TSCI 5072

Patient-Oriented Clinical Research Biostatistics-1

Fall 2022

CLASS DAYS and TIME: Thursdays (August 26 – December 16, 2022), 3:00 – 5:00 pm

CLASSROOM: LIB 2.015

COURSE DIRECTOR: Jonathan Gelfond, MD, PhD

OFFICE LOCATION and HOURS: ADM 3.314, Monday – Friday (8:00 am – 5:00 pm by appointment)

EMAIL: gelfondjal@uthscsa.edu

TELEPHONE: 210-567-0836

READ THIS DOCUMENT CAREFULLY – YOU ARE RESPONSIBLE FOR ITS CONTENTS

COURSE DESCRIPTION AND OBJECTIVES

This interdisciplinary course is the first in a two-semester sequence designed to train participants in the conduct of patient-oriented clinical research.

Pre-requisites – There are no pre-requisites for this course.
Semester credit hours – 2.0 SCH

By the end of the second semester, degree candidates will be able to:

1. Use graphical tools to discover useful patterns in a data set and to describe statistical results
2. Interpret and present descriptive statistics in oral and written form.
3. Understand the role of random processes in nature and in the conduct of medical research.
4. Apply fundamental principles of statistical analysis to collection, preparation, analysis, and interpretation of data in medical research
5. Analyze, interpret and present results from randomized and non-randomized studies comparing two or more groups.
6. Analyze, interpret and present results from linear and logistic regression analyses.

COURSE ORGANIZATION

The main teaching modalities used in this course include:

1. Lectures
2. In-class assignments and discussions requiring active student participation.

Materials:

Computer Requirements:

Students are required to have a laptop computer that can connect to and operate over a wireless network.

Software required:

- R & RStudio (Open source, free, latest version)
  https://www.rstudio.com/products/RStudio/
  https://www.r-project.org/
- Microsoft Office Suite (A personal copy of the latest version can be purchased at The UTHSCSA bookstore at student pricing with a student ID)

All laptops will connect to The UTHSCSA network via the HSCwave broadcast wireless connection. Authentication for wireless use is based on The UTHSCSA domain username and password.

Verification of proper operation **prior** to the start of class is highly recommended.

Assistance is available thru the IMS Service Desk

- Telephone:(567-7777)
- E-mail (ims-servicedesk@uthscsa.edu)

Assistance is also available at the IMS Student Support Center (4.421T, DTL).

Reading Assignments – Reading assignments will be listed in the individual class sections of this syllabus.

ATTENDANCE

Attendance at scheduled classes and examinations is crucial to meeting course objectives. Therefore, regular attendance in class is expected of each student.

- Attendance is defined as being present within 15 minutes after the scheduled beginning of the class and until 15 minutes before the scheduled ending of the class.
- Excused absences may be granted by the Course Director in cases such as formal presentations at scientific meetings, illness, or personal emergency.
- Excused absences are considered on an individual basis and require electronic communication with the Course Director to request an excused absence. The e-mail request to the Course Director for consideration of an excused absence must provide details regarding the circumstances and specific dates.
- It is expected that students will provide *advanced notice* of absence for scheduled events.
- If a student has excessive unexcused absences in a given course, they will automatically receive a grade of *unsatisfactory* unless *makeup* has been approved by the Course Director.
- Makeup of absences (both excused and unexcused) is allowed at the discretion of the Course Director.
- Allowable unexcused absences will be determined by the credit hours of the course as follows:

Course Semester Credit Hours	Allowable Unexcused Absences
3.0	3
2.0	2
1.0	1

TEXTBOOKS

Recommended Not Required

Kabacoff, Robert. *R in action: data analysis and graphics with R*. Manning Publications Co., 2015.

Lander, Jared P. *R for Everyone: Advanced Analytics and Graphics*. Pearson Education, 2014.

Lang TA, Secic M. *How to report statistics in medicine: Annotated guidelines for authors, editors, and reviewers (2nd Ed.).* Philadelphia, PA: American College of Physicians, 2006.

GRADING POLICIES AND EXAMINATION PROCEDURES

1. Class attendance is essential for anyone who wishes to obtain credit for the course. You must attend 14 of the 16 lectures in order to obtain credit for the course. You can make up any sessions missed due to unexpected schedule conflicts, professional travel, or other extenuating circumstances, provided you contact your course director as soon as you know you will need to miss a class. Any student who fails to meet this requirement will receive an UNSATISFACTORY grade for the course.
2. An in-class final examination on the last day of class will contribute 1/3 of the grade. This will be graded on a 100-point scale.
3. Two data analysis assignments, each from two in-class sessions, are to be completed during the semester and account for 2/3 of the final grade by weighted average. These assignments are posted on Canvas. Each assignment will be scored on a 100-point scale. ***You must complete and turn-in 2 data analysis assignments on time and complete the final examination and receive a minimum score of 70/100 points on each assignment in order to receive credit for the course.***
    a. A student who completes 2 of the assignments with 70/100 points, but fails to complete the final exam with a score of 70/100 points, will receive an incomplete.
    b. A student who completes 2 of the assignments and the final examination with an average score of less than 70/100 points will receive an UNSATISFACTORY grade for the course.
4. A student who receives an INCOMPLETE must meet with the Course Director and develop a plan of action to complete the outstanding work. All outstanding work must be completed within 6 months after the end of the course; otherwise the grade will be changed to UNSATISFACTORY.
5. A student who receives an UNSATISFACTORY grade must retake the course in order obtain a change of grade.

<u>Grading System</u>

Include a grading scale used to determine final grades, see example below

S = Satisfactory U = Unsatisfactory

A = 90-100% B = 80-89% C = 70-79% F = < 69%

REQUESTS FOR ACCOMODATIONS FOR DISABILITIES

In accordance with policy 4.2.3, **Request for Accommodation Under the ADA and the ADA Amendments Act of 2008 (ADAAA)**, any student requesting accommodation must submit the appropriate request for accommodation under the American with Disabilities Act (ADA, form 100). to his/her appropriate Associate Dean of their School and a copy to the ADA Coordinator. Additional information may be obtained at http://uthscsa.edu/eeo/request.asp.

ACADEMIC INTEGRITY AND PROFESSIONALISM

Any student who commits an act of academic dishonesty is subject to discipline as prescribed by the UT System Rules and Regulations of the Board of Regents. Academic dishonesty includes, but is not limited to, cheating, plagiarism, collusion, the submission for credit of any work or materials that are attributable in whole or in part to another person, taking an exam for another person, signing attendance sheets for another student, and any act designed to give unfair advantage to a student or the attempt to commit such an act. Additional information may be obtained at http://catalog.uthscsa.edu/generalinformation/generalacademicpolicies/academicdishonestypolicy/

TITLE IX AT UTHSCSA

Title IX Defined:
Title of the Education Amendments of 1972 is a federal law that prohibits sex discrimination in education. It reads "no person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance."

University of Texas Health Science Center San Antonio's Commitment:
University of Texas Health Science Center San Antonio (UTHSCSA) is committed to maintaining a learning environment that is free from discriminatory conduct based on gender. As required by Title IX, UTHSCSA does not discriminate on the basis of sex in its education programs and activities, and it encourages any student, faculty, or staff member who thinks that he or she has been subjected to sex discrimination, sexual harassment (including sexual violence) or sexual misconduct to immediately report the incident to the Title IX Director.

In an emergency, victims of sexual abuse should call 911. For non-emergencies, they may contact UPD at 210-567-2800. Additional information may be obtained at http://students.uthscsa.edu/titleix/

EMAIL POLICY

All correspondence will be sent to the student using the student's livemail address and CANVAS. All correspondence from the student to the course director should be sent to the course director's e-mail as listed on the first page of this syllabus.

USE OF RECORDING DEVICES

Only with course director's or instructor's permission.

ELECTRONIC DEVICES

Cell phones must be turned off during all class meetings and exams. Computers and electronic tablets are allowed only for participating in classroom activities (*e.g.*, viewing slides presented in lecture or conference materials). No texting, tweeting, e-mailing, web-surfing, gaming, or any use of electronic devices that is not directly connected with classroom activities is permitted.

TENTATIVE CLASS SCHEDULE

TSCI 5072
Patient-Oriented Clinical Biostatistics – 1
Fall2022

Week	Date	Module	Title/Instructor(s)
1	08/25/22	**Introduction to biostatistics**	Introduction to biostatistics (Gelfond)
2	09/01/22		Descriptive statistics with R (Gelfond)
3	09/08/22		Exploring and visualizing data (Gelfond)
4	09/15/22		Hypothesis Testing: Comparison of Two Means (Gelfond))
5	09/22/22		Comparing Probabilities of Events: Measures of Risk (Gelfond)
6	09/29/22	**Science of Uncertainty**	Practical data analysis (Gelfond)
7	10/06/22		Linear regression and correlation (Gelfond)
8	10/13/22		Practicing regression 1 (Gelfond)
9	10/20/22		Statistical interactions and Logistic regression (Gelfond)
10	10/27/22		Applied linear and logistic regression (Gelfond)
11	11/03/22	**Identifying patterns within data**	Introduction to survival analysis (Gelfond)
12	11/10/21		Practical survival analysis
13	11/17/21		Confounding and Mediation
14	11/24/22		**THANKSGIVING WEEK – NO CLASS**
15	12/01/22		Practicing regression 2 (Gelfond)
16	12/08/21		Study Planning; Integrating Study Design and Statistics (Gelfond)
17	12/15/21		Final examination if necessary

Week: 1
Date: August 25, 2022 (3:00 - 5:00 pm)
Room: LIB 2.015
Instructor(s): Gelfond

Topic: Introduction to biostatistics and probability

Learning Objectives and Competencies– Participants will be able to:

1. Explain the role of statistics in translational research.
2. List and define the features of statistical estimates.
3. List some common types of data.
4. Describe components of statistical models.

Class Assignment: None.

Readings: descriptive_stats101.pdf (Intro to probability, 15 pages)

Week: 2

Date: September 1, 2022 (3:00 - 5:00 pm)

Room: LIB 2.015

Instructor(s): Gelfond

Topic: Getting Started with R

Learning Objectives and Competencies– Participants will be able to:

1. Download are start R.
2. Read a spreadsheet of data into R.
3. Create descriptive statistics with R.

Class Assignment: Students will operate R software to perform basic functions.

Readings: data-import-cheatsheet.pdf, ggplot2-cheatsheet.pdf,base-r.pdf

Week: 3

Date: September 08, 2022 (3:00 - 5:00 pm)

Room: LIB 2.015

Topic: Exploring and visualizing data

Instructor(s): Jonathan Gelfond, MD, PhD

Learning Objectives – Participants will be able to:

1. Create tables with R
2. Explain some of the principles of visualization of quantitative data
3. Edit the basic features of an R graph
4. Create graphs with ggplot2
5. List some of the most common types of statistical graphics

Class Assignment: Students will operate R software to perform basic functions.

Readings:
ggplot2-cheatsheet.pdf

Week: 4

Date: September 15, 2022 (3:00 - 5:00 pm)

Room: LIB 2.015

Topic: Hypothesis Testing: Comparison of Two Means (Gelfond))

Instructor(s): Jonathan Gelfond, MD, PhD

Learning Objectives – Participants will be able to:

1. Define a p-value, null and alternative hypothesis
2. Describe measurements of central tendency and dispersion
3. Compute, estimate, and graph measures of centrality and dispersion
4. Compute p-values for comparing means

Class Assignment: Read assigned material and come to class prepared to discuss.

Readings: pvals_sensitivity_specificity_hypothesis.pdf.

Week: 5

Date: September 23, 2022 (3:00 - 5:00 pm)

Room: LIB 2.015

Topic: Comparing Probabilities of Events: Measures of Risk

Instructor(s): Jonathan Gelfond, MD, PhD

Learning Objectives – Participants will be able to:

1. Describe difference between OR and RR
2. Calculate OR from data from a case-control study
3. Demonstrate effects of confounding
4. Use chi-square test to "Test" whether OR is 1.0 (Null hypothesis)
5. Describe use of Logistic Regression

Class Assignment: Read assigned material and be prepared to discuss.

Readings: odds_ratio_relative_risk.pdf

Week: 6

Date: September 30, 2022 (3:00 - 5:00 pm)

Room: LIB 2.015

Topic: Practical data analysis

Instructor(s): Jonathan Gelfond, MD, PhD

Learning Objectives – participants will be able to:

1. Define, compute, and estimate risks
2. Create tables for risk estimation
3. Graph risks
4. Interpret odds ratios

Class Assignment: In class assignment.

Readings: linear_regression_review.pdf

Week: 7

Date: October 7, 2022 (3:00 - 5:00 pm)

Room: LIB 2.015

Topic: Linear regression and correlation

Instructor(s): Jonathan Gelfond, MD, PhD

Learning Objectives – Participants will be able to:

1. Describe linear regression and correlation.
2. Compute, estimate, and visual linear regression and correlation parameters
3. Describe the assumptions of linear regression and correlation
4. Describe data transformations and nonparametric alternatives for linear regression and correlation analysis.

Class Assignment: Read assigned material and be prepared to analyze data and discuss.

Readings: linear_regression_review.pdf

Week: 8

Date: October 14, 2022 (3:00 - 5:00 pm)

Room: LIB 2.015

Topic: Practicing regression 1 (Gelfond)

Instructor(s): Jonathan Gelfond, MD, PhD

Learning Objectives – Participants will be able to:

1. Describe linear regression and correlation.
2. Compute, estimate, and visual linear regression and correlation parameters
3. Describe the assumptions of linear regression and correlation
   Describe data transformations and nonparametric alternatives for linear regression and correlation analysis.

Class Assignment: In class assignment.

Readings: linear_regression_review.pdf

Week: 9

Date: October 20, 2022

Room: LIB 2.015

Topic: Applied linear and logistic regression

Instructor(s): Jonathan Gelfond, MD, PhD

Learning Objectives – Participants will be able to:

1. Describe linear regression and correlation.
2. Compute, estimate, and visual linear regression and correlation parameters
3. Describe the assumptions of linear regression and correlation
4. Describe data transformations and nonparametric alternatives for linear regression and correlation analysis.

Class Assignment: Introduction to logistic regression analysis and reporting.pdf

Readings: None.

Week: 10

Date: October 27, 2022

Room: LIB 2.015

Topic: Applied linear and logistic regression

Instructor(s): Jonathan Gelfond, MD, PhD

Learning Objectives – Participants will be able to:

1. Apply logistic regression models.
2. Identify regression outliers
3. Compare fit of different models

Class Assignment: Read assigned material and be prepared to analyze data and discuss.

Readings: Introduction to logistic regression analysis and reporting.pdf

Week: 11

Date: November 3, 2022 (3:00 - 5:00 pm)

Room: LIB 2.015

Topic: Introduction to survival analysis

Instructor(s): Jonathan Gelfond

Learning Objectives – Through homework and class room activities, participants will be able to:

1. Explain right censoring and resultant bias.
2. Describe survival and hazard functions.
3. Estimate basic Kaplan-Meier curves with censored data.
4. Interpret the logrank test.

Class Assignment: Read assigned material and be prepared to analyze data and discuss.

Readings: intro_2_survival_bell_bewick.pdf be announced.

Week: 12

Date: November 10, 2022

Room: LIB 2.015

Topic: Practical survival analysis

Instructor(s): Jonathan Gelfond, MD, PhD

Learning Objectives- Participants will be able to:

1. Represent survival data in statistical software
2. Create Kaplan-Meier plots
3. Perform logrank test
4. Fit Cox proportional Hazard models

Class Assignment: Read assigned material and be prepared to discuss.

Readings: intro_2_survival_bell_bewick.pdf

Week: 13

Date: November 17, 2022

Room: LIB 2.015

Topic: Confounding and mediation

Instructor(s): Jonathan Gelfond, MD, PhD

Learning Objectives – Participants will be able to:

4. Describe linear regression and correlation.
5. Compute, estimate, and visual linear regression and correlation parameters
6. Describe the assumptions of linear regression and correlation
7. Describe data transformations and nonparametric alternatives for linear regression and correlation analysis.

Class Assignment: Read assigned material and be prepared to analyze data and discuss.

Readings: Hernan_confounding_2002.pdf

Week: 15

Date: December 1, 2022 (3:00 - 5:00 pm)

Topic: Practicing regression 2 (Gelfond)

Room: LIB 2.015

Instructor(s): Jonathan Gelfond, MD, PhD

Learning Objectives – Participants will be able to:

1. Define multiple regressions.
2. Compute, estimate, and visualize multiple regressions.
3. Describe and implement methods of variable/model selection in linear regression.
4. Explain the challenges in logistic regression relative to linear regression.
5. Compute, estimate, and visualize logistic regression models.

Class Assignment: In class assignment.

Readings: None.

Week: 14

Date: November 24, 2022

TOPIC: THANKSGIVING WEEK – NO CLASS

Week: 16
Date: December 8, 2022 (3:00 - 5:00 pm)
Room: LIB 2.015
Topic: Study Planning; Integrating Study Design and Statistics
Instructor(s): Jonathan Gelfond, MD, PhD
Learning Objectives – Participants will be able to: 1. Define power and relate to sample size and experimental cost. 2. Estimate power to detect differences in means and proportions. 3. Write a statistical analysis plan for differences in means and proportions.
Class Assignment: Read assigned material and be prepared to analyze data and discuss.
Readings: power_and_sampleSize.pdf

Week: Final Exam if necessary
Date: December 15, 2022 (3:00 - 5:00 pm)
Room: LIB 2.015
Topic: Final Examination
Instructor(s): Jonathan Gelfond MD, PhD
1.