DEPARTMENT: Biostatistics and Bioinformatics

COURSE NUMBER: BIOS 520    SECTION NUMBER:       EMESTER: Spring 2012

CREDIT HOURS: 2

COURSE TITLE: Clinical Trials Methodology

INSTRUCTOR NAME: Zhengjia (Nelson) Chen

INSTRUCTOR CONTACT INFORMATION

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SCHOOL ADDRESS OR MAILBOX LOCATION: WCI #B4110

OFFICE HOURS: By Appointment

BRIEF COURSE DESCRIPTION

This course provides an introduction to the fundamentals of clinical trials, including the design, conduct, analysis, and interpretation of trial results. Topic includes the state-of-the-art designs for contemporary Phase I, II, and III clinical trials, protocol writing, hypothesis, methods of randomization, blinding, sample size determination, ethics, subject recruitment, data collection, quality control, monitoring outcomes and adverse events, interim analysis, data analysis, issues with data analysis, reporting, interpreting results, and current advances in clinical trials.

LIST SCHOOL LEVEL, DEPARTMENT, AND/ OR PROGRAM COMPETENCIES

Assist medical and public health professionals in determining an appropriate research design for their research study
Estimate the appropriate sample size for conducting the study
Perform the appropriate statistical analyses of study data
Use computer statistical software for both data management and data analyses
Assist in the interpretation of study results
Interpret statistical results of biomedical studies effectively
Adhere to guidelines of responsible research
Assist in the development of new statistical methods as needed to address public health or medical problems
Apply existing statistical theory and methods to a broad range of medical or public health problems
Conduct appropriate statistical analyses for a broad range of applications
Communicate the results of statistical studies both orally and in writing to senior statisticians and other investigators
LIST LEARNING OBJECTIVES ASSOCIATED WITH THE COMPETENCIES

This course is intended to not only provide a basic grounding in all aspects of the conduct of clinical trials from the perspective of a biostatistician, but also teach students the state-of-the-art knowledge in clinical trials.

A student completing this course should be able to:

- Identify key operational requirements for a clinical trial before initiating it
- Effectively design a clinical trial and produce a clinical trial proposal
- Identify key operational requirements to monitor during a trial
- Collaborate effectively in the design and conduct of a trial
- Produce sample size estimation of a trial
- Design/evaluate safety and outcome monitoring plan
- Produce/evaluate statistical section of a clinical protocol
- Collaborate effectively in the analysis and reporting of a trial
- Critically evaluate clinical trial articles in medical literature
- Identify strengths and weaknesses in the design of a clinical trial from a study proposal

EVALUATION

- Attendance and participation (10%).
- Homework (50%): A total of 5 home works. Practice the materials taught in class. Due two week after assignment.
- Final group project (20%) (A protocol or a review): A final project presentation consists of 10-minute presentation and 5-minute questions. A final written project consists of maximum of 10 pages (double spaced) and is due on the day of presentation. Each student’s contribution to the project will be evaluated by group members and will be used to adjust for the grade from the final project.
- In class exam (20%): administered at the end of the course. 2-hour in class test with open book and notes. Consists of short answers and simple statistical computation.

ACADEMIC HONOR CODE

The RSPH requires that all material submitted by a student in fulfilling his or her academic course of study must be the original work of the student.