

## Biostatistics and Clinical Research Methods

### PHAR 7274

Spring Semester 2020

#### Catalogue 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 human subjects research, 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, W.T. Brookshire Hall Room# 137

#### Course Coordinator

Osama A. Shoair, PhD

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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 contains UT Tyler and the FCOP course policies and procedures. These are available as a PDF at <https://www.uttyler.edu/pharmacy/academic-affairs/files/fcop-syllabus-policies.pdf>

#### Required Materials

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

1. \*Malone PM, Malone MJ, Park SK. *Drug Information: A Guide for Pharmacists*. 6<sup>th</sup> ed. McGraw-Hill Education; 2018. ISBN: 978-1-259-83797-5.

2. \*Yang Y, West-Strum D. *Understanding Pharmacoepidemiology*. 1<sup>st</sup> 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://uttyler.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. Apply and interpret statistical tests that are commonly used in medical research	1	NA	1	ES	NA	4
2. Evaluate research methods and study designs that are commonly used in medical research	1	NA	1	ES	NA	4
3. Recognize the ethical and regulatory issues surrounding the conduct of human subjects research	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

<b>Individual Component</b>	<b>85%</b>
iRATs	15%
Individual Applications	7%
CITI Training	3%
Midterm Exam	25%
Final Exam	35%
<b>Team Component</b>	<b>15%</b>
tRATs	5%
Team Applications	10%
<b>Total</b>	<b>100%</b>

### 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 2020)

WK	DAY	TOPIC	INSTRUCTOR	CLO	Disease State
1	1/17	Biostatistics: Descriptive Statistics	Shoair	1	S20.01
2	1/24	Biostatistics: Probability and Hypothesis Testing	Shoair	1	S20.01
3	1/31	Biostatistics: Comparing Proportions	Shoair	1	S20.01
4	2/7	Biostatistics: Comparing Means	Shoair	1	S20.01
5	2/14	Biostatistics: Correlation and Regression	Shoair	1	S20.01
6	2/21	Biostatistics: Logistic Regression and Survival Analysis	Shoair	1	S20.01
7	2/28	Biostatistics: Power and Sample Size	Shoair	1	S20.01
8	3/6	Biostatistics: Statistical vs. Clinical Significance	Shoair	1	S20.01
	3/13	<b>Spring Break</b>			
9	3/20	<b>Midterm Exam (Content covered from 1/17 to 3/6)</b>			
10	3/27	Research Design: The Anatomy and Physiology of Clinical Research	Shoair	2	S20.01
11	4/3	Research Design: Randomized-Controlled Trials	Shoair	2	S20.01
12	4/10	Research Design: Observational Study Designs	Shoair	2	S20.01
13	4/17	Research Design: Superiority, Equivalence, and Non-Inferiority Clinical Trials	Shoair	2	S20.01
14	4/24	Research Design: Narrative Reviews, Systematic Reviews, and Meta-Analyses	Shoair	2	S20.01
15	5/1	<b>Deadline to upload CITI training completion certificate via Canvas*</b>	Shoair	3	S20.01
		<b>Final Exam (Content covered from 1/17 to 4/24)</b>			
<p>*Information regarding registration and submission of completed CITI training certificate will be reviewed during first class. Please note that 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.</p>					