



**Susan G. Komen
Research Grants – Fiscal Year 2014**

This research grant was approved by Komen's national board of directors for FY2014 Research Programs funding. This grant will be funded upon the execution of grant agreements between Komen and the grantee institutions.

Validation and implementation of genomic testing for chemotherapy and endocrine sensitivity

Investigator(s): William Symmans, M.D.

Lead Organization: UT M.D. Anderson Cancer Center

Grant Mechanism: KS

Grant ID: SAC110034

Public Abstract:

The investigators have developed a microarray-based predictive test that can be measured from a routine biopsy of HER2-negative invasive breast cancer at the time of diagnosis or surgery in order to predict whether a person with newly diagnosed breast cancer would benefit from neoadjuvant or adjuvant chemotherapy containing a sequence of taxane and anthracycline-containing chemotherapy, and/or subsequent adjuvant endocrine (hormonal) therapy. An independent retrospective evaluation of this test showed that in 28% of patients who were predicted to be treatment sensitive their probability of being alive and without metastatic disease at 3 years after diagnosis was 92%, and this was significantly (18%) higher than the probability if they were predicted to be insensitive to the treatment. This proposal is to conduct a prospective trial to establish the true prevalence of these prediction results in a representative population of people with newly diagnosed breast cancer, and to test the feasibility of routinely performing this test within the clinical pathology laboratory using tumor biopsy samples obtained from patients at the time of needle biopsy or at the time of surgery. Feasibility will be defined as acceptable quality test results obtained from at least 85% of samples. The test results will be recorded in the clinical laboratory but not reported to the medical record. Recorded prediction results will subsequently be compared to the tumor response and survival outcomes of the patients who receive treatment that is relevant to the intended use of the test. This study has 80% power to confirm whether the probability of survival at 3 years of follow up is as high as was described in the previous (retrospective) study. This research will establish a higher level of clinical confidence in the performance and utility of genomic testing in a pathology diagnostic laboratory.