

**The Fifth Annual
Janet L. Norwood Award
For Outstanding Achievement by a Woman
in the Statistical Sciences**

Dr. Janet Turk Wittes

Friday, October 13, 2006

9:30 AM

Alys Stephens Center
Reynolds-Kirschbaum Recital Hall
1200 Tenth Avenue South
Birmingham AL

Seminar Topic:

Censoring, Multiplicity, and Over-classification:

Some Statistical Approaches for Failing to Identify Harms in Randomized Clinical Trials

Seminar Abstract:

Several recent large randomized trials have identified unexpected harms of drugs. The Woman's Health Initiative showed that hormone therapy for post-menopausal women causes stroke and heart attacks. Three trials of cox-2 inhibitors have shown drug-related increases in cardiovascular events among patients at high risk for the development of colorectal polyps. A major trial of strategies for preventing diabetes was ended early because of major liver toxicity. This talk deals with some commonly used statistical approaches that by their very nature are poised to fail to identify potential problems with drugs early. Instead, analysis of data on potential harms needs to be flexible and responsive to observations. One approach that provides a reasonable balance between statistical rigor and likelihood of identifying harms is to define a "sentinel event" when a hint of problems arise. The talk ends with a discussion of approaches for judging relative benefits and harms.