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# PHA5223 Pharmacoepidemiology and Drug Safety

Fall 2019

2 Credit Hours – A-E Grading

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*The goal of this course is to familiarize students with the concepts and tools of pharmacoepidemiology and drug safety. Students will develop a base understanding of the evaluation of study designs and drug safety programs, how these fields influence regulation and policy of medications and other treatments, and how to use this information to make evidence-based decisions to achieve positive care outcomes for individual patients or within patient populations.*

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## Teaching Partnership Leader

Joshua Brown, Pharm.D., Ph.D.

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Yu-Jung “Jenny” Wei, M.S., Ph.D.

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- Phone: 352-294-5340
- Office Hours: By appointment ONLY.

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

## Entrustable Professional Activities

This course will prepare you to perform the following activities which the public entrusts a Pharmacist to perform:

1. EPA A3. Formulate evidence-based care plans in collaboration with an interprofessional team. Utilize clinical guidelines in the development of a pharmacotherapy plan.
2. EPA C2. Recommend solutions to needs in the medication use system and the healthcare system.

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## Course-Level Objectives

Upon completion of this course, the student will be able to:

1. Identify and distinguish the basics of pharmacoepidemiological study designs, including cohort study and case-control study.
2. Apply the knowledge of study design to evaluation of drug safety in pharmacoepidemiological studies.
3. Analyze the effect bias and confounding may have on the results of a study and understand ways to minimize these threats to validity.
4. Describe comparative effectiveness research (CER) on treatment options and common pitfalls of CER studies.
5. Describe how the pharmacoepidemiological studies and drug safety programs are used to guide federal regulations and other policies for medications and other therapies.
6. Make evidence-based decisions through critical appraisal of the literature to achieve positive care outcomes for individual patients or patient populations.

## Course Pre-requisites

1. Completion of all Year 2 Pharm.D. program coursework including milestones.

## Course Co-requisites

1. PHA5165L Professional Practice Skills Lab VI

## 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.

<b>DATE</b> <i>Recommended Dates for Independent Study</i>	<b>Delivery Date</b>	<b>Mod #</b>	<b>Unit Topic</b>	<b>Contact Hours [hr.]a</b>	<b>Faculty Author</b>	<b>Learning Objectives Covered</b>
		1	Module 1: Pharmacoepidemiology Study Design	5.0hr	Wei	1, 2
9/09/19		1.1	Watch: What is Pharmacoepidemiology Study?	0.5hr	Wei	
9/10//19		1.2	Watch: Review of Major Methodology and Terminology	0.5hr	Wei	
9/11/19		1.3	Watch: Cohort Studies	1.0hr	Wei	
9/12/19		1.4	Watch: Case-Control Studies	1.5hr	Wei	

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9/13/19			Read: Article 1 (Canvas)	1.5hr		
	09/16/19 10:40am - 12:35pm	1	Active Learning Session 1: Cohort vs. Case Control	2.0hr	Brown, Wei	1, 2
		2	Module 2: Bias	2.0hr	Wei	2, 3
9/17/19		2.1	Watch: Overview of Bias	0.25hr	Wei	
9/18/19		2.2	Watch: Selection Bias	0.5hr	Wei	
9/19/19		2.3	Watch: Information Bias	0.5hr	Wei	
9/20/19		2.4	Watch: Measurement Error	0.25hr	Wei	
9/20/19		2.5	Watch: Misclassification	0.5hr	Wei	
	Due: 9/23/19 @11:59pm		Assignment: Study Critique Practice – Bias			
		3	Module 3: Confounding	2.0hr	Wei	2, 3
9/23/19		3.1	Watch: Review of Confounding	0.5hr	Wei	
9/23/19		3.2	Watch: Confounding in Pharmacoepidemiology	1.0 hr	Wei	
9/24/19		3.3	Watch: Approaches for Handling Confounding	0.5hr	Wei	
	Due: 9/24/19 @11:59pm		Assignment: Study Critique Practice – Confounding			
	09/25/19 8:30am – 10:25am	2-3	Active Learning Session 2: Bias and Confounding	2.0hr	Wei	2, 3, 5
		4	Module 4: Outcomes Measurement	3.5hr	Brown	2, 3, 5
9/26/19		4.1	Watch: Surrogate vs. Clinical Outcomes	1.0hr	Brown	
9/27/19		4.2	Watch: Composite Outcomes	0.5hr	Brown	
9/30/19		4.3	Watch: Patient-Reported Outcomes (PROs)	0.5hr	Brown	
10/1/19			Read: eBook Chapter 6 – Outcome Definition and Measurement (Canvas)	1.25hr		

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<b>Date</b> <i>Recommended Dates for Independent Study</i>	<b>Delivery Date</b>	<b>Mod #</b>	<b>Unit Topic</b>	<b>Contact Hours [hr.]a</b>	<b>Faculty Author</b>	<b>Learning Objectives Covered</b>
	Due: 10/01/19 @ 11:59pm		Assignment: Review journal article <i>HRT and Atrial Fibrillation (on Canvas)</i> to prepare for Active Learning Session #2			
	Due: 10/01/19 @ 11:59pm		Assignment: Review the <b>results section only</b> of article <i>Evolocumab Clinical Outcomes in Patients with Cardiovascular Disease (on Canvas)</i> to prepare for Active Learning Session #2			
	10/02/19 8:30am – 10:25am	4	Active Learning Session 3: Evaluating outcome measures in clinical research	2.0hr	Brown	1-6
		5	Module 5: Comparative Effectiveness Research (CER)	5.5hr	Brown	1, 5
10/03/19		5.1	Watch: What is CER?	0.25hr	Brown	
10/03/19			Read: eBook Chapter 1 – Study Objectives and Questions (Canvas)	1.0hr		
10/04/19		5.2	Watch: Study Design of CER	0.5hr	Brown	
10/04/19			Read: eBook Chapter 2 – Study Design Considerations (pp. 28-31) (Canvas)	0.25hr		
10/07/19		5.3	Watch: Bias and Confounding in CER Studies	0.5hr	Brown	
10/07/19			Read: eBook Chapter 3 – Estimation and Reporting of Heterogeneity of Treatment Effects (Canvas)	0.75hr		
10/08/19			Read: eBook Chapter 4 – Exposure Definition and Measurement (Canvas)	0.75hr		
10/08/19			Read: eBook Chapter 11 – Sensitivity Analysis (pp. 146-150) (Canvas)	0.25hr		
10/09/19		5.4	Watch: Pragmatic Clinical Trials	0.5hr	Brown	

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10/09/19		5.5	Watch: Real-World Applications of CER	0.5hr	Brown	
		6	Module 6: Databases, toolbox, and careers	2.0hr	Brown	1, 2
10/10/19		6.1	Watch: Administrative and Clinical Databases for Drug Safety Research	0.5hr	Brown	
10/10/19			Read: eBook Chapter 8 – Selection of Data Sources (pp. 109-116) (Canvas)	0.5hr		
10/11/19		6.2	Watch: Programs and Resources for Drug Safety Research	0.5hr	Brown	
10/11/19		6.3	Watch: Pharmacist Careers in Drug Safety	0.5hr	Brown	
		7	Module 7: FDA Drug Policy and Role of Pharmacoepidemiology	2.0hr	Winterstein	1-6
10/14/19		7.1	Watch: The U.S. Drug Safety Regulatory Framework and Phase 4 Safety Commitments	0.5hr	Winterstein	
10/14/19		7.2	Watch: FDA Post-Marketing Surveillance	1.0hr	Winterstein	
10/14/19		7.3	Watch: Risk Evaluation and Mitigation Systems (REMS)	0.5hr	Winterstein	
	Due: 10/15/19 @11:59pm		Assignment: Review article RIV bleeding (on Canvas) to prepare for Active Learning Session #3			
		8	Module 8: Critiquing Pharmacoepidemiology and Drug Safety Literature for Decision-Making	2.0hr	Brown	1-6
10/15/19		8.1	Watch: Critical Evaluation of the Literature for Pharmacists	0.5hr	Brown	
10/15/19			Read: Article 2 (Canvas)	0.75hr		
10/15/19			Read: Article 3 (Canvas)	0.75hr		
10/15/19			Read: Article 4 and use for Discussion Board Activity Below	.25		

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<b>Date</b> <i>Recommended Dates for Independent Study</i>	<b>Delivery Date</b>	<b>Mod #</b>	<b>Unit Topic</b>	<b>Contact Hours [hr.]a</b>	<b>Faculty Author</b>	<b>Learning Objectives Covered</b>
	Due: 10/22/19 @ 11:59pm		Assignment: Critical Appraisal			
	10/16/19 10:40am - 12:35pm	5-8	Active Learning Session 4: Decision- making using comparative effectiveness research	2.0hr	Brown	1-6
	10/23/19 10am - 12pm	1-8	Final Exam: Modules 1-8			
			Total Contact Hours in Course:	33hr		

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# Required Textbooks/Readings

There are no required textbooks for this class. Any required readings will be made available on Canvas.

- Use [UF VPN to access UF Libraries Resources](#) when off-campus.
- The UF HSC library staff can assist you with questions or issues related to accessing online library materials. For assistance contact your College of Pharmacy librarian or visit the [HSC Library Website](#) at this URL: <http://www.library.health.ufl.edu/>

# Suggested Textbooks/Readings

Suggested readings will be posted on Canvas.

# Other Required Learning Resources

None

# Materials & Supplies Fees

None

# Student Evaluation & Grading

Evaluation Methods and How Grades are calculated.

Assessment Item	Grade Percentage
Individual Readiness Assessments [3 @ 5% ea.]	15%
Team Readiness Assessments [3 @ 5% ea.]	25%
Self-Assessments [2 @ 5% ea.]	10%
Discussion Board Activity	10%
Final Exam	40%
Total	100%

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Table 1. Grading Scale

**Rounding of grades:**

Final grades in Canvas will be rounded to the 2<sup>nd</sup> 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: <https://curriculum.pharmacy.ufl.edu/current-students/course-policies/>

**Course Evaluation Process**

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/>



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# Appendix A. Course Directory

## Teaching Partnership Leader/Course Director:

Joshua Brown, Pharm.D., Ph.D.

Email: [joshua.brown@cop.ufl.edu](mailto:joshua.brown@cop.ufl.edu)

Office: HPNP 3320

Phone: 352-294-8593

Office Hours: By appointment ONLY.

Yu-Jung “Jenny” Wei, M.S., Ph.D.

Email: [jenny.wei@cop.ufl.edu](mailto:jenny.wei@cop.ufl.edu)

Office: HPNP 3321

Phone: 352-294-5340

Office Hours: By appointment ONLY

### Questions to Ask:

- Questions about grades
- Concerns about

performance

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

## Instructional Designer:

Name: Elliot Tordoff

Office: HPNP 4309

Email: [etordoff@cop.ufl.edu](mailto:etordoff@cop.ufl.edu)

Phone: 352-294-5215

## Academic Coordinator:

Name: Misti Merrill

Office: HPNP 4312

Phone: 352-273-5617

Absent/Tardy Email: [absent3pd@cop.ufl.edu](mailto:absent3pd@cop.ufl.edu)

## Educational Coordinator

Name: McKenzie Wallen

Email: [mwallen@cop.ufl.edu](mailto:mwallen@cop.ufl.edu)

Office: Jacksonville Campus

Name: Iverta Allen

Email: [iallen1@cop.ufl.edu](mailto:iallen1@cop.ufl.edu)

Office: Orlando Campus

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**Questions to Ask:**

- Issues related to course policies (absences, make up exams, missed attendance)
- Absence 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 gradebook (missing grades, wrong grade)
- Assistance with ExamSoft® (Distant campus students may contact Education Coordinator for use of SofTest and assistance during exams. The Academic Coordinator is the contact person for issues related to grading and posting of ExamSoft grades.)

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## **Other Teaching Partnership Faculty Members:**

Almut Winterstein, RPh, Ph.D., FISPE

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