Sample Size for Equivalence Trials: 
A Case Study from a Vaccines Lot Consistency Trial

For some trials, simple but subtle assumptions can have a profound impact on the size of the trial. A case in point is a vaccine lot consistency (or equivalence) trial. Standard sample size formulas used for designing lot consistency trials rely on only one component of variation, namely, the variation in antibody titers within lots. The other component, the variation in the means of titers between lots, is assumed to be equal to zero. In reality, some amount of variation between lots, however small, will be present even under the best manufacturing practices. Using data from a published lot consistency trial we demonstrate that when the between-lot variation is only 0.5% of the total variation the increase in the sample size is nearly 300% when compared to the size assuming that the lots are identical. The increase in the sample size is so pronounced that in order to maintain power one is led to consider a less stringent criterion for demonstration of lot consistency. The appropriate sample size formula that is a function of both components of variation is provided. We also discuss the increase in the sample size due to correlated comparisons arising from 3 pairs of lots as a function of the between-lot variance.

Thursday, November 15, 2012
4:00 p.m. — 203 TMCB

Faculty and graduate students are invited to meet with Allen Izu at a reception held before the seminar at 3:30 p.m. in 235 TMCB.