

## Bankhead-Coley Cancer Research Program

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*Clinical Translational Science Institute  
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*2009 Program  
Florida Research Challenge  
(2-year project)*

**Project Title:** When Are Clinical Trials Ethical for Both Future and Study Patients?

**Project Summary:** Clinical trials are widely considered the most important vehicle for generating evidence about successful treatments that can improve outcomes of patients with cancer. Unfortunately, design and conduct of clinical trials are often ripe with ethical dilemmas, the chief of which is related to so-called therapeutic misconception [TM], a state that “exists when individuals do not understand that the defining purpose of clinical research is to produce generalizable knowledge regardless of whether the subjects enrolled in the trial may potentially benefit from the intervention under study.” The scientific and ethical problems related to TM are further exacerbated by the existing disagreements between ethicists (who maintain that the purpose of clinical trials is to benefit future patients) and doctors/researchers (who believe that well-designed studies benefit current patients more than treating them outside of the research protocols). Our goal is to find the common ground between these two diametrically opposite positions by identifying those clinical situations when enrollment into clinical trials serves equally well both trial and future patients. We hypothesize that this in turn will improve IRB approval rate of such studies, increase patients’ willingness to participate in clinical cancer research, and thus help speed discovery of new therapeutic interventions against cancer.