Abstract:
The substantial gap in translation of therapeutic evidence into widespread practice has been a matter of concern over recent years, especially as more evidence for life-saving therapies accumulates. Large-scale clinical trials have produced evidence in the form of statistically significant comparisons and, in many cases, observational analyses have produced relatively consistent results. However, for each new piece of evidence, two major questions remain unanswered: is there an effective mechanism to embed this evidence into routine practice and if so, are the results robust to varying approaches for implementation? One promising mechanism for exploring these questions is the large scale pragmatic clinical trial that will be possible through the universal adoption of the electronic health record. Another avenue, which does not rely on the clinical setting, is through a newly recognized need to involve the community. In this presentation, we demonstrate one approach to implementing such a community study. Issues regarding the definition of appropriate outcome measures and the estimation of statistical power for an intervention that is applied broadly, but targets a specific subset of the population, are discussed.

Biography:
Dr. DeLong is Professor and Chair, Department of Biostatistics and Bioinformatics, Duke University Medical Center and Co-Director of the Cardiovascular Outcomes Research group in the Duke Clinical Research Institute (DCRI). Her interests are in the field of comparative effectiveness with regard to cardiovascular outcomes and quality-of-care, with emphasis on risk adjustment methodology, assessment of risk prediction models, and provider profiling. With more than 20 years of biostatistics, clinical research, and bioinformatics experience, her responsibilities have included administrative and data analytic functions, as well as statistical methods development. She has also taught several Biostatistics courses in the Medical School, and has led the department to establish a Masters in Biostatistics degree. Approval to offer a PhD degree is expected in the fall of 2013.