PHC 6021: Fundamentals of Clinical Trials

Fall 2020

CRN | Section # 001 | 3 Credit Hours

COURSE SYLLABUS

Course Description	The course will familiarize students with the issues in the design, and conduct of clinical trials. Factors involved in randomizing subjects, determining sample size, reporting and interpreting of results, analyzing data from the study will be considered.		
Pre-requisites	PHC 6050 & PHC 6051, or PHC 6756 & 6757	**Course Website**	http://my.usf.edu (Canvas)
Co-requisites	None	**Delivery Method**	Campus

Instructor Information	Henian Chen, PhD	**COPH 2128**
	hchen1@usf.edu	**Tuesday 10-11am/2-3 pm**
	813-974-4285	**Email**
	Students can expect to receive an email response as follows: Emails received Monday - Thursday: response usually sent within 48 hrs; Emails received Friday - Sunday: response usually sent within 72 hrs (i.e., Monday). Exceptions are as follows: 1) holidays: response usually sent within 24 hours of the next regular business day; if the instructor is traveling, students will be notified of the dates and/or modifications in response time or contact instructions.	

Course Requirements

Required Materials	Lecture slides and assigned readings will be posted on canvas, 1 week before class. Permission to Use Lecture Materials: Materials used in this course are the property of the instructor. Students are not permitted to sell notes, slides, tapes, and outlines, or post them (including clinical trials data) online without written permission of the instructor.
Recommended Materials	1. S. Piantadosi. Clinical Trials: A Methodologic Perspective. 2. L. M. Friedman, C. D. Furberg, D. L. DeMets. Fundamentals of Clinical Trials.

Course Schedule

Course Meeting Schedule: Tuesdays: 11:00 AM – 1:45 PM

Lesson [release date]	Topic	Assignment	Due Date
Lesson 1 (August 25)	Introduction		
Lesson 2 (September 1)	Design of Clinical Trials		
Lesson 3 (September 8)	Randomization and Blinding		
Lesson 4 (September 15)	Sample Size Determination	Quiz #1	
Lesson 5 (September 22)	Power Consideration		
Lesson 6 (September 29)	Baseline Assessment, ITT and Subgroup Analysis	*Quiz #2*	
Lesson 7 (October 6)	Missing Data in Clinical Trials		
Lesson 8 (October 13)	Basic RCT Data Analysis		
Lesson 9 (October 20)	Advanced RCT Data Analysis		
Lesson 10 (October 27)	RCT Presentation (1)	Quiz #3	
Lesson 11 (November 3)	RCT Presentation (2)		
Lesson 11 (November 10)	Reporting and Interpreting of RCT Results		
Lesson 12 (November 17)	Validity of RCT		
November 24	Prepare Your Final Project		
December 1	Prepare Your Final Project		
December 6	Submit Your Final Project before 5pm	Final Project	

Grading Policies and Procedures

Grading Scale

Letter Grade	Percentage (%)
A	90 - 100
B	80 - 89
C	70 - 79
D	60 - 69
F	0 - 59

Grading Criteria

Assessment	Percent of Final Grade
Quizzes (5)	*50%*
Presentation of a Clinical Trial Study	*10%*
Final Project: Proposal for an RCT	*40%*
Total	**100%**

Grading Policies

In order to receive full credit for each assignment, they must be turned in on time and all sections completed. Detailed instructions for completion of these exercises will be provided on course website. Students who fail to appear for the examination or other course grading event, who did not receive permission in advance for the absence, will receive a "0" for that assignment.

1. **Quizzes (45%):** There are three quizzes in this course. Course readings, lectures, discussions, and exercises will all be examined. Each quiz will be rigorous, closed-book, and will include predominantly short answer, essay questions, data analysis and SAS programs. Quantitative questions requiring calculations may be included. Quizzes are design to be approximately 30 minutes in length, commencing at 10:50am (or shortly thereafter). Students may arrive and begin the exam at any time during the quiz period. However, ALL quiz papers will be collected at the appointed time after the start of the exam. There will be no additional time given for students who arrive late, unless the lateness is due to a documented personal or family emergency.

2. **Presentation of a clinical trial** study (10%): Students will be individually assigned an article on clinical trial. Each student will make PowerPoint slides and a 20 minute oral presentation of the paper. Emphasis should be on study design, sample size calculation, randomization method, strengths and weaknesses of the study.

3. **Final project: proposal for a RCT (45%):** All students are required to complete a final project. The final report for this course will be an abbreviated research protocol for a randomized controlled trial (RCT). The intervention can be anything related to health. Detailed instructions for the final project will be posted on the course website.

There will be no opportunity for "extra credit" in this course.

Course Competencies and Objectives

Alignment Matrix

CONCENTRATION COMPETENCIES (CC): *APPLIED BIOSTATISTICS*	**COURSE OBJECTIVES:** *PHC 6020 DESIGN AND CONDUCT OF CLINICAL TRIALS*	**MEETS CC**	**ASSESSMENTS***	**SESSION #**
A. Apply biostatistical methods to the design of experimental and observational studies with respect to sample selection, randomization, and power. B. Use statistical techniques including descriptive statistics, data exploration, estimation, hypothesis testing, and modeling. C. Demonstrate basic data management skills and use common statistical software packages for data analysis. D. Use real data to practice how to formulate research problems that often arises in public health setting, identify the correct statistical methods for data analysis, and interpret analysis results. E. Develop written and oral presentations based on statistical analyses and field experience.	The Student will be able to:			
	1. describe concept of a clinical trial	A,	Quiz	
	2. classify the various types of clinical trials	A	Quiz	
	3. understand the ethical issues of clinical trials	D, E	Quiz, Presentation	
	4. do randomization for a clinical trial using SAS	B, C, D	Quiz	
	5. determine sample size and power calculation using SAS	B, C, D	Quiz	
	6. analyze clinical trial data using SAS	B, C, D	Quiz	
	7. address missing data issues in clinical trials	A, B, C, D	Quiz	
	8. report and interpret findings from clinical trials	A, D	Quiz	
	9. report and interpret findings from clinical trials	A, D, E	Individual Project	

* **Assessment Types:** Quiz, Web quest, Journal/Blog, Discussion Board, Written Assignment, Exam (including essays), Poster, Individual Project, Group Project, Group Presentation, Case Study, Research Paper, Demonstration/Simulation and Other

Additional Course Information

Reference List

Other Information

Course Policies

Attendance

Course Meeting Schedule: Tuesdays: 11:00 AM – 1:45 PM.

Students are expected to attend class unless they are ill or make prior arrangements with the instructor.

See Institutional Policies for Emergency Preparedness for Academic Continuity.

Class Participation

This course will consist of in class lectures, group discussion and student clinical trial project reports. The course is intensive and will require students to read substantial amount of course materials prior to class, review the lecture notes and complete homework assignments.

Institutional Policies

Academic Integrity of Students

Academic integrity is the foundation of the University of South Florida System's commitment to the academic honesty and personal integrity of its university community. Academic integrity is grounded in certain fundamental values, which include honesty, respect, and fairness. Broadly defined, academic honesty is the completion of all academic endeavors and claims of scholarly knowledge as representative of one's own efforts. The final decision on an academic integrity violation and related academic sanction at any USF System institution shall affect and be applied to the academic status of the student throughout the USF System, unless otherwise determined by the independently accredited institution.

Disruption to Academic Process

Disruptive students in the academic setting hinder the educational process. Disruption of the academic process is defined as the act, words, or general conduct of a student in a classroom or other academic environment which in the reasonable estimation of the instructor: (a) directs attention away from the academic matters at hand, such as noisy distractions, persistent, disrespectful or abusive interruption of lecture, exam, academic discussion, or general University operations, or (b) presents a danger to the health, safety, or well-being of self or other persons.

Student Academic Grievance Procedures

The purpose of these procedures is to provide all undergraduate and graduate students taking courses within the University of South Florida System an opportunity for objective review of facts and events pertinent to the cause of the academic grievance. An "academic grievance" is a claim that a specific academic decision or action that affects that student's academic record or status has violated published policies and procedures, or has been applied to the grievant in a manner different from that used for other students.

Disability Access

Students with disabilities are responsible for registering with Students with Disabilities Services (SDS) in order to receive academic accommodations. SDS encourages students to notify instructors of accommodation needs at least 5 business days prior to needing the accommodation. A letter from SDS must accompany this request.

Sexual Misconduct/Sexual Harassment Reporting

USF is committed to providing an environment free from sex discrimination, including sexual harassment and sexual violence (USF System Policy 0-004). The USF Center for Victim Advocacy and Violence Prevention is a confidential resource where you can talk about incidents of sexual harassment and gender-based crimes including sexual assault, stalking, and domestic/relationship violence. This confidential resource can help you without having to report your situation to either the Office of Student Rights and Responsibilities (OSSR) or the Office of Diversity, Inclusion, and Equal Opportunity (DIEO), unless you request that they make a report. Please be aware that in compliance with Title IX and under the USF System Policy, educators must report incidents of sexual harassment and gender-based crimes including sexual assault, stalking, and domestic/relationship violence. If you disclose any of these situations in class, in papers, or to me personally, I am required to report it to OSSR or DIEO for investigation. Contact the USF Center for Victim Advocacy and Violence Prevention: (813) 974-5757.

Other Institutional Policies and Resources

Download other Institutional Policies and Resources at: https://tinyurl.com/ya32b32x

Please note: The information in this syllabus is subject to change, as needed, by the instructor. You will be notified of any changes via an announcement on the course site or e-mail. It is your responsibility to keep up with any changes.