

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

**Dr. Nancy L. Geller**

Wednesday, September 16, 2009

9:30 AM

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

**Seminar Topic:**

Clinical Trial Design in the 21<sup>st</sup> Century

**Seminar Abstract:**

With the accelerating pace of biomedical discoveries and the drive for personalized medicine, many randomized clinical trials are being proposed to confirm the validity of a biomarker as predictive of the response to therapy. How will we decide which trials to undertake and create designs that are most efficient? We discuss the level of evidence required prior to undertaking a confirmatory trial of a hypothesized predictive marker. Designs of trials to confirm that a marker is predictive are reviewed and cardiovascular examples are detailed. Use of unconventional endpoints and new analysis methods are provided to illustrate how to make such clinical trials more efficient.

<http://www.soph.uab.edu/ssg/norwoodaward/eighthaward>