PHP 2030: Clinical Trials Methodology
Fall Semester, 2017
M 1:00-3:30 PM
121 S. Main Rm 247

Instructor:	Ilana Gareen
Office Hours:	By appointment
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Prerequisites:	(PHP 2120 or 2150) and (PHP 2508, 2510 or 2520)
Description:	We will examine the modern clinical trial as a methodology for evaluating interventions related to treatment, rehabilitation, prevention and diagnosis. Topics include the history and rationale for clinical trials, ethical issues, study design, protocol development, sample size considerations, quality assurance, statistical analysis, systematic reviews and meta-analysis, and reporting of results.
Goals:	Students will learn how to design a clinical trial. They will be able to identify methods to limit study biases, and they will develop a clinical trials protocol.
Time expectations for this Course:	Over 14 weeks, students will spend 2.5 hours per week in class (35 hours total). Required reading for the seminar meetings in expected to take up approximately 7 hours per week (98 hours). In addition, work on the study protocol completed as part of this class, which includes preparing to discuss elements of your protocol each week, as well as preparing a protocol abstract, outline, and final complete protocol, is estimated at approximately 50 hours over the term.
Competencies:	• Design a research study that can appropriately and efficiently examine an epidemiologic research question of interest; write and submit a proposal to support this research) • Develop strong understanding of what scientific misconduct is and the impact unethical conduct can cause within and outside of the research community

Required Textbook: Friedman L, Furberg C, Demets D: Fundamentals of Clinical Trials, 5th Edition, Springer.

Available on Amazon: https://www.amazon.com/Fundamentals-Clinical-Trials-Lawrence-Friedman/dp/3319185381/ref=sr_1_1?ie=UTF8&qid=1503348373&sr=8-1&keywords=clinical+trials+friedman

Requirements:

Homework/Class participation	10%
Mid-term exam	20%
Final exam	30%
Research Proposal (detailed description distributed separately)	40%

Date	Subject	Reading	Discussion Question/Assignment
9/11/2017	Introduction to Clinical Trials Methodology	Canvas Reading Module: 1)Why we need clinical trials Text: *Friedman et al. Chapters 1,2, 3*	--
9/18/2017	Framing the Research Question and Study Design 1	Canvas Reading Module: 1)Study Design 2) Ethical Issues Text: *Friedman et al. Chapter 4*	**What is your Research Question? (Discuss your intervention, outcomes, and hypothesized effect)**
9/25/2017	Framing the Research Question and Study Design 2	Canvas Reading Module: 1) External Validity/Generalizability Text: *Friedman et al. Chapters 5*	**What is your study population? (Discuss why you have chosen this population, pros and cons of your choice)**
10/2/2017 BEFORE CLASS	**Abstract of proposed study, including background, specific aims, brief description of methods**		
10/2/2017	Study Population and Methods to Reduce Bias	Canvas Reading Modules: 1) Randomization Text: *Friedman et al. Chapters 6*	**What is your specific aim?**
10/9/2017	Fall Break	--	**--**
10/9/2017 BEFORE CLASS	**Specific Aims, Background and Significance sections and detailed outline of study design from Study Protocol Due**		
10/16/2017	Study Population and Methods to Reduce Bias 2 Sample Size Considerations 1	Canvas Reading Modules: 1) Blinding Text: *Friedman et al. Chapters 7,8*	**What are 3 features of your study design that you will use to control potential biases?**
10/23/2017	First half of class: Mid-term Second half of class: Sample Size Considerations 2	--	**Midterm**
10/30/2017	How am I going to do that-Part I	Canvas Reading Module: 1) Data collection and management 2) Endpoint Ascertainment 3) Audit and Monitoring Text: *Friedman et al. Chapters 9,11*	**How do you plan to collect your intervention data? How do you plan to collect your outcomes data?**
11/6/2017	How am I going to do that-Part II	Canvas Reading Module: 1) Recruitment 2) Adherence 3) Audit and Monitoring 4) Data Safety and Monitoring Boards Text: *Friedman et al. Chapters 10,14*	**Identify an approach that you will use to enhance recruitment and an approach that you will use to enhance adherence.**
11/13/2017	QoL, Pragmatic Trials, Multi-Center Trials Meta-analyses,Comparative Effectiveness Research	Canvas Reading Module: 1) PROs 2) CER Text: *Friedman et al. Chapters 13,20*	**How do you plan to analyze your data?**
11/20/2017	Use of Survival Analysis in Clinical Trials and Sample Size Considerations	Text: *Friedman et al. Chapters 15,16*	**Limitations of your study design?**
11/22/2017	**Final Version of Protocol Due**		
11/27/2017	Analysis and Reporting of Clinical Trials	Canvas Reading Module: 1) ITT 2) Reporting Text: *Friedman et al. Chapters 17,19*	
12/4/2017	Class Presentations		
12/11/2017	Class Presentations (if needed)	--	**--**
12/16/2017	Final Exam 9:00 AM	--	**--**