

CALIFORNIA STATE UNIVERSITY, LONG BEACH

THE MATHEMATICS COLLOQUIUM

Presents

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Speaking on

*Determination of Sample Sizes for Demonstrating Efficacy
of Radiation Countermeasures*

Friday, February 27, 2009 10:30am – 11:30am

FO3-200A

Abstract:

In response to the ever increasing threat of radiological terrorism, active development of non-toxic new drugs and other countermeasures to protect against and/or mitigate adverse health effects of radiation is ongoing. Although the classical LD_{50} *estimation* study used for many decades as a first step in preclinical toxicity testing of new drugs has been largely replaced by experiments that use fewer animals, the conduct of traditional LD_{50} *testing* studies to evaluate the radioprotective efficacy of new drugs is a regulatory requirement where human studies are not ethical or feasible. There is, however, no readily available method to determine the number of animals needed for establishing efficacy in these comparative potency studies. This presentation describes the derivation of a sample-size formula for comparative potency testing of response modifiers in total body irradiation experiments. Monte Carlo simulation is used to demonstrate the formula's performance in terms of size and power for Student's t , Wald, and Likelihood Ratio tests in both logistic and probit models. The results show potential for justifying the use of substantially fewer animals than are customarily used in these studies. The sample-size formula is expected to stimulate dialogue among researchers who use animals for radioprotection survival studies, institutional animal care and use committees, and drug regulatory bodies to reach a consensus on the number of animals needed to obtain statistically robust results for establishing the efficacy of radioprotective drugs.

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