BIOS 675 Clinical Trials and Intervention Studies

Catalog Description: A fundamentals course on issues in the design, operation and analysis of controlled clinical trials and intervention studies. Emphasis on randomized long-term multicenter trials. (3 units)

Course Topics:
- Randomization
- Experimental Design
- Analysis of Phase III Trials
- Missing Data
- Cluster RCTs
- Statistical Analysis
- Sample Size
- Monitoring
- Pilot and Feasibility Studies
- Phase I & Phase II Non-inferiority

Course Objectives: During this course, students will:
- Develop a foundation in the design, conduct, analysis and reporting of randomized trials and intervention studies.

Learning Outcomes (Competencies Obtained): Upon completion of this course students will be able to:

1. Describe the roles biostatistics serves in the discipline of public health
2. Apply basic informatics techniques and vital statistics and public health records in the description of public health characteristics and in public health research and evaluation
3. Communicate understanding of the assumptions necessary for a given statistical procedure as well as the ability to determine if the assumptions are met for a given dataset
4. Demonstrate the ability of communicate effectively in writing reports, giving oral presentations, and teaching basic statistic material in a formal classroom setting
5. Be capable of assuming positions of leadership in a career in academia, research, institutes, government, and/or industry
6. Identify appropriate statistical tools to address specific to address specific scientific questions
7. Select appropriate research designs to meet the needs of various studies, and be able to explain the limitations of implemented designs
8. Skillfully engage in statistical collaboration with mentors, colleagues, and clients
9. Demonstrate excellent presentation skills and the ability to explain statistical concepts and findings to a general scientific audience
10. Demonstrate understanding of methods of data analysis and data monitoring