BIOSTAT 6615 – Design and Analysis of Clinical Trials  
(Crosslisted with PUBH-BIO 7215)  
2 semester hour course

**Conversion Note:** Converted from a 4 quarter hour course, with some material removed.

**Class Distribution:** Two 55 minute lectures per week

**Prereq:** Stat 5301 or Stat 528 and 529 or equivalent

**Exclusions:** No credit for students with Biostat 615 or PUBH-BIO 7215

**Course Description:** Design, monitoring, and analysis of clinical trials; includes protocol development, randomization schemes, sample size methods, and ethical issues.

**Text:** Introduction to Statistical Methods for Clinical Trials. By Thomas D. Cook and David L. DeMets. Chapman & Hall/CRC, 2008; or a comparable resource.

**Topics:**

1. Probabilistic concepts in medicine  
2. Regulatory systems and guidelines (ICH, FDA)  
3. Ethical considerations and choice of control groups (negative, active, positive)  
4. Phase I-IV trials;  
5. Study designs in medical research and sample protocol  
6. Statistical principles in designing clinical trial  
7. Randomized Control Trial (RCT)  
8. Sample size determination  
9. Efficacy and safety considerations  
10. Clinical endpoints (primary, secondary, surrogate)  
11. Superiority and non-inferiority studies  
12. Modeling concepts (dose-response)  
13. Covariate adjustment (baseline adjustment) and Intent To Treat analysis  
14. Hypothesis testing in clinical trials  
15. Pharmacogenomics (drug and device co-development)