



**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.

Early phase clinical trials of targeted therapy for metastatic breast cancer

Investigator(s): Claire Dees, M.D.

Lead Organization: University of North Carolina at Chapel Hill

Grant Mechanism: KS

Grant ID: SAC110044

Public Abstract:

Metastatic breast cancer (MBC) claims over 40,000 lives each year in this country. Clearly new therapies are needed. Historically only a small percentage of cancer patients are treated on clinical trials in this country. This is particularly true for patients with metastatic breast cancer. The vast majority of women with metastatic breast cancer are treated off-protocol and with off-label drugs and regimens, particularly in the third and later line setting of treatment. However, there are a wide range and growing number of targeted anti-cancer drugs in early development with potential usefulness in breast cancer treatment. Over the past decade oncologists have gained a better understanding of this disease with respect to particular types and subtypes and variations in pathways that might be targeted by drugs in order to get a better response to therapy. Further, a growing understanding of genetics has revealed relevant changes in a variety of drug metabolism genes that may impact on response to particular therapies. It is likely that careful patient selection based on tumor characteristics will be necessary to fully achieve best response to new targeted therapies. Therefore early phase clinical trials are often now more narrowly focused on relevant patient and tumor populations. Many trials now require pre-screening for relevant tumor characteristics or host features. The overall goal of this project is to increase the accrual of women with metastatic breast cancer to phase I clinical trials of new agents, particularly those trials that are designed with correlative studies which examine tumors for predictive markers of response. Efforts to increase the number of MBC patients on new phase I trials will not only speed up how we gain this knowledge about new targeted therapies but also will improve patient access to new drugs. This project focuses on developing an infrastructure and research team that will improve our accrual of women with MBC to early phase clinical trials at UNC. Specifically we will establish and maintain the UNC metastatic breast cancer database, dedicate a research assistant to screening and accrual efforts, support and augment ongoing tissue collection protocols to focus on metastatic breast cancer, support the correlative endpoints of several underfunded investigator-initiated trials of novel targeted therapies in MBC, fund a research nurse dedicated to early phase clinical trials in patients with MBC, and link with ongoing efforts to speed time to activation of novel trials.