

Department of Applied Mathematics and Statistics
The Johns Hopkins University
and
Department of Biostatistics
Johns Hopkins Bloomberg School of Public Health

JOINT SEMINAR

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October 1, 2009
111 Mergenthaler Hall
Refreshments: 3:30 p.m.
Seminar: 4:00 p.m.

**OPTIMIZING GROUP SEQUENTIAL DESIGNS THAT ALLOW CHANGES
TO THE POPULATION SAMPLED BASED ON INTERIM DATA**

ABSTRACT

We consider randomized trials in which the composition of the population sampled may be changed during the course of the trial, in response to data already collected. Such designs can have greater probability of demonstrating effectiveness of a treatment, compared to static designs, when it is initially uncertain in which subpopulations a treatment will be most effective. However, in allowing such data-dependent changes to the population sampled, care must be taken to ensure family-wise Type I error is controlled. We give a general method for constructing trial designs that (i) allow for changes (based on a prespecified decision rule) to the population sampled based on interim data, (ii) make no model assumptions, and (iii) guarantee asymptotically correct, family-wise Type I error.

(This is joint work with Mark van der Laan.)