Statistics 252  
*Advanced Topics in Biostatistics: Clinical Trials*

**Lecture:** MW 1:10-2:30pm, Kerr 493  
**Instructor:** Rahman Azari  
367 Kerr Hall  
752-7709  
**Office Hours:** MWF 4:10-5:00pm, or by appointment  
752-7709  
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**Course Goals:** The course is primarily aimed at Ph.D. students, however, masters level students who are preparing for a career in biostatistics will also benefit from the course. The course will introduce basic statistical principals of clinical designs, including bias, randomization, blocking and masking along with practical applications of widely used designs, including dose-finding, comparative and cluster randomization designs. It will also cover advanced statistical procedures in relation to the analysis of data collected in clinical trials. The course requires methods from generalized linear models, and accordingly BST/STA 223 is a prerequisite. The course has strong methodological and applied components. The applied and computational components will be covered in a joint discussion/computing laboratory session to be held once per week. The course serves to prepare students for independent research in this area.

**Entry Level:** Prerequisite is course BST/STA 223 or consent of the instructor.

**Grading and Course Requirements:** Grading is based on homework assignments, projects and exams. Students receive a letter grade. Computing, applied data analysis projects, and presentation by students studying specific topics and analyzing data are an integral part of the course.

**References:** The course material is extracted from a variety of sources, including journals such as *Biometrics, Biometrika, Statistics in Medicine, Applied Statistics*, and the *New England Journal of Medicine*. Relevant reference books are:


**Computing:** The course emphasizes statistical computing. Students will become familiar with relevant statistical packages and will learn how to conduct appropriate analyses.
**Discussion/Lab:** In the discussion/lab section, a teaching assistant will, under the supervision of the instructor, support lecture materials by (i) presenting computational methods, including the use of statistical software, pursuant lecture material in computer laboratory sessions, (ii) giving and discussing assignments for computer laboratory work in computer laboratory sessions, (iii) presenting and discussing analyses of real data illustrating the statistical methodology discussed in class, and (iv) working theoretical problems similar to those assigned for homework, and answering questions related to lecture material and homework.

**Topical Outline:**

*Introduction* (1 lecture)

*Ethical Considerations* (1 lecture)

- Historical and modern perspectives
- Professional Ethics

*Basics of Designing Clinical Trials* (2 lecture)

- Design concepts
- Clinical trial design types
- Bayesian view

*Bias and Random Errors* (2 lecture)

- Random errors
- Clinical and statistical biases

*Objectives and Endpoints* (1 lecture)

- Objectives and endpoints in different trials

*Sample Size, Power and study cohort* (3 lectures)

- Relation between power and sample size
- Sample size for different trials
- Simulations

*Data-Dependent Stopping* (1 lecture)

- Likelihood, frequentist and Bayesian methods
Treatment Allocation (1 lecture)

Types of randomization for treatment allocation

Analysis of Data Collected in Clinical Trials (Part I) (3 lectures)

Statistical methods used for analysis of data collected in clinical trials

Reporting (1 lecture)

Quality and contents of clinical trial reports
Authorship

Special Designs (3 lectures)

Factorial designs
Cross-over designs
Sequential designs

Cluster randomization (6 lectures)

Historical development
Planning a cluster randomization trial
Sample size and power

Analysis of Data Collected in Clinical Trials (Part II) (3 lectures)

Statistical methods for analysis of cluster randomized data

Exams and Review (2 lectures)

Homework: Homework and readings assignments will be given on a weekly basis.

Midterms: The midterm examination will be given on Wednesday, April 28.

Grading: HOMEWORK 20%, PROJECTS and PRESENTATIONS 30% MIDTERM 20%, FINAL 30%

Course Web Page: http://www.stat.ucdavis.edu/~azari/sta252