Overview and Objectives: 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.

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 which will involve writing a study protocol for 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%
- A 92-95%
- A- 90-91%
- B+ 88-89%
- B 82-87%
- B- 80-81%
- C 70-79%
- D 60-69%
- 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 and Equivalence Trials*

**Required readings:**
1) Pocock Chapter 8: Crossover Trials  

**Supplemental Readings:**

**Homework Assignment 1:** Find examples of a crossover trial and an equivalence or non-inferiority trial. Describe each trial with respect to each of the items: (1) Title (2) Objective (3) Interventions (4) Design and Participants (5) Primary outcome (6) Results for primary outcome (7) Conclusions for primary outcome. Include the full citation and abstract for each trial.

### Session 2
**Emergency Medicine trials**

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

**Homework Assignment 2:** Find examples of a surgical trial and an emergency medicine trial (including prehospital). Describe each trial with respect to each of the items: (1) Title (2) Objective (3) Interventions (4) Design and Participants (5) Primary outcome (6) Results for primary outcome (7) Conclusions for primary outcome. Include the full citation and abstract for each trial.

**Homework 1 is due.**

### Session 3
**Group Randomized Trials**
*Complementary and Alternative Medicine*

**Homework Assignment 3:** Find examples of a complementary and alternative medicine trial and a group/cluster randomize trial. Describe each trial with respect to each of the items: (1) Title (2) Objective (3) Interventions (4) Design and Participants (5) Primary outcome (6) Results for primary outcome (7) Conclusions for primary outcome. Include the full citation and abstract for each trial.

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

**Supplemental Readings:**

### Session 4

**Small clinical trials and trials for rare diseases**

**Small group discussions of trials**

#### Homework Assignment 4:
Find two trials from two rare diseases from the NIH Office of Rare Diseases Research [http://rarediseases.info.nih.gov/RareDiseaseList.aspx?PageID=1](http://rarediseases.info.nih.gov/RareDiseaseList.aspx?PageID=1). Describe each trial with respect to each of the items: (1) Title (2) Objective (3) Interventions (4) Design and Participants (5) Primary outcome (6) Results for primary outcome (7) Conclusions for primary outcome. Include the full citation and abstract for each trial.

**Homework Assignments 2 and 3 are due.**

### Session 5

**Behavioral medicine interventions**

**Pediatric trials and minority recruitment**

#### Homework Assignment 5:
Find examples of a behavior medicine trial and a pediatric trial. Describe each trial with respect to each of the items: (1) Title (2) Objective (3) Interventions (4) Design and Participants (5) Primary outcome (6) Results for primary outcome (7) Conclusions for primary outcome. Include the full citation and abstract for each trial.

### Session 6

**Oncology Trials**

**Critical Care/Pediatrics Trial**

#### Required

**Homework Assignment 6**: Find an example of an oncology trial and a critical care medicine trial. Describe the trial with respect to each of the items: (1) Title (2) Objective (3) Interventions (4) Design and Participants (be sure to fully describe the unit of randomization versus the unit of analysis) (5) Primary outcome (6) Results for primary outcome (7) Conclusions for primary outcome. Include the full citation and abstract for each trial.

**Homework Assignments 4 and 5 are due.**

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<th>Session 7</th>
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**Homework Assignment 7**: Find examples of a women’s health trial and an exercise or physical therapy trial. Describe each trial with respect to each of the items: (1) Title (2) Objective (3) Interventions (4) Design and Participants (5) Primary outcome (6) Results for primary outcome (7) Conclusions for primary outcome. Include the full citation and abstract for each trial.

| Session 8 | Presentation of individual module 3 projects |