

Students requiring accommodations as a result of disability must contact the Centre for Students with Disabilities 778-782-3112 or csdo@sfu.ca

### Instructor: Dr. Joan Hu

## **Prerequisite:**

STAT 450 or permission of the instructor

# Textbook:

Recommended:

- 1. Fundamentals of Clinical Trials, L M Friedman, C D Furberg, and D L DeMets, Springer-Verlag, New York.
- 2. *Clinical Trials: A Methodologic Perspective*, Second Edition, Piantadosi S., New York, NY: John Wiley & Sons.
- 3. *Epidemiologic Methods: Studying the Occurrence of Illness.* T D Koepsell and N S Weiss, Oxford University Press.

## **Calendar Description:**

Principles, methods and applications of basic quantitative approaches in biomedical studies are presented. Topics include introduction to epidemiology; design of cohort and case-control studies; experimental versus observational data, and cross-sectional versus longitudinal studies; issues of confounding, causation and missing data; design of clinical trials; data monitoring and interim analysis.

## **Outline:**

- 1. History, concepts and terminology of epidemiology.
- 2. Measures of disease occurrence and association.
- 3. Design of medical studies: cohort and case-control studies; controlled clinical experiments.
- 4. Models and analysis in prospective and retrospective studies.
- 5. Confounding, causal diagrams, and missing data.
- 6. Clinical trial design principles: bias control, random error control, randomization, blocking, masking
- 7. Types of clinical trials: phases of trial, translational, dose-finding, cross-over, safety and efficacy, and comparative trials.
- 8. Study monitoring: sequential methods.

## **Grading Scheme:**

Assignments 50% Projects 50%

Students should be aware that they have certain rights to confidentiality concerning the return of course papers and the posting of marks. Please pay careful attention to the options discussed in class at the beginning of the semester. Students are reminded that Academic Honesty is a cornerstone of the acquisition of knowledge. Scholarly integrity is required of all members of the University. Students are encouraged to review policies pertaining to academic integrity available on Student Services webpage at <u>http://students.sfu.ca/academicintegrity.html</u>