

New Biostatistics Course

# STAT 6390 - Statistical Methods in Clinical Trials

*Spring 2005*

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## What it is all about:

A **clinical trial** is a research study on human volunteers to answer specific health questions. Carefully conducted clinical trials are the fastest and safest way to find effective treatments and deliver them to people.

With respect to the ethical treatment of research participants, current U.S. regulations require that clinical trials are designed in such a way that "*risks to subjects are reasonable in relation to anticipated benefits*".

To minimize the risk of participants, most clinical trials are designed **sequentially**. That is, results are being monitored, and the optimal continuation of the trial - the optimal treatment allocation, dosage, and other conditions - are selected based on the interim analysis. For example, sequential design allows a treatment arm or the entire trial to be stopped early if there is clear evidence of unacceptable adverse effects.

This course will discuss standard sequential statistical methods used in design and analysis of clinical trials. We start by discussing fundamental concepts of clinical trials and introducing [Sequential Analysis](#) as a general subject and proceed to study sequential hypothesis testing for treatment comparison, evaluation of probabilities of Type I and Type II errors, sequential methods for binary data and survival data that often appear in clinical research.

This is not meant to be the first course in Statistics. I will assume undergraduate knowledge of Probability and Mathematical Statistics (see prerequisites below).

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## Where and when:

*Time:* MW 5<sup>30</sup> - 6<sup>45</sup> pm

*Room:* CB 1.112

*Instructor:* Michael Baron

*Office:* ECSN 3.912

*Email:* mbaron@utdallas.edu

*Phone:* 972-UTD-6874

*Text:* *Group Sequential Methods with Applications to Clinical Trials*  
by C. Jennison and B. Turnbull, Chapman & Hall/CRC, 2000

**Prerequisite:** STAT 4351/4352 or 5351/5352 or equivalent courses in Probability and Mathematical Statistics at a senior undergraduate or low graduate level.

Not sure? Talk to the instructor.

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## In the end of the day:

The grade consists of:

Quizzes	35 %	Weekly close-book quizzes will cover the material of the preceding week and the corresponding homework assignment. Each quiz will consist of 1 short problem for 10-15 minutes.
Homework	0 %	Homework will be assigned but will not be collected or graded. Answers will be provided, solutions will be discussed.
Midterm exam	25 %	A 1 <sup>1/4</sup> -hour midterm is scheduled on 03/02/05.
Final exam	40 %	A 2 <sup>1/2</sup> -hour final covers the second half of the course but it is cumulative indirectly. Scheduled 04/27/05 at <b>5<sup>00</sup>pm.</b>
Both exams are open-book, -notes, etc. Plus, on each exam, you may skip one problem of your choice.		
90-100 % = A, 75-90 % = B, 55-75 % = C		

Michael Baron

2004-12-16