TSCI 5072

Patient-Oriented Clinical Research Biostatistics-1

Fall 2016

CLASS DAYS and TIME: Thursdays (August 23 – December 13, 2016), 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 regression analyses with continuous variables.

COURSE ORGANIZATION

The main teaching modalities used in this course include:

1. Lectures
2. Class 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:

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

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

Required:

1. ***Textbooks (required)***

   Kirkwood BR, Sterne JA. *Essential medical Statistics*. Malden, MA: Blackwell Science Ltd, 2003.

2. ***Textbooks (recommended)***

   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. Three data analysis assignments, one for each R session, are to be completed during the semester. These assignments are posted on Blackboard. Each assignment will be scored on a 100-point scale. ***You must complete and turn-in all 3 data analysis assignments on time 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 at least 2 of the assignments with 70/100 points, but fails to complete the 3rd assignment with a score of 70/100 points, will receive an incomplete.
   b. A student who completes less than 2 of the assignments with a score of 70/100 points will receive an UNSATISFACTORY grade for the course.
3. 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.
4. 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
Fall2016

Week	Date	Module	Title/Instructor(s)
1	08/25/2016	**Introduction to science of data analysis**	Retraction Rates, Reproducibility and Scientific Integrity (Gelfond)
2	09/01/2016		Getting Started with R (Gelfond)
3	09/08/2016		Introduction to data science (Gelfond)
4	09/15/2016		Data analysis programming (Gelfond)
5	09/22/2016		The practice of data analysis (Gelfond)
6	09/29/2016	**Science of Uncertainty**	Exploring and visualizing data (Gelfond)
7	10/06/2016		Probability and variation in populations (Gelfond)
8	10/13/2016		Comparing Probabilities of Events: Measures of Risk (Gelfond)
9	10/20/2016		Testing hypotheses with data (Gelfond)
10	10/27/2016		Hypothesis Testing: Comparison of Two Means (Gelfond)
11	11/03/2016	**Identifying patterns within data**	Hypothesis Testing: Chi-squared Tests for 2x2 Tables (Gelfond)
12	11/10/2016		Linear and correlations regression (Gelfond)
13	11/17/2016		Linear Regression: t-test and ANOVA (Gelfond)
14	11/24/2016		**THANKSGIVING WEEK – NO CLASS**
15	12/01/2016		Applied linear regression (Gelfond)
16	12/08/2016		Logistic regression (Gelfond)
17	12/15/2016		Study Planning; Integrating Study Design and Statistics (Gelfond)

Week: 1
Date: August 25, 2016 (3:00 - 5:00 pm)
Room: LIB 2.015
Instructor(s): Gelfond
Topic: Retraction Rates, Reproducibility and Scientific Integrity
Learning Objectives and Competencies– Participants will be able to:

1. Understanding the different meanings of reproducible research.
2. Describe several examples of real-world erroneous research.
3. Explain the role of statistics and robust data analysis in rigorous research.
4. Describe accountability and relate this to research data analysis.

Class Assignment: None.

Readings:

A Sharp Rise in Retractions Prompts Calls for Reform. New York Times, April 16, 2012

Announcement: Reducing our irreproducibility. Nature, April 24, 2013

Major Scientific Journal Joins Push to Screen Statistics in Papers It Publishes, Scientific American. July 6, 2014

Gelfond JAL, et al . How to tell the truth with statistics: The case for accountable data analyses in team-based science. J Transl Med Epidemiol 2014; 2: 1025.

Week: 2

Date: September 1, 2016 (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. List the major data type within R.

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

Readings: Handouts at time of class

Week: 3

Date: September 8, 2016 (3:00 - 5:00 pm)

Room: LIB 2.015

Topic: Introduction to data science

Instructor(s): Jonathan Gelfond, MD, PhD

Learning Objectives – Participants will be able to:

1. Distinguish between statistics, probability, data management, and data science
2. Explain the roles of data scientists within biomedical research
3. Describe the data-use cycle

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

Readings:

Elements of data analytic style by Jeff Leek OR **On being a modern scientist by Jeff Leek**

Week: 4

Date: September 15, 2016 (3:00 - 5:00 pm)

Room: LIB 2.015

Topic: Data analysis programming

Instructor(s): Jonathan Gelfond, MD, PhD

Learning Objectives – Participants will be able to:

1. Define what is a program
2. Describe some good programming practices
3. Write a R program that reads and graphs data

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

Readings: Handouts to be distributed prior to class.

Week: 5
Date: September 22, 2016 (3:00 - 5:00 pm)
Room: LIB 2.015
Topic: The practice of data analysis (Gelfond)
Instructor(s): Jonathan Gelfond, MD, PhD
Learning Objectives – Participants will be able to: 1. Discuss the structure of data analysis. 2. Perform basic R markdown tasks. 3. Implement an automated structured analysis.
Class Assignment: Read assigned material and be prepared to discuss.
Readings: Handouts to be distributed prior to class.

Week: 6
Date: September 29, 2016 (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. Explain some of the principles of visualization of quantitative data 2. Edit the basic features of an R graph 3. Create graphs with ggplot2 4. List some of the most common types of statistical graphics
Class Assignment: Read assigned material and be prepared to discuss.
Readings: Handouts to be distributed prior to class.

Week: 7

Date: October 4, 2016 (3:00 - 5:00 pm)

Room: LIB 2.015

Topic: Probability and variation in populations

Instructor(s): Jonathan Gelfond, MD, PhD

Learning Objectives – Participants will be able to:

1. Describe measurements of central tendency and dispersion
2. Compute, estimate, and graph measures of centrality and dispersion

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

Readings:

Kirkwood and Stern: Chapters 1 – 4

Lang A, Secic M. How to report statistics in medicine. 1. Summarizing Data

Week: 8

Date: October 13, 2016 (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. Define probability
2. Define conditional probability, relative risks, and odds ratios
3. Define, compute, and estimate risks
4. Graph risks

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

Readings and Bibliography:

Kirkwood and Stern: Chapter 15 – 16

Lang A, Secic M. How to report statistics in medicine.

2. Comparing Probabilities of Events: Reporting Measures of Risk

12. Describing Patterns of disease and disability in populations

Week: 9

Date: October 20, 2016

Room: LIB 2.015

Topic: Testing hypotheses with data

Instructor(s): Jonathan Gelfond, MD, PhD

Learning Objectives – Participants will be able to:

1. Define a p-value, null and alternative hypothesis
2. Describe posterior probability
3. Describe confidence interval and coverage probability
4. Define conservative, nominal tests, and anti-conservative
5. Compute p-values for comparing means and odds ratios

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

Readings:

1. Kirkwood and Stern: Chapters 7 and 30
2. Lang A, Secic M. How to report statistics in medicine. 4. Comparing Groups with P values

Week: 10

Date: October 27, 2016 (3:00 - 5:00 pm)

Room: LIB 2.015

Topic: Hypothesis Testing: Comparison of Two Means

Instructor(s): Jonathan Gelfond

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

1. Graph variation and measures of centrality
2. Evaluate assumptions, outliers, and sample size in statistical tests
3. Consider nonparametric vs. parametric tests
4. Implement rank-based tests

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

Readings: To be announced.

Week: 11

Date: November 3, 2016

Room: LIB 2.015

Topic: Hypothesis Testing: Chi-squared Tests for 2x2 Tables

Instructor(s): Jonathan Gelfond, MD, PhD

Learning Objectives- Participants will be able to:

1. Describe the uses of case-control studies and cohort studies
2. Identify the strengths and weaknesses of case-control study designs considering confounding and bias
3. Compute, estimate, and visualize odds ratios, relative risks for stratified data

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

Readings:

- Kirkwood and Stern: Chapter 17 (pp. 165-174)
- Kirkwood and Stern: Chapter 21 (pp. 214-219)
- Lang A, Secic M. How to report statistics in medicine.
  4. Comparing Groups with P values

Week: 12

Date: November 10, 2015

Room: LIB 2.015

Topic: Linear and correlation and 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: Read assigned material and be prepared to analyze data and discuss.

Readings: To be announced

Week: 13

Date: November 17, 2016 (3:00 - 5:00 pm)

Topic: Linear Regression: t-test and ANOVA

Room: LIB 2.015

Instructor(s): Jonathan Gelfond, MD, PhD

Learning Objectives – Participants will be able to:

1. Explain the applications and limitation of t-tests and ANOVA
2. Describe the meaning of interaction terms in ANOVA
3. Compute, estimate, and visualize ANOVA and t-test results
4. Describe relationship between ANOVA, ANCOVA, and linear regression

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

Readings:

Kirkwood and Stern: Chapter 9

Week: 14

Date: November 22, 2016

TOPIC: THANKSGIVING WEEK – NO CLASS

Week: 15

Date: December 1, 2016 (3:00 - 5:00 pm)

Room: LIB 2.015

Topic: Applied linear regression

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.

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

Readings: To be announced

Week: 16

Date: December 8, 2016 (3:00 - 5:00 pm)

Room: LIB 2.015

Topic: Logistic regression

Instructor(s): Jonathan Gelfond MD, PhD

Learning Objectives – Participants will be able to:

1. Describe the purpose of logistic regression.
2. Explain the challenges in logistic regression relative to linear regression.
3. Compute, estimate, and visualize logistic regression models.

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

Readings: To be announced.

Week: 17

Date: December 15, 2016 (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:

Kirkwood and Stern: Chapter 34

Kerkwood and Stern: Chapter 35