

FUNDAMENTALS OF CLINICAL TRIALS

BIostatistics 540A

YALE UNIVERSITY, FALL 2017

Lectures Thursdays, 10:00 AM – 11:50 AM – LEPH 101
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Office Hours 9:30 – 10:30 Tuesday, 11:00-12:00 Wednesday
47 College St, Room TBA

Session	Date	Topic
1	08/31/17	Protocol design. Background of clinical trials.
2	09/07/17	Randomization. Stratification (I).
3	09/14/17	Stratification (II). Endpoints. Introduction to study designs.
4	09/21/17	Sample size estimation.
5	09/28/17	Additional considerations in sample size.
6	10/05/17	Design of non-inferiority trials.
	10/12/17	Midterm exam – In class during the usual class time.
7	10/19/17	No class (Professional Skills Workshop) (1st year MPH students)
8	10/26/17	Counting and attributing events in clinical trials. Analysis of time-to-failure data (I).
9	11/02/17	Analysis of time-to-failure data (II)/covariate adjustment.
10	11/09/17	Survival Analysis. Time-dependent covariates
11	11/16/17	Missing data analysis and the Institute of Medicine Report.
	11/23/17	Fall Recess- No Class.
12	11/30/17	Methods for early termination. Data Monitoring Committees
13	12/07/17	Analysis of longitudinal data with SAS. Propensity score analysis
	12/14/17	Final exam – In class during the usual class time.