

**University of Florida**  
**College of Public Health and Health Professions and College of Medicine**  
**PHC 6020: Clinical Trials Methods**  
**Fall 2012**

**Instructor:** Xiaomin Lu, Ph.D.  
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Office: Dauer Hall 455

**Class Schedule:** Tuesday 1:55 – 3:50pm and Thursday 1:55 – 2:45pm @ Dauer Hall 433

NO CLASS ON TUESDAY, SEP 11 AND THURSDAY, SEP 13, 2012

**Office Hour:** 10-11:30am Tuesdays, 3:15-4:15pm Thursday or by appointment

**Course Webpage:** <https://lss.at.ufl.edu/>

I will post the lecture slides, homework assignments, data sets and other material on the course web site in Sakai (e-learning: <https://lss.at.ufl.edu/>).

#### **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 IV 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. Texts that you may wish to consult for further reading 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 are STA 6207/STA 6208, regression analysis and design of experiments I or equivalent and basic inference and probability at the STA 6326/STA 6327 level.

### COURSE REQUIREMENTS

Homework: Homework will be assigned approximately once every two to three weeks. Homeworks will contain both analytical problems and data analysis problems. Students are encouraged to consult one another on homework problems, but everyone should turn in their own homework, and no “blind copying” permitted. 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.

Homework will be collected **at the beginning of class on the date it is due**. It should be **neat, all work should be shown, and no late homework accepted unless prearranged with the instructor. There will be no exceptions to this policy.**

Midterm and Final Exams: We will have one midterm exam and one final exam during this semester. These will be **in-class** and closed book tests. The two exams are tentatively scheduled in class time on October 9, 2012 and December 4, 2011. The final exam will be comprehensive, but the majority part of it will involve material covered since midterm.

### GRADING

All homework 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:

Homework	10%
Midterm Exam	40%
Final Exam	50%

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		

Score below 65 will be handled on a case-by-case basis

Depending on overall class performance, these ranges may be adjusted (but only downward – criteria will only become easier, not harder).

## **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 and we can make appointments to discuss them.

## **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.*