

**Biostatistics 619
Clinical Trials
Fall 2008**

Instructor: Dr. Thomas Braun
Time: Friday 10:00am - noon
Location: M1152 SPH II
Class will NOT be held on:
10/03 (Biostat Faculty Retreat)
11/28 (Thanksgiving Break)
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Phone: (734) 936-9844
Office Hours: Friday 9:00am-10:00am or by appointment
Course Homepage: On Ctools

Description: This course will explore a variety of aspects related to design and analysis of randomized clinical trials that most biostatisticians will encounter in their careers.

Pre-requisites: Completion of, or concurrent enrollment in, Biostatistics 601.

Textbooks: There is no required textbook for this class. The following four textbooks are recommended as good general references for the material discussed in this class:
(1) *Fundamentals of Clinical Trials*, Third Edition, by Laurence M. Friedman, Curt D. Furberg, & David L. DeMets
(2) *Clinical Trials: A Methodologic Perspective*, Second Edition by Steven Piantadosi
(3) *Introduction to Statistical Methods for Clinical Trials* by Thomas D. Cook and David L. DeMets
(4) *Introduction to Randomized Controlled Clinical Trials*, Second Edition, by John N.S. Matthews

Software: We will be programming with the statistical package *R*.

Course Objectives:

After completion of this course, a student can ordinarily expect to be able to:

- 1) Differentiate clinical trials from other types of research on humans
- 2) Understand and explain the different stages of clinical trial research

- 3) Understand and explain hallmarks of Phase III clinical trials
- 4) Create source code and interpret output for clinical trial simulations in *R*
- 5) Understand how to derive sample size formulae for a variety of clinical trial settings
- 6) Critically review and evaluate published clinical trial results

Grading:

Homework 50%

Two or three homework assignments will occur throughout the semester. Assignments will consist of a variety of problems including data analysis, computer simulations, and/or questions about a published manuscript.

Selected topics from the homework will be discussed in class each week. Students are expected to volunteer answers but I will call on students if needed.

Final Group Project 50%

The final project will be a group project in which each group will propose and design a clinical trial in a specific disease, as well as present this work orally to the rest of the class on the final day of class.

UM-SPH Standard of Academic Conduct:

The faculty of the School of Public Health believes that the conduct of a student registered or taking courses in the School should be consistent with that of a professional person. Courtesy, honesty, and respect should be shown by students toward faculty members, guest lecturers, administrative support staff, and fellow students. Similarly, students should expect faculty to treat them fairly, showing respect for their ideas and opinions and striving to help them achieve maximum benefits from their experience in the School.

Student academic misconduct refers to behavior that may include plagiarism, cheating, fabrication, falsification of records or official documents, intentional misuse of equipment or materials (including library materials), and aiding and abetting the perpetration of such acts. The preparation of reports, papers, and examinations, assigned on an individual basis, must represent each student's own effort. Reference sources should be indicated clearly. The use of assistance from other students or aids of any kind during a written examination, except when the use of aids such as electronic devices, books or notes has been approved by an instructor, is a violation of the standard of academic conduct.