

George C. Challis Lecture Series, Nov 15-16, 2004

Speaker: Susan Ellenberg  
Center for Biologics Evaluation and Research  
Food and Drug Administration

Statistics Lecture

Title: STATISTICS AND BIOETHICS: A NECESSARY INTEGRATION

Day: Monday, November 15, 2004

Time: 4:00 pm

Place: HSC, Communicore, C1-3

Abstract: A fundamental ethical principle underlying medical research is that the research be designed and conducted in a scientifically valid way. The Declaration of Helsinki, an international statement of ethical principles for medical research, includes as one of its articles, "Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and on adequate laboratory and, where appropriate, animal experimentation." In addition to the statistician's role in ensuring the validity of research design and conduct (and thereby its ethical acceptability), statisticians are well positioned to identify aspects of study designs that raise specific ethical concerns, and to develop approaches that avoid such concerns. In this presentation, I will review a number of ethical issues that have arisen regarding the design and conduct of clinical trials, and discuss the role of statisticians in addressing these issues. Particular issues for discussion include interim data monitoring and early decision-making, use of placebo controls and design of active control trials, randomized consent designs, adaptive allocation to treatment arm, and trials in special populations.