

PHAR 7274: Biostatistics and Clinical Research Methods

Spring Semester 2021

Course Description

This course introduces pharmacy students to the principles of applied biostatistics and clinical research methods. The goal of this course is for students to develop the ability to critically appraise health and drug literature in order to make evidence-based decisions in their practice.

Additional Course Information

This course provides students with the knowledge and skills needed to interpret and evaluate quantitative findings in the pharmacy and medical literature. Topics include using statistical methods to summarize data, testing research hypotheses, making statistical inferences, and differentiating between statistical and clinical significance of research findings. The course also introduces the students to basic elements of the research framework, ethical and regulatory issues surrounding conduct of research with human subjects, various experimental and observational study designs, and literature aggregation methods.

Course Credit

Two (2) credit hours

Pre-Requisites

None

Co-Requisites

None

Class Meeting Days, Time & Location

Friday 2:00 pm – 4:00 pm, online via Zoom and/or W.T. Brookshire Hall Rooms 234, 235, 236. This is the link to join the class via Zoom: <https://uttyler.zoom.us/j/92448320747?pwd=RE1VSGd0NDNOZEVLWko0WVNiYTJ3UT09>

Course Coordinator

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Office hours: Wednesday/Friday 12:00 pm – 1:30 pm, and by appointment

Preferred method of contact: E-mail

Fisch College of Pharmacy (FCOP) and UT Tyler Policies

This is part 1 of the syllabus. Part 2 of the syllabus contains UT Tyler and the FCOP course policies and procedures, which is available as a PDF at <https://www.uttyler.edu/pharmacy/academic-affairs/files/fcop-syllabus-policies.pdf>. Part 3 of the syllabus contains specific-policies adapted regarding instruction during COVID-19, which is available at <https://www.uttyler.edu/pharmacy/academic-affairs/files/fcop-syllabus-part-3.pdf>. For experiential courses (i.e., IPPE and/or APPE), the Experiential Manual contains additional policies and instructions that supplement the syllabus. Please note, the experiential manual may contain policies with different deadlines and/or instructions. The manual should be followed in these cases.

Required Materials

Most course required materials are available through the Robert R. Muntz Library. These materials are available either online* (<http://library.utt Tyler.edu/>) or on reserve.

1. *Malone PM, Malone MJ, Park SK. *Drug Information: A Guide for Pharmacists*. 6th ed. McGraw-Hill Education; 2018. ISBN: 978-1-259-83797-5.
2. *Yang Y, West-Strum D. *Understanding Pharmacoepidemiology*. 1st ed. McGraw-Hill Education; 2011. ISBN: 978-0-07-163500-4.
3. Biomedical Research Module: Collaborative Institutional Training Initiative (CITI) available at <https://about.citiprogram.org/en/homepage/>
4. Other required materials will be posted on the classes' Canvas site. The site address is <http://utt Tyler.edu/canvas>

Recommended Materials

None.

Course Format

The course may include, but is not limited to, the following activities:

1. Independent study of selected readings
2. Preclass assignments
3. Individual readiness assessment tests (iRATs)
4. Individual applications
5. Team-based learning, active learning strategies:
 - a. Team readiness assessment tests (tRATs)
 - b. Team application of content and concepts
 - c. Team presentation of content and concepts
6. Completion of online trainings/quizzes
7. Educational video clips (online and in class)

Course Learning Outcomes (CLOs)

CLOs	PLO(s) Assessed for this CLO (1-15)	EPAs (1.1-6.1)	Assessment Methods	Grading Method	PPCP Skill(s) Assessed (1-5)	ACPE Std. 11 & 12 (1-4)
1. Evaluate the use of commonly employed statistical tests in published research studies and the validity of conclusions based on the application of those tests	1	NA	1	ES	NA	4
2. Evaluate the research methods and protocol designs required to conduct valid and reliable studies to test hypotheses or answer research questions	1	NA	1	ES	NA	4
3. Recognize the historical perspectives, ethical principles, and regulatory issues surrounding the conduct of research with human subjects	1	NA	2	Online Quizzes	NA	4

Course Assessment Methods

	Assessment Method	Description
1	Midterm and Final Written Exams	<i>Standard multiple-choice, select all that apply, matching, true/false, hot spot, fill-in-the-blank, and short essay questions</i>
2	Completion of CITI Training Biomedical Research Online Module	<i>Standard multiple-choice questions</i>

Grading Policy & Grade Calculation

Grades will be determined based on evaluation of individual and team readiness assessment tests (iRATs, tRATs), individual and team cumulative assessment tests (iCATs, tCATs), midterm examinations, final written examinations, skills assessments, graded application assignments, participation in team-based projects, peer evaluations and other assessment methods that may include Objective Structured Clinical Examinations (OSCE). Examinations, RATs and CATs may consist of multiple-choice, true/false, short-answer, essay, and problem-based questions.

During the time the course is in progress, students whose cumulative course percentage falls below 70.0% may receive an academic alert and be subject to periodic course content review in special sessions with the course instructor(s). The student's faculty advisor may receive an academic alert to act upon on the student's behalf.

All examinations, tests, and assignments, including the final examination, may be **cumulative**. Students are responsible for material presented during the prior courses. The grading scale for all graded material is below. The final course grade will be assigned according to the calculated percentage and the percentages will not be rounded upward or downward. For additional information, see examination/assessment policy below.

Standard Grade Calculation

INDIVIDUAL COMPONENTS	95%
iRATs	10%
Individual Applications	7%
CITI Training	3%
Midterm Exam	35%
Final Exam	40%
TEAM COMPONENTS	5%
tRATs	2%
Team Applications	3%
TOTAL	100%

Final Course Letter Grade

A	90 - 100 %
B	80 - 89.999 %
C	70 - 79.999 %
D	65.0 - 69.999 %
F	< 65.0 %

PHAR 7274 Course Schedule
Spring Semester 2021

WK	DAY	TOPIC	INSTRUCTOR	CLO	Disease State
1	1/15	Biostatistics: Descriptive Statistics	Shoair	1	S20.01
2	1/22	Biostatistics: Probability and Hypothesis Testing	Shoair	1	S20.01
3	1/29	Biostatistics: Comparing Proportions	Shoair	1	S20.01
4	2/5	Biostatistics: Comparing Means	Shoair	1	S20.01
5	2/12	Biostatistics: Correlation and Regression	Shoair	1	S20.01
6	2/19	Biostatistics: Logistic Regression and Survival Analysis	Shoair	1	S20.01
7	2/26	Biostatistics: Power and Sample Size	Shoair	1	S20.01
8	3/5	Biostatistics: Statistical vs. Clinical Significance	Shoair	1	S20.01
	3/12	Spring Break			
9	3/19	Midterm Exam (Content covered from 1/15 to 3/5)			
10	3/26	Research Design: The Anatomy and Physiology of Clinical Research	Shoair	2	S20.01
11	4/2	Research Design: Randomized-Controlled Trials	Shoair	2	S20.01
12	4/9	Research Design: Observational Study Designs	Shoair	2	S20.01
13	4/16	Research Design: Superiority, Equivalence, and Non-Inferiority Clinical Trials	Shoair	2	S20.01
14	4/23	Research Design: Narrative Reviews, Systematic Reviews, and Meta-Analyses	Shoair	2	S20.01
15	4/30	Deadline to upload CITI training completion certificate via Canvas*	Shoair	3	S20.01
		Final Exam (Content covered from 1/15 to 4/23)			
<p><i>Dates, topics, and assignments are subject to change. In the event of a change, you will be given ample notification of the changes. The dates of the RATs for this course may not be announced, so you should be prepared to have RATs during any of the classes.</i></p> <p>*Information regarding registration for CITI training and submission of completion certificate on Canvas will be reviewed during first class.</p>					