Biostatistics 619 – Clinical Trials
Fall 2014

Instructor:	Phil Boonstra, PhD
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Time:	Fridays, 10am–12pm
	There will be no class on Nov. 28
Location:	M1112, SPH II
Office Hours:	Fridays, 1–3pm

Course Description: This is a two-credit Master's level course focusing on statistical concepts and issues related to the design, conduct, and analysis of clinical trials.

Co/pre-requisite: Students must have completed or currently be enrolled in Biostatistics 601 or a similar graduate level course covering an introduction to distributional theory.

Topics covered: Phase I (dose-escalation, including algorithmic and model-based designs), Phase II (early stopping, randomization, biomarkers), Phase III (randomization, interim analyses, sample size determination), paying close attention to current issues and debates. Also, we will cover how to use statistical software to simulate and analyze data from clinical trials.

Grading: Assessment will be based on 4-5 homework assignments (60%), occasional very brief, pre-announced quizzes (10%), group presentations on a recently published clinical trial or discussion paper regarding clinical trial methodology (15%), and class attendance/participation (15%). There will be no final exam or project.

Textbooks: *None required.* Some material covered in lectures will be based on content from:

Optional
$\begin{cases}\end{cases}$
· Senn, Stephen. *Statistical Issues in Drug Development*, 2nd ed. (2008)
· Cook, Thomas D. and DeMets, David L. (Editors) *Introduction to Statistical Methods for Clinical Trials*, (2007)
· Piantadosi, Steven. *Clinical Trials A Methodologic Perspective*, 2nd ed. (2005)

Software: I will teach with (and, as best as I can, offer help with) the `R` language and environment, which is freely available at `http://cran.us.r-project.org/`.

Core Public Health Competencies:

1. Describe the roles biostatistics serves in the discipline of public health.
2. Describe preferred methodological alternatives to commonly used statistical methods when assumptions are not met.
3. Distinguish among the different measurement scales and the implications for selection of statistical methods to be use d based on these distinctions.
4. Apply descriptive techniques commonly used to summarize public health data.
5. Apply common statistical methods for inference.
6. Apply descriptive and inferential methodologies according to the type of study design for answering a particular research question.
7. Interpret results of statistical analyses found in public health studies.
8. Develop written and oral presentations based on statistical analyses for both public health professionals and educated lay audiences.

Biostatistics MS Competencies:

9. Develop knowledge to communicate and collaborate effectively with scientists in a variety of health-related disciplines to which biostatistics are applied
10. Become well-versed in the application of core statistical and 4-5 selected statistical specialization techniques.
11. Select appropriate techniques and apply them to the processing of data from health studies.
12. Interpret the results of statistical analysis and convert them into a language understandable to the broad statistical community.
13. Develop written and oral presentation skills and other scientific reporting skills, based on statistical analyses for public health, medical and basic scientists and educated lay audiences.

UM-SPH Standard of Academic Conduct:
The faculty of the School of Public Health believes that the conduct of a student registered or taking courses in the School should be consistent with that of a professional person. All students should demonstrate courteous, honest, and respectful behavior with all faculty members, guest lecturers, administrative

support staff, and fellow students. Similarly, students should expect faculty to treat them fairly, showing respect for their ideas and opinions and striving to help them achieve maximum benefits from their experience in the School.

Student academic misconduct refers to behavior that may include plagiarism, cheating, fabrication, falsification of records or official documents, intentional misuse of equipment or materials (including library materials), and aiding and abetting the perpetration of such acts. The preparation of reports, papers, and examinations, assigned on an individual basis, must represent each student's own effort. Reference sources should be indicated clearly. The use of assistance from other students or aids of any kind during a written examination, except when the use of aids such as electronic devices, books or notes has been approved by an instructor, is a violation of the standard of academic conduct.