# STATISTICS SEMINAR
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## Master's Defense
Wednesday, December 10, 2014
Dickens Hall 302, 3:30 p.m.

## A STATISTICAL INVESTIGATION INTO NONINFERIORITY TESTING FOR TWO BINOMIAL PROPORTIONS

In clinical research, noninferiority trials are becoming an important tool for investigating whether a new treatment is useful. The outcome measured can be either continuous (e.g. blood pressure level), time-to-event (e.g. days until heart attack), or binary (e.g. death). Rather than showing that the new treatment is superior to an active control, i.e. standard drug or treatment already available, one tests whether the new treatment is not meaningfully worse than the active control.

Here we consider a binary outcome such as success or failure following an intervention. Evaluation of the treatment relative to control becomes a comparison of two binomial proportions; without loss of generality it will be assumed the larger the probability of success for an intervention the better. Simulation studies under these assumptions were programmed over a variety of different sample sizes and true population proportions to determine the performance between asymptotic noninferiority methods based on calculations of risk differences (with and without a continuity correction), relative risks, and odds ratio from two independent samples. Investigation was done to compare type I error rates, power when true proportions were exactly the same, and power when the true proportion for treatment group was less than the control, but not meaningfully inferior. Simulation results indicate most analysis methods have comparable type I error rates, however the method based on relative risk has higher power under most circumstances. Due to the ease of interpretation with the relative risk, its use is recommended for establishing noninferiority of a binomial proportion.