Course Syllabus:

**Adaptive Randomized Trial Designs**  
140.850, 4th Quarter, 2011  
Johns Hopkins Bloomberg School of Public Health

Instructor: Michael Rosenblum  
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**Dates:** March 28, April: 1, 4, 11, 15, 18, 22. (Note April 8 is excluded.)  
**Time:** 10:30AM-11:50AM.  
**Room:** W2009

3 credits  
(All are invited to attend, even if not taking for credit.)

**Summary:**  
The course will give an overview of adaptive randomized trial designs. The aim of the course is to familiarize students with the advantages, limitations, and open problems in adaptive randomized trial designs.

**Assignment:** There will be a single assignment for those taking the course for credit—to complete one of the following:  
1) Conduct simulations comparing two or more existing adaptive designs.  
2) Propose a novel adaptive design and compare to existing designs,  
(where comparison is via simulation or asymptotic results, you choose).  
3) Use the clinical trials database [http://clinicaltrials.gov](http://clinicaltrials.gov) to investigate how often different adaptive design types are used, and under what settings. E.g. searching under the term “adaptive design” yields 42 clinical trials; you could classify these by type of adaptation, Phase of the trial, and condition type.

The project is not meant to be onerous, just a chance to experiment with the ideas we discuss. It should be written up in at most four pages, single spaced, 12 point font.

Readings (The date below indicates when the papers will be discussed.):  

**All papers are available on the course website given above.**

**March 28:** Overview of Adaptive Randomized Trial Designs: Some Skeptics’ Perspectives

[N.B. There is no expectation that the following two papers will be read before the first class meeting.]


**April 1:** U.S. FDA Guidances. Adapting Randomization Probabilities


**April 4:** Adapting Randomization Probabilities


**April 11:** Adapting Sample Size


**April 15:** Seamless Phase II/III Designs


April 18: Adapting Hypothesis Tested


April 22: Bayesian Designs


Rosner, GL, and Bekele, BN
Bayesian Designs in Clinical Trials

Giles, FJ, Kantarjian, HM, Cores, JE, Garcia-Manero, G, Verstovsek, S, Faderl, S et al. (2003) Adaptive Randomized Study of Idarubicin and Cytarabine Versus Troxicitabine and Cytarabine Versus Troxicitabine and Idarubicin in Untreated Patients 50 Years or Older With Adverse Karyotype Acute Myeloid Leukemia