

PHAR 7274: Biostatistics and Clinical Research Methods

Spring Semester 2023

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 9:00 am – 11:00 am, W.T. Brookshire Hall Room 236

Course Coordinator

Osama A. Shoair, Ph.D.

W.T. Brookshire Hall Room 346

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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/>

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*. 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://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 of content and concepts
5. Team-based assignments
 - a. Team readiness assessment tests (tRATs)
 - b. Team application of content and concepts
 - c. Team presentation of content and concepts
6. Completion of online training and quizzes

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 appropriate use of commonly employed statistical tests in published research studies and accurately interpret the results from those tests	1	NA	1	ES	NA	4
2. Describe the various study designs and research methods commonly used to test hypotheses or answer health-related 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	Summative 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 the evaluation of individual and team readiness assessment tests (iRATs, tRATs), individual and team-graded application assignments, individual cumulative assessment tests, midterm examinations, final written examinations, skills assessments, completion of online training/modules, 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, select-all-that-apply, true/false, fill-in-the-blank, essay, matching, ranking, 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 the material presented during the prior courses. The grading scale for all graded materials 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 the examination/assessment policy available in Part 2 of the syllabus available as a PDF at <https://www.utt Tyler.edu/pharmacy/academic-affairs/>

Standard Grade Calculation

Individual Components	95%
iRATs	10%
Individual Applications	8%
CITI Training	2%
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 2023

WK	DAY	TOPIC	INSTRUCTOR	CLO	Disease State
1	1/13	Biostatistics: Descriptive Statistics	Shoair	1	\$20.99
2	1/20	Biostatistics: Probability and Hypothesis Testing	Shoair	1	\$20.99
3	1/27	Biostatistics: Comparing Proportions	Shoair	1	\$20.99
4	2/3	Biostatistics: Comparing Means	Shoair	1	\$20.99
5	2/17	Biostatistics: Correlation and Regression	Shoair	1	\$20.99
6	2/24	Biostatistics: Logistic Regression and Survival Analysis	Shoair	1	\$20.99
7	3/3	Biostatistics: Power and Sample Size	Shoair	1	\$20.99
		Biostatistics: Statistical vs. Clinical Significance	Shoair	1	\$20.99
8	3/10	Second Exam from 9:00 am – 11:00 am (Content covered from 1/13 to 3/3)			
9	3/17	Spring Break: No Classes			
10	3/24	Research Design: Fundamentals of Clinical Research	Shoair	2	\$20.99
11	3/31	Research Design: Randomized-Controlled Trials	Shoair	2	\$20.99
12	4/7	Research Design: Observational Study Designs	Shoair	2	\$20.99
13	4/14	Research Design: Superiority, Equivalence, and Non-Inferiority Clinical Trials	Shoair	2	\$20.99
14	4/21	Research Design: Narrative Reviews, Systematic Reviews, and Meta-Analyses	Shoair	2	\$20.99
15	4/26	Deadline to upload CITI training completion certificate to Canvas[#]			
		Final Exam from 9:00 am – 12:00 pm (Content covered from 1/13 to 4/21)			
*Dates, topics, and assignments are subject to change. In the event of a change, you will be given ample notification of the changes.					
[#] Information regarding registration for CITI training and submission of completion certificate on Canvas will be reviewed during first class.					