful to the teacher.
- Be respectful to fellow students in discussions.
- Address concerns about performance or course material directly with the Teaching Partnership Leader/Course Director.
- Seek assistance with academic or personal difficulties as soon as possible.

Communications

Email Communications

The course faculty will communicate with you via your official University of Florida email address (_____@ufl.edu). When communicating with faculty via email, the subject line should include the course number and title. You should also include your full name, your academic year, campus/site, and team number in the email.

Faculty will do their best to respond to email communications within 24 hours between Monday and Friday at 12 noon. Responses on weekends and holidays will be sporadic.

Discussion Board

Students with questions about course content should post questions on the discussion board. The purpose of the discussion board is to provide a venue for you to enhance your learning. This is accomplished by having a thread for each module where you can post questions to the course faculty. Interaction with faculty on the discussion boards will allow you to clarify your questions and apply what you are learning in other parts of the course. The goal of these discussions is to help you learn.

Faculty will do their best to respond to discussion board postings within 24 hours of the posting between Monday and Friday at 12 noon. Responses on weekends and holidays cannot be assured.

Student Etiquette on the Discussion Board:

1. Post your comment on the correct discussion thread. If you have a question about Module 1, post it in the discussion thread for Module 1.
2. Be mindful of best practices of online communication (from [The Core Rules of Netiquette by Virginia Shea](#)):
 - a) Remember the Human: compose a post that you would feel comfortable saying in front of the person receiving the message. Be aware of how the reader may interpret the tone of the post and edit when necessary. If you are unsure of the perceived tone of a post, have a trusted friend/family member edit it prior to posting.
 - b) Adhere to the same standards of behavior online that you follow in real life: be ethical.
3. The discussion board has been designed to allow you a place to ask further questions on the material to clarify any confusion, gain a deeper understanding of the material, or ask general course questions.

Academic Integrity Policy

Students are expected to act in accordance with the University of Florida policy on [academic integrity and the UF Student Honor Code](#). Below is the UF Honor Pledge outlined in the UF Honor Code:

We, the members of the University of Florida community, pledge to hold ourselves and our peers to the highest standards of honesty 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."

This Honor Code specifies a number of behaviors that are in violation of this code and the possible sanctions. Furthermore, you are obliged to report any condition that facilitates academic misconduct to appropriate personnel. If you have any questions or concerns, please consult the course's Teaching Partnership Leader/Course Director.

Assignments given in courses in the curriculum may be either individual or team assignments. Faculty will provide descriptions of expectations for each assignment when it is assigned. For assignments categorized as *individual* assignments, it is expected that all work submitted is the original work of the individual student. Collaboration with others is not permitted. For assignments categorized as *team/group* assignments, it is expected that all work submitted is the original work of the team/group members submitting the assignment. Collaboration with others who are not members of the team/group is not permitted. Deviations from these expectations are a violation of the UF Honor Code and will be taken seriously.

Faculty Lectures/Presentations/Course Materials Download Policy

Photography, audio-visual recording, and transmission/distribution of classroom lectures, course materials, and discussions is prohibited unless there is expressed written permission.

Recorded lectures and class sessions are authorized solely for the purpose of individual or group study with other UF College of Pharmacy students enrolled in the same class. Such recordings may not be reproduced, shared, or uploaded to publicly accessible web environments. Students who do not adhere to this policy will be considered to be breaching College of Pharmacy copyrights and/or Family Educational Rights and Privacy Act (FERPA) law.

Computer and Other Technology Requirements (Device Readiness)

Students are required to have a personal laptop compliant with the [entry-level program computer requirements](#). Students are required to use this personal laptop for all quizzes, exams and other classroom learning activities that are electronically administered.

ExamSoft® is used for administration of exams and students are required to follow the procedures that are established for exam administration. Students must bring a personal laptop to class to complete exams. Students must also complete mock exams prior to the actual exam to assure that all personal laptop features are supported by ExamSoft®.

If a student's personal laptop is not functioning and the student needs to take a quiz or exam, the student will be provided a paper-based format up to two (2) times during a semester. Any additional administrations of a paper-based quiz/exam must be approved by Assistant Dean for Curricular Affairs.

If a student's personal laptop is not functioning, the student is expected to have the personal laptop fixed immediately. If the student experiences a problem with a personal laptop available due to a repair, the student should immediately contact the academic/educator coordinator and develop a plan for securing a functioning laptop and achieving compliance with the entry-level program computer requirements.

Quiz & iRAT/tRAT Policies

1. Students must bring their laptop or tablet to class in order to participate in the quiz/iRAT/tRAT.
2. All quizzes/iRATs/tRATs are closed book unless otherwise noted by the instructor.
3. Students who arrive late for the quiz/iRAT will not be allowed extra time to complete the assessment. They must complete the quiz/iRAT in the time remaining.
4. When a student completes a quiz/readiness-assessment test (RAT), they must close their laptop or turn over their tablet to indicate they are finished with the assessment. These devices should not be used until the instructor has announced that the quiz/RATs have ended.
5. Students who miss the iRAT may take the tRAT if they are in class at the start of the tRAT. (The Academic or Education Coordinator will assess the time of arrival and indicate to students who enter the classroom late whether they can join their team and participate in the tRAT.)
6. Students may not leave the room during the iRAT and tRAT.
7. All students must remain quiet during the iRATs and as other teams are completing the tRATs.
8. For tRATs delivered using immediate feedback assessment technique (IF-AT) forms, "accidental" scratches will result in partial scoring for that item.
9. For tRATs, a team may appeal the answer to a question to the instructor after the active learning session within 24 hrs. The appeal must be evidence-based and in writing. Such an appeal process is not applicable to quizzes, iRATs, and exams.
10. Video surveillance/recording via technologies may be used during quizzes and iRATs/tRATs and may be used as evidence of academic dishonesty.

Exam Policies

During any Exam:

1. Students must wait outside the testing room until the proctor enters

2. Access to the following items is not permitted during the exam: cell phones, other electronic or digital devices including smart watches, pagers, photographic devices, and recording devices. These items must be stowed in an area away from the designated testing space.
3. All backpacks, 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 (e.g., gloves, sunglasses, umbrellas) 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. Items allowed at the student's desk are a see-through water bottle with no label or writing, laptop charger, and laptop mouse.
4. 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 15 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. In situations where a make-up exam is granted due to lateness, the exam grade will be no higher than 69.5% (C-).
5. There must be no talking or other disruptive behavior during the distribution or taking of the exam.
6. Calculators must meet the following requirements: Only non-programmable calculators are allowed unless the course has a specific policy.
7. If you encounter calculator problems (e.g., dead battery), contact the Proctor.
8. Other exam rules may be instituted during the progression of the course.
9. 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.
10. Video surveillance/recording via technologies may be used during exams and may be used as evidence of academic dishonesty.
11. If there is urgent need to use the restroom, the Proctor will provide guidance.

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

After an Exam

Policy across All 1PD-3PD courses where ExamSoft is used:

Students are required to upload the encrypted exam file immediately after completing the exam.

Technical issues that prevent this from occurring must be immediately reported to a proctor to record the incident.

Exam appeals

There are no exam appeals/rebuttals except in instances where the student deems there is a possible grading/grade calculation error. Following release of the exam grades, the student has 3 business days to contact the Teaching Partner and Academic Coordinator to clarify questions and appeal any possible grading errors.

Make-up Quiz/iRAT/Exam Policy

Make-up assessments are given only under special circumstances and only for excused absences. The method to request an excused absence for an assessment is the same as the method for requesting an excused absence from a class session (See Course Policy: Excused/Non-excused Absences). If appropriate, the instructor will arrange an alternate deadline for the assessment consistent with the University examination policies.

The questions on the make-up assessment may be in the form of essay, short answer, or multiple-choice and will be the same level of difficulty as the assessment administered during the scheduled time. Failure to be present for the make-up assessment will result in a grade of zero for the assessment. No precedence can be drawn from any courses in the College of Pharmacy or any other college within University of Florida.

Grading Scale

<i>Grading Scale</i>	
92.50-100%	A
89.50-92.49%	A-
86.50-89.49%	B+
82.50-86.49%	B
79.50-82.49%	B-
76.50-79.49%	C+
72.50-76.49%	C
69.50-72.49%	C-
66.50-69.49%	D+
62.50-66.49%	D
59.50-62.49%	D-
< 59.50%	E

Rounding of Grades

Final grades in Canvas will be rounded to the 2nd decimal place. If the decimal is X.495 or higher, Canvas will round the grade to X.50. The above scale depicts this policy and grades are determined accordingly. Grade assignment is made using this policy and **no exceptions** will be made in situations where a student's grade is "close."

University Grading Policies

Please review the [UF Undergraduate Catalog](#) to understand how the University uses the course grade to compute your overall GPA.

Faculty and Course Evaluations

Students are expected to provide professional and respectful feedback on the quality of instruction in every course by completing course evaluations online via GatorEvals. Guidance on how to give feedback in a professional and respectful manner is available at <https://gatorevals.aa.ufl.edu/students/>. Students will be notified when the evaluation period opens, and can complete evaluations through the email they receive from GatorEvals, in their Canvas course menu under GatorEvals, or via <https://ufl.bluera.com/ufl/>. The PharmD calendar contains scheduled time for students to complete evaluations, and students are encouraged to use this time to provide thoughtful feedback on the quality of instruction. Summaries of course evaluation results are available to students at <https://gatorevals.aa.ufl.edu/public-results/>.

Concerns, Appeals, and Complaints

Students who have concerns about their evaluation of performance and/or student-faculty relations should review the Student-Faculty Handbook for guidance. The Student-Faculty Handbook also outlines the chain of command for any appeals and/or complaints. Concerns about a course (e.g., course requirements, quizzes, exams) should first be discussed with the appropriate course instructor and the Teaching Partnership Leader/Course Director. If a satisfactory resolution is not achieved, the student may appeal to the Assistant Dean for Curricular Affairs who will also engage other individuals depending on the request (e.g., campus dean, department chair, Assistant Dean for Student Affairs). If the student finds the decision unsatisfactory, the student may appeal to the Associate Dean for Professional Education. If this decision is unsatisfactory, the student may appeal to the Dean of Students Office.

Psychomotor and Learning Expectations

Psychomotor expectations relate to the ability to meet the physical demands of the pharmacy curriculum. Physically impaired students and students with learning disabilities such as hearing impairment, visual impairment, dyslexia or other specific learning disabilities such as sensory deficit or sensory-motor

coordination problems should cooperate with the faculty and staff in addressing these circumstances in order to meet academic standards.

How to Request Learning Accommodations

To request accommodations, students with disabilities should first register with the [Disability Resource Center](#) (352-392-8565) by providing appropriate documentation. Once registered with the Disability Resource Center, students will receive an accommodation letter which must be presented to both the instructor and academic coordinator to utilize classroom accommodations. Students registered with the Disability Resource Center who are requesting clinical accommodations for rotations or clinical experiences should contact their Learning Specialist in the Disability Resource Center. Students with disabilities should follow this procedure as early as possible in the semester.

Additionally, students at all College of Pharmacy campuses are expected to provide a copy of the accommodation letter of the Office of Student Affairs by email (accommodations@cop.ufl.edu), phone (352-273-6523) or in person at room 4312 in the Health Professions, Nursing and Pharmacy Building since some learning activities, exams, and assessments require additional assistance. The College of Pharmacy highly encourages that this procedure be completed before each course begins. Being proactive in this process will ensure that accommodations are in place for each student's learning activities, exams, and assessments because grades cannot be retroactively changed.

How to Access Services for Student Success

Students who need guidance for course success or who are having academic difficulty should contact the Teaching Partnership Leader/Course Director. In addition, students are encouraged to contact their advisor or Campus Director/Assistant Dean for Student Affairs for assistance.

Counseling and Wellness Center

Students who are experiencing issues and events that could adversely affect academic performance and personal health are encouraged to meet with the student affairs coordinators on their respective campuses or Assistant Dean for Student Affairs for guidance. In a crisis situation, 911 should be called. For non-crisis situations, students can self-refer to the UF Counseling and Wellness Center or to the Pharmacy Counselor. To access services, students should contact the [UF Counseling and Wellness Center](#) at 352-392-1575. This line is answered 24 hours a day. Students in Gainesville have the option to identify as pharmacy students to be put in contact with the Pharmacy Counselor. If a Gainesville student does not identify as a pharmacy student, they will be placed with any available counselor at the Wellness Center. Jacksonville and Orlando students must identify as pharmacy students to access services with the College of Pharmacy Counselor.

Student Crisis

Your well-being is important to the University of Florida. The U Matter, We Care initiative is committed to creating a culture of care on our campus by encouraging members of our community to look out for one another and to reach out for help if a member of our community is in need. If you or a friend is in distress, please contact umatter@ufl.edu so that the U Matter, We Care Team can reach out to the student in distress. A nighttime and weekend crisis counselor is available by phone at 352-392-1575. The U Matter, We Care Team can help connect students to the many other helping resources available including, but not limited to, Victim Advocates, Housing staff, and the Counseling and Wellness Center. Please remember that asking for help is a sign of strength. In case of emergency, call 9-1-1.

Students who are experiencing issues and events are also encouraged to contact their local crisis center. For Alachua County the Crisis Center number is 352-264-6789; for Jacksonville and Duval County 904-632-0600 and toll free for Northeast Florida at 1-800-346-6185; and for Orlando 407-425-2624.

The following national call numbers are also available for students who reside outside of the main COP campuses: a) 1-800-273-8255, and b) 1-800-784-2433.

Emergencies

Call the University Police Department (Gainesville campus only) for emergencies: 392-1111 or 9-1-1

Version Date: August 12, 2019

PHAXXXX Oncology Clinical Trial Evaluation

Spring 2020

2 Semester Credit Hours Block 18 A-E Grading

This course is designed to allow student pharmacists with a strong interest in oncology to further develop the skills necessary to make optimal decisions regarding treatment and supportive care pharmacotherapy in patients with cancer. Students will be required to read and evaluate primary oncology literature including study design, methodology, biostatistical analysis, and applicability to clinical practice. Student pharmacists will supplement their current knowledge of oncology and supportive care through an in-depth discussion of clinical trials and debates related to controversies in clinical practice.

Teaching Partnership Leader

David DeRemer, Pharm.D., BCOP, FCCP, FHOPA

- Email: dderemer@ufl.edu
- Office: HPNP 3308/GNV
- Phone: 352-294-8891
- Office Hours: By appointment ONLY.

See Appendix A. for Course Directory of Faculty and Staff Contact Information.

Entrustable Professional Activities

3. Establish patient-centered goals and create a care plan for a patient in collaboration with the patient, caregiver(s), and other health professionals that is evidence based and cost-effective.

5.2 Evaluate the selected monitoring parameters to determine the therapeutic and adverse effects related to the treatment plan

9. Maximize the appropriate use of medications in a population.

11.1 Lead a discussion regarding a recently published research manuscript and its application to patient care.

12.1 Retrieve and analyze scientific literature to make a patient-specific recommendation.

12.2 Retrieve and analyze scientific literature to answer a drug information question.

Course-Level Objectives

Upon completion of this course, the student will:

1. Evaluate scientific manuscripts including study design, methodology, biostatistics, and applicability to clinical practice for an oncology patient population.
2. Apply statistical knowledge and skills to interpret the usefulness of clinical drug studies
3. Develop a formalized journal club review document that summarizes essential criteria of assigned oncology based clinical trial
4. Apply applicability of trial outcomes to clinical practice

Course Pre-requisites

Successful completion of Blocks 1-15 of the Doctor of Pharmacy curriculum including milestones

Course Co-requisites

None required

Course Outline

Please routinely check your campus calendar and the Canvas course site for any messages about changes in the schedule including meeting dates/times, deadlines, and room changes

<i>Date</i>	<i>Mod #</i>	<i>Activity</i>	<i>Contact hours</i>	<i>Learning Objectives Covered</i>	<i>Faculty Module Leader</i>
4/20/2020 Times TBD	1	Module 1: Biosimilars and Their Role in Cancer Therapy			DeRemer
	1.1	WATCH: Biosimilars in Oncology Practice	1 hr		DeRemer
		READ: A Comparison of Proposed Biosimilar LA-EP2006 and Reference Pegfilgrastim for the Prevention of Neutropenia in Patients With Early-Stage Breast Cancer Receiving Myelosuppressive Adjuvant or Neoadjuvant Chemotherapy: Pegfilgrastim Randomized Oncology (Supportive Care) Trial to Evaluate Comparative Treatment (PROTECT-2), a Phase III, Randomized, Double-Blind Trial. <i>Oncologist</i> 2016 Jul;21(7):789-94	0.5 hr		
	1.2	PREPARE: Trial #1 Assessment	0.5 hr		
	1.3	Active Learning Session 1:	1 hr		

		- Team Primary Literature Presentation			
4/21/2020	2	Module 2: Vaccine Recommendations in the Cancer Population			DeRemer
	2.1	WATCH: Overview of Vaccines in Cancer Populations	1 hr		DeRemer
	2.2	READ: Impact of the influenza vaccination on cancer patients undergoing therapy with immune checkpoint inhibitors (ICI). Journal of Clinical Oncology 2018 36:15_suppl, 3053-3053	0.5 hr		
	2.3	PREPARE: Trial #2 Assessment	0.5 hr		
	2.4	Active Learning Session 2: - Team Primary Literature Presentation	1 hr		
4/22/2020	3	Module: Emergence of Immunotherapy in the Treatment of Non-Small Cell Lung Cancer			DeRemer
	3.1	WATCH: Current Landscape of Immunotherapy in Lung Cancer	1 hr		DeRemer
	3.2	READ: Pembrolizumab versus docetaxel for previously treated, PD-L1-positive, advanced non-small-cell lung cancer (KEYNOTE-010): A randomised controlled trial. <i>Lancet</i> 2016;387(10027):1540–1550.	0.5 hr		
	3.3	PREPARE: Trial #3 Assessment	0.5 hr		
	3.4	Active Learning Session 3: - Team Primary Literature Presentation	1 hr		
4/23/2020	4	Module: Small Molecule Inhibitors to Treat Leukemias – CML			DeRemer
	4.1	WATCH: Inhibiting BCR-ABL	1hr		DeRemer
	4.2	READ: <u>Groups A-C</u> – IRIS Study – Imatinib compared with interferon and low dose cytarabine for newly diagnosed chronic phase CML. <i>N Eng J Med</i> 2003; 348:994-1004; <u>Groups D-F</u> – DASISION Study – Dasatinib versus imatinib in newly diagnosed chronic phase CML. <i>N Eng J Med</i> 2010; 2260-2270. <u>Groups</u>	0.5 hr		

		G-I – ENESTnd – Nilotinib versus imatinib for newly diagnosed CML. N Eng J Med 2010; 2251-2259			
	4.3	PREPARE: Trial #4 Assessment	0.5 hr		
	4.4	Active Learning Session 4: - TEAM DEBATE: Which front-line BCR-ABL inhibitor is the best in front line therapy?	1 hr		
4/24/2020	5	Module: AML			Adams/DeRemer
	5.1	WATCH: Acute Myeloid Leukemia - Integration of Novel Therapies into Clinical Practice	1 hr		Adams
	5.2	READ: CPX-351 (cytarabine and daunorubicin) Liposome for Injection Versus Conventional Cytarabine Plus Daunorubicin in Older Patients With Newly Diagnosed Secondary Acute Myeloid Leukemia. J Clin Oncol. 2018 Sept 10;36(26):2684-92	0.5 hr		
	5.3	PREPARE: Trial # 5 Assessment	0.5 hr		
	5.4	Active Learning Session 5: - Team Primary Literature Presentation - Online Mock Final Exam	1 hr		
4/27/2020	6	Module: Pediatric ALL			Kowalski/DeRemer
	6.1	WATCH: Pediatric Adult Lymphoblastic Leukemia – Promise and Challenges	1 hr		Kowalski
	6.2	READ: Intravenous pegylated asparaginase versus intramuscular native Escherichia coli L-asparaginase in newly diagnosed childhood acute lymphoblastic leukaemia (DFCI 05-001): a randomised, open-label phase 3 trial. Lancet Oncol 2015;16:1677-90	0.5 hr		
	6.3	PREPARE: Trial #6 Assessment	0.5 hr		
	6.4	Active Learning Session 6: - Team Primary Literature Presentation	1 hr		
4/28/2020	7	Module: CLL			DeRemer
	7.1	WATCH: Ibrutinib – Changing the Landscape of the Treatment of CLL	1 hr		DeRemer
	7.2	READ: Ibrutinib as initial therapy for patients with chronic lymphocytic	0.5 hr		

		leukemia. N Eng J Med 2015 Dec 17;373(25):2425-37			
	7.3	PREPARE: Trial #7 Assessment	0.5 hr		
	7.4	Active Learning Session 7: - Team Primary Literature Presentation	1 hr		
4/29/2020	8	Module: MM			Richards/DeRemer
	8.1	WATCH: Multiple myeloma	1 hr		Richards
	8.2	READ: Daratumumab, lenalidomide, and dexamethasone for multiple myeloma. N Engl J Med 2016; 375(14):1319-1331	0.5 hr		
	8.3	PREPARE: Trial #8 Assessment	0.5 hr		
	8.4	Active Learning Session 8: - Team Primary Literature Presentation	1 hr		
4/30/2020	9	Module: Lymphoma			Wheeler/DeRemer
	9.1	WATCH: Lymphomas	1 hr		Wheeler
	9.2	READ: Dose-Adjusted EPOCH-R Compared With R-CHOP as Frontline Therapy for Diffuse Large B-Cell Lymphoma: Clinical Outcomes of the Phase III Intergroup Trial Alliance/CALGB 50303. J Clin 2019 (epub ahead of print)	0.5 hr		
	9.3	PREPARE: Trial #9 Assessment	0.5 hr		
	9.4	Active Learning Session 9: - Team Primary Literature Presentation	1 hr		
5/1/2020	10	Module: CART			Wheeler /DeRemer
	10.1	WATCH: The Emergence of Chimeric Antigen Receptor T-Cell Therapy (CART) in the Treatment of Hematologic Malignancies	1 hr		Wheeler
	10.2	READ: Axicabtagene Ciloleucel CAR T-Cell Therapy in Refractory Large B-Cell Lymphoma. N Engl J Med 2017 Dec 28;377(26):2531-2544	0.5 hr		
	10.3	PREPARE: Trial #10 Assessment	0.5 hr		
	10.4	Active Learning Session 10: - Team Primary Literature Presentation	1 hr		

Required Textbooks/Readings

- There are no required textbooks for this course.
- Required readings will be posted on Canvas.

Other Required Learning Resources

None

Materials & Supplies Fees

None

Student Evaluation & Grading

Assessment Item	Grade Percentage
Online pre-ALS quizzes (5 at 4% each)	20%
Mock Online Final Exam	10%
Trial Assessments (10 at 3% each) (group submission) (Appendix B)	30%
Participation in active learning sessions (10 at 1% each) (See Appendix C)	10%
Team debate (See Appendix D)	5%
Final Exam	25%
Total	100%

Rounding of grades:

Final grades in Canvas will be rounded to the 2nd decimal place. If the decimal is X.495 or higher, Canvas will round the grade to X.50. The above scale depicts this policy and grades are determined accordingly. Grade assignment is made using this policy and NO EXCEPTIONS will be made in situations where a student's grade is "close."

Educational Technology Use

The following technology below will be used during the course and the student must have the appropriate technology and software.

1. ExamSoft™ Testing Platform
2. Canvas™ Learning Management System

For technical support, navigate to [Educational Technology and IT Support Contact Information](#) at this URL:

<http://curriculum.pharmacy.ufl.edu/current-students/technical-help/>

Percentage Range	Letter Grade
92.50-100%	A
89.50-92.49%	A-
86.50-89.49%	B+
82.50-86.49%	B
79.50-82.49%	B-
76.50-79.49%	C+
72.50-76.49%	C
69.50-72.49%	C-
66.50-69.49%	D+
62.50-66.49%	D
59.50-62.49%	D-
< 59.50%	E

Pharm.D. Course Policies

The Policies in the following link apply to this course. Review the [Pharm.D. Course Policies](#) carefully, at this URL: <http://curriculum.pharmacy.ufl.edu/current-students/course-policies/>

Appendix A. Course Directory

Teaching Partnership Leader/Course Director:

David DeRemer, Pharm.D. BCOP, FCCP, FHOPA

- Email: dderemer@ufl.edu
- Office: HPNP 3308/GNV
- Phone: 352-294-8891
- Office Hours: By appointment ONLY

Questions to Ask:

- Concerns about performance
- Guidance when there are performance problems (failing grades)
- General questions about content

Academic Coordinator:

Misti Merrill

Email: mmerrill@cop.ufl.edu

Office: HPNP 4312

Phone: 352-294-8677

Absence/Tardy Email: absent2PD@cop.ufl.edu or absent3PD@cop.ufl.edu

Educational Coordinators:

McKenzie Wallen

Email: mwallen@cop.ufl.edu

Office: Jacksonville Campus

Iverta Allen

Email: iallen1@cop.ufl.edu

Office: Orlando Campus

Questions to Ask:

- Issues related to course policies (absences, make up exams, missed attendance)
- Absence/tardy requests (Only the Academic Coordinator handles absence requests)
- Questions about dates, deadlines, meeting place
- Availability of handouts and other course materials
- Assignment directions
- Questions about grade entries in gradebook (missing grades, incorrect grade)
- Assistance with ExamSoft® (Distance campus students may contact the Educational Coordinator for use of Examplify and assistance during exams. The Academic Coordinator is the contact person for issues related to grading and posting of ExamSoft grades.)

Other Teaching Partnership Faculty Members:

Course Faculty and Office Hours

Teaching Partnership Leader:

Brooke Adams, Pharm.D., BCOP

Phone: 352-XXX-XXXX

Clinical Specialist – Blood and Marrow Transplantation

Email: caada0002@shands.ufl.edu

Kaitlyn Kowalski, PharmD,

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Ashley Richards, Pharm.D., BCOP

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Clinical Specialist – Blood and Marrow Transplantation

Email: ricash@shands.ufl.edu

Sarah Wheeler, Pharm.D., BCOP

Phone: 352-XXX-XXXX

Clinical Specialist – Blood and Marrow Transplantation

Email: whees@shands.ufl.edu

Appendix B. Trial Assessment Rubric

Group Name:				
Article Title:				
5 Accomplished	4 Developing	3 Acceptable, but Needs Development	2 Needs Significant Development	1 Unacceptable
ALL parts appropriately critiqued, accurately and completely reported, summarized well	MOST parts appropriately critiqued, some relevant information was not provided	SOME parts appropriately critiqued, several key components of discussion were omitted	Did not accurately and/or completely report relevant trial components	Failed to appropriately critique, inaccurate information and conclusions presented
Outcome				
Outcome		Points	Comment	
Relevance: <ul style="list-style-type: none"> • Provides sufficient background information • Identifies trial purpose/importance • Identifies study question/objective(s) 		1 2 3 4 5		
Methodology: <ul style="list-style-type: none"> • Appropriately explains: <ul style="list-style-type: none"> ○ Study design ○ Selection bias? ○ Exclusion/inclusion criteria ○ Endpoints ○ Study groups ○ Baseline characteristics 		1 2 3 4 5		
Complete Explanation of Discussion & Analysis: <ul style="list-style-type: none"> • Appropriately explains: <ul style="list-style-type: none"> ○ Data and Statistical Analysis ○ Results ○ Discussion ○ Conclusions 		1 2 3 4 5		
Clinical Trial Evaluation & Practice Application <ul style="list-style-type: none"> • Critique of: <ul style="list-style-type: none"> ○ Strengths & Limitations ○ Statistics • Addressed author's conclusion, but formulates own conclusion as well • Explains impact and/ or application to current clinical practice • Future studies needed? 		1 2 3 4 5		
Written Presentation <ul style="list-style-type: none"> • Organization and Preparedness <ul style="list-style-type: none"> ○ Handout: accurate, concise, organized, grammatically correct ○ Information delivered logically 		1 2 3 4 5		

Total Score = ____ Conversion to a percentage grade:

Appendix C: Rubric for Assessing Student Participation in Class

This document will be used to provide an assessment of the student's overall participation at the end of the course. Instructors will keep track of student participation during each session.

	Exemplary (Score = 5)	Proficient (Score = 4)	Developing (Score = 3)	Unacceptable (Score = 0)
Frequency of participation in class	Student initiates contributions more than once in each recitation.	Student initiates contribution once in each recitation.	Student initiates contribution at least in half of the recitations	Student does not initiate contribution and needs instructor to solicit input.
Quality of comments	Comments always insightful and constructive; uses appropriate terminology. Comments balanced between general impressions, opinions and specific, thoughtful criticisms or contributions.	Comments mostly insightful and constructive; mostly uses appropriate terminology. Occasionally comments are too general or not relevant to the discussion.	Comments are sometimes constructive, with occasional signs of insight. Student does not use appropriate terminology; comments not always relevant to the discussion.	Comments are uninformative, lacking in appropriate terminology. Heavy reliance on opinion and personal taste, e.g., "I love it", "I hate it", "It's bad" etc.
Listening Skills	Student listens attentively when others present materials, perspectives, as indicated by comments that build on others' remarks, i.e., student hears what others say and contributes to the dialogue.	Student is mostly attentive when others present ideas, materials, as indicated by comments that reflect and build on others' remarks. Occasionally needs encouragement or reminder from T.A of focus of comment.	Student is often inattentive and needs reminder of focus of class. Occasionally makes disruptive comments while others are speaking.	Does not listen to others; regularly talks while others speak or does not pay attention while others speak; detracts from discussion; sleeps, etc.

Total Score = ____ Conversion to a percentage grade:

15 = 100%, 14 = 93.3%, 13 = 86.6%, 12 = 80%, 11 = 73.3%, 10 = 66%, 9 = 60%, 8 = 53.3%, 7 = 46.6%, 6 = 40%, 5 = 33.3% , 4 = 26%, 3 = 15%

Appendix D: Rubric for Classroom Debate

Criteria	4 points	3 points	2 points	1 points	Total Points
Respect for other team	All statements and body language were respectful to others	Most statements and body language were respectful to others, some sarcasm	Borderline inappropriate statements or responses, some sarcasm	Statements and responses were not respectful of others	
Information	Clear, accurate, and thorough information	Most information was clear and accurate.	Some information was accurate, but there were some minor inaccuracies	Information had some major inaccuracies	
Rebuttal	Counter-arguments are strong , relevant	Most counter-arguments were accurate and relevant, but several were weak	Some counter arguments were weak and irrelevant	Counter-arguments were not accurate and/or relevant	
Factual	Major points supported with relevant facts	Most points were supported by facts, relevance on some questionable	Some points were supported well, others were not	Points not supported by facts	
Delivery	Communicated clearly and confidently, maintained eye contact, excellent voice inflection and delivery	Communicated clearly, frequent eye contact, good voice	Lacked self-confidence, poor eye contact	Failed to communicate clearly, no eye contact	
Understanding of Topic	Team understood topic in depth and presented info very well	Team seemed to understand the main points of the topic and presented well	Team understood main points but didn't present topic	Team lacked understanding of topic	
Total Points= __/24 (conversion to a percentage grade)					
Commentary:					

