

**University of Florida**  
**College of Public Health and Health Professions and College of Medicine**  
**PHC 6020: Clinical Trials Methods**  
**Spring 2019 (Jan 7 – Apr 24)**

**Instructor:** Zhigang Li, PhD  
Associate Professor, Department of Biostatistics  
College of Public Health and Health Professions & College of Medicine  
University of Florida, P.O. Box 117450  
Gainesville, FL 32611  
Tel: 352-294-5915 (office); 352-294-1930 (fax);  
Email: [zhigang.li@ufl.edu](mailto:zhigang.li@ufl.edu)  
Office: Room 5234, Clinical and Translational Research Building

**TA:** Haocheng Ding, MS, (first year biostats PhD student)  
Department of Biostatistics  
College of Public Health and Health Professions & College of Medicine  
University of Florida  
Gainesville, FL 32611  
Email: [haochengding@ufl.edu](mailto:haochengding@ufl.edu)  
Office: Individual study tables, CTRB 5<sup>th</sup> floor

**Class Schedule:** Tuesdays 1:55 – 3:50pm @ HPNP G312  
Thursdays 1:55 – 2:45pm @ HPNP G316  
NO CLASS ON March 5 & 7 (Spring Break)

**Instructor Office Hour:** 3:50-4:50pm, Tuesdays

**TA Office Hour:** 10:30am-11:30am, Wednesdays or by appointment

**Course Webpage:** We will use the e-learning CANVAS system of the address <http://elearning.ufl.edu/>. Once you logged into the system, click on “Courses” in the menu on the left side. Then, you should be able to find the course PHC 6020. I will post lecture slides, homework assignments, handouts and other materials on the course web site.

#### **COURSE DESCRIPTION AND GOALS**

This course will introduce some basic statistical concepts and methods used in Epidemiology and will focus on the statistical principles and methods used in clinical trials, including designs and analysis methods in phase I to III clinical trials. Although the class will have emphasis on phase III trials, we will also discuss the feature and statistical issues in phase I and II clinical trials. For phase III trials, we will discuss ways of treatment allocation that will ensure valid inference on treatment comparison. Other topics include sample size calculation, survival analysis and early stopping of a clinical trial and noncompliance.

## COURSE MATERIALS

Reference Textbook: The course will be based primarily on lecture notes that will be handed out periodically in class and available on the course website. Online students have the access to the edited videos of lectures, besides the lecture notes. My recommended books that you may wish to read are:

Steven Piantadosi (2005) *Clinical Trials: A Methodologic Perspective*, Wiley-Interscience, 2nd edition

Friedman, L.M., Furberg, C.D. and DeMets, D.L. (1999) *Fundamentals of Clinical Trials*, Springer, 3rd edition

## PREREQUISITES

Officially, the prerequisites of this course include STA 6207/STA 6208 or equivalent (i.e., regression analysis and design of experiments I) and some basic knowledge on probability and statistical inference at the level of STA 6326/STA 6327. You can consult with the instructor to see whether the course is appropriate for you in the case you did not take these courses in advance.

## COURSE REQUIREMENTS

Homework: We will have 3-4 homework assignments during the semester. Homeworks will contain both analytical problems and data analysis problems. Students are encouraged to discuss with each another on homework problems, but everyone should fully understand the solutions, write up the solutions independently, and turn in your own homeworks. To implement the data analyses, we recommend using SAS/R; examples of the use of these software packages are included in the lecture notes and will be discussed in class.

Each homework will be collected **at the beginning of a class on the day it is due**. It should be **neat, all work should be shown, and no late homework will be accepted unless prearranged with the instructor. There will be no exceptions to this policy. Online students should turn in your homeworks through the online system.**

Midterm and Final Exams: We will have one midterm exam and one final exam during this semester. These exams will be **in-class** and closed book exams. The final exam will be comprehensive, but its majority part will involve material covered since the midterm exam. The midterm exam is tentatively scheduled on February 26 (Tuesday), and the final exam is on April 30 (Tuesday).

## GRADING

All homeworks and exams will be graded on a scale of 0-100. A numerical final score on this scale will be determined according to the following breakdown:

Homeworks	40%
Midterm Exam	20%
Final Exam	40%

The numerical final score will be converted to the letter grades according to the following scale:

93-100 = A	90-92.9 = A-	85-89.9 = B+
80-84.9 = B	75-79.5 = B-	70-74.9 = C+
65-69.5 = C		

Scores below 65 will be handled on a case-by-case basis.

Depending on the overall class performance, these ranges may be adjusted.

### **ATTENDANCE POLICY**

Students are strongly recommended to attend the classes. It is understandable if you would like to skip one or two classes to attend the conferences or meetings of your interest. But be sure to let me know in advance. If you have difficulty in catching up with the missed materials, feel free to contact me during my office hours. Online students should watch all posted videos and ask questions online or by emails.

### **MAKE-UP POLICY**

Make-up Policy: No late assignments or tests will be allowed, except for urgent need.

### **STUDENTS WITH DISABILITIES**

Students requesting a disability accommodation must first register with the Dean of Students Office, which will provide documentation to the student. The student should then provide this documentation to the instructor.

### **ACADEMIC INTEGRITY**

Students are expected to act in accordance with the University of Florida policy on academic integrity (see Graduate Student Handbook for details). Cheating or plagiarism in any form is unacceptable and inexcusable behavior.

*We, the members of the University of Florida community, pledge to hold ourselves and our peers to the highest standards of honesty and integrity.*

### **COUNSELING AND STUDENT HEALTH**

Students may occasionally have personal issues that arise in the course of pursuing higher education or that may interfere with their academic performance. If you find yourself facing problems affecting your coursework, you are encouraged to talk with an instructor and to seek confidential assistance at the University of Florida Counseling Center, 352-392-1575, or Student Mental Health Services, 352-392-1171. Visit their web sites for more information: <http://www.counsel.ufl.edu/> or <http://www.health.ufl.edu/shcc/smhs/index.htm#urgent>

The Student Health Care Center at Shands is a satellite clinic of the main Student Health Care Center located on Fletcher Drive on campus. Student Health at Shands offers a variety of clinical services, including primary care, women's health care, immunizations, mental health care, and

pharmacy services. The clinic is located on the second floor of the Dental Tower in the Health Science Center. For more information, contact the clinic at 392-0627 or check out the web site at: [www.health.ufl.edu/shcc](http://www.health.ufl.edu/shcc)

Crisis intervention is always available 24/7 from: Alachua County Crisis Center: (352) 264-6789.

*BUT – Do not wait until you reach a crisis to come in and talk with us. We have helped many students through stressful situations impacting their academic performance. You are not alone so do not be afraid to ask for assistance.*