Overview and Objectives: The Special Topics in Clinical Trials course will provide information on the different types of clinical trials beyond the Phase III superiority parallel group design. We will use manuscripts on special types of clinical trials to facilitate learning of concepts discussed in class.

Competencies:
Because the majority of class sessions will be spent learning about different types of trials from the literature, the overarching competencies covered in this course are:

- **Problem Formulation:** Critically review published studies that use various research methodologies and identify possible sources of bias and potential health disparities therein.
- **Methodology:** Design basic features of research protocols based on specific research questions, appropriately addressing bias.

The homeworks and final project will also help you develop competence in:

- **Written Communication:** Prepare written presentations of research at a variety of stages to a range of audiences, technical and non-technical, and respond to constructive criticism and questions.

Responsibilities:
There will be reading assignments on selected articles and guidelines. Students will be assigned written exercises that will be graded. All homework assignments will be assigned with a due date. There will be a final project that will involve your critical review of specific aspects of a “special” clinical trial that has been recently completed or is ongoing at the University of Pittsburgh. You are encouraged to work together on class projects and homework assignments, but you should write up your results individually, i.e. very similar papers will not be accepted. Attendance and participation in class are required. Evaluation criteria will be based on completion of the writing assignments, completion of the final project, and attendance of meetings with instructors.

**Course Requirements**

- Class attendance 5%
- Written assignments 65%
- Final project 30%

**Course Grading Scale:**
For the computation of the final course grade as well as for the course assignments, the following grading scale will be used:

- A+ >95%
- B+ 88-89%
- C 70-79%
- A 92-95%
- B 82-87%
- D 60-69%
- A- 90-91%
- B- 80-81%
- F <60%
NOTE: Homework assignments, course information, and communication will be available at http://courseweb.pitt.edu.


**Other highly recommended textbooks to be used as references:**
- Clinical Trials: A Practical Approach, 1996, Stuart J. Pocock, John Wiley & Sons
- Clinical Trials: Design, Conduct, and Analysis, 1986 Curtis L. Meinert, Oxford
- Clinical Trials: A Methodologic Perspective, 2005, Steven Piantadosi, John Wiley & Sons
# Course Syllabus

## Session 1
- Intro to course and final project
- Crossover Trials
- Equivalence Trials

### Required readings:
1. Reed JF. Analysis of two-treatment, two period crossover trials in emergency medicine. 2004; 43(1) 54-58.
2. Pocock *Clinical Trials: A practical approach* Chapter 8: Crossover Trials

### Supplemental Readings:

### Homework Assignment 1: Due Session 2.

## Session 2
- Pediatric trials and minority recruitment
- Trauma Surgery Trials

### Supplemental Reading:
1. Federal Register volume 61, no 192, page 51498 (Informed consent in emergency medical interventions)

### Homework Assignment 2. Due Session 3

## Session 3
- Physical Therapy and Exercise Trials
- Complementary and Integrative Medicine

### Homework Assignment 3: Due Session 4

## Session 4
- Critical Care/Pediatrics Trial
- Trials in Adolescent Medicine

### Homework Assignment 4: Due Session 5
### Session 5
**Group Randomized Trials**
**Behavioral medicine interventions**

**Required readings:**
1. Friedman, Furberg, and DeMets text: pp 119-122.

**Supplemental Readings:**

**Homework Assignment 5: Due Session 6.**

### Session 6
**Small clinical trials and trials for rare diseases**
**Pragmatic and CER trials**

**Homework Assignment 6: Due Session 7**

### Session 7
**Presentation of individual projects**

**Homework Assignment 7: Due Session 8**

### Session 8
**Presentation of individual projects**