Biost 524
Design of Medical Studies

Syllabus
Spring, 2010

Instructor : Scott S. Emerson, M.D., Ph.D.
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Assistant : Tanya Granston (granston@uw.edu)
Office hours : TBA

Time and Place : Lectures : MW 8:00 - 9:20 HSB T625

Class Web Pages: http://www.emersonstatistics.com/b524/

The web page will be used to post notices, handouts, etc. I urge you to check this site regularly. Questions that are submitted to me (via email or otherwise) that I think might be of general interest will have their answers posted on the web page, as well.

Prerequisites : Biost 511 or 517
(or permission of instructor)

Texts:
Required : Friedman LM, Furberg CD, and DeMets DL: *Fundamentals of Clinical Trials*, 3rd ed. Mosby-Year Book, Inc., St. Louis, Missouri.
Recommended : Pocock SJ: *Clinical Trials: A Practical Approach*, Wiley and Sons, New York.

Attendance : Lectures : Highly recommended (but they will be recorded)

Assignments : Written homeworks (approximately 3-4) and a final project.

Homework problems requiring a written solution will be due approximately every two-three weeks. Students are encouraged to seek help from the instructor, the TAs or other students with the written homework problems. However, the work that is handed in should reflect only that student's work. We reserve the right to grade only selected portions of the written homework.

Grading :

Written homeworks	10%
Project (proposal)	75%
Project (site visit)	15%

Project:

There will be one major course project. Students will be grouped into research teams which will consist of up to 5 students and will be heterogeneous with respect to area of specialization (e.g., clinical, epidemiologic, biostatistical). Each research team will respond to a Request for Proposal (RFP) by

writing a grant application which recommends and justifies a study design, monitoring plan, and plan for analysis of the data. As a part of this project, each team will also "site visit" the application of another research group.

Course Objectives

This course will provide an introduction to the design of medical studies, with emphasis on the design of randomized, controlled clinical trials. Topics to be covered include: ethics, selection of comparison group, eliminating bias, reducing variability, selecting eligibility criteria, choice of endpoints, determining sample size, compliance issues, monitoring of trials, interpreting results, protocol definition. At the end of Biost 524 a student should have made significant progress toward being able to:

1. Critique the design and plans for monitoring and analyzing a randomized clinical trial.
2. Design a clinical trial to address an important scientific problem, including
   a. addressing the key issues that must be considered in developing informed consent forms,
   b. defining an interventional treatment in a manner that can be tested in a clinical trial,
   c. selecting an appropriate comparison group and specifying the scheme by which treatment assignment will occur,
   d. defining eligibility criteria,
   e. defining primary and secondary endpoints for measures of treatment outcome,
   f. defining methods for data collection and management,
   g. specifying methods for analysis of the results, and
   h. justifying the sample size requirements for the study.

I welcome student suggestions regarding ways in which these goals can be best achieved. If you have questions regarding the content or structure of the class, please feel free to talk (or write) to me at any time during the quarter.