## University of Manitoba Department of Statistics

## STAT 7240 T01, CRN 13211 Design and Analysis of Clinical Trials Fall 2013

**Instructor** Dr. Xikui Wang

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**Lecture Hours** Monday and Wednesdays 4:00 – 5:15 pm

**Office Hours** Mondays and Wednesdays 1:30 pm - 3:00 pm, or by appointment

**Description** The goal of this course is to lay solid foundation on ethical, statistical and logistical issues about designing and analyzing clinical trials. The

emphasis is on important methods of designing and analyzing response adaptive clinical trials. Topics include Phase I/II/III/IV trial designs, adaptive randomization, selection bias, response adaptive designs, large

sample inference, practical issues and open problems.

Prerequisites Consent of instructor. Good knowledge on stochastic processes,

frequentist and Bayesian statistics, and asymptotic statistics is essential.

**References**1. Clinical trial design – Bayesian and frequentist adaptive methods, by Guosheng Yin, John Wiley & Sons, New Jersey, 2012.

2. Randomization in clinical trials – theory and practice, by William F.

Rosenberger and John M. Lachin, John Wiley & Sons, 2002 3. *The theory of response-adaptive randomization in clinical trials*, by Feifang Hu and William F. Rosenberger, John Wiley & Sons, 2006

4. Publications on design and analysis of response adaptive clinical trials

**Evaluation** Assignments 30%

Project (Due 4 pm, Dec 17, 2013) 20%

Final Exam (2 – 4 pm, Dec 18, 2013, 316 Machray Hall) 50%

Academic dishonesty:

Plagiarism or any other form of cheating in the exams is subject to serious academic penalty. We wish to draw you attention to the university policy on academic dishonesty including 'plagiarism and cheating' and 'examination impersonation' as outlined in *The Undergraduate calendar*.

It is the responsibility of the student to know the rules! For details, see http://umanitoba.ca/science/undergrad/resources/webdisciplinedocuments.html