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DEPARTMENT OF MEDICINE, DIVISION OF ONCOLOGY

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Consent To Participate In Autologous Transplantation  
For Patients With High Risk Stage II - III or Metastatic Breast Cancer  
Using A Conditioning Regimen Of Busulfan And Cyclophosphamide and anti-TNF $\alpha$  Therapy

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#### BACKGROUND AND PURPOSE

Patients with early breast cancer who have 10 or more positive lymph nodes are at very high risk of developing metastatic disease. The remissions obtained by treatment with chemotherapy in metastatic breast cancer are almost always temporary. They usually last for months rather than years.

Investigators have not proven, but hypothesize, that high dose combination chemotherapy will reduce the number of tumor cells in the patient over that achieved with "standard doses." This intensive combination therapy destroys the normal bone marrow so no new blood cells are produced. The patient's stored marrow is given to repopulate the marrow spaces to produce red cells, white cells and platelets.

This new treatment program has been designed with the hope that it will prove to be much more effective than standard treatments now available. We hope that your life will be lengthened by this treatment. There is, however, a chance that your life will be shortened because of the treatment. Because the treatment is designed to eliminate as many cancer cells as possible, the treatment will have many side effects which will be unpleasant and can result in your death.

This new treatment program has been designed to determine the maximum tolerated doses of the chemotherapy drugs busulfan and cyclophosphamide when used in combination with drugs which inhibit tumor necrosis factor (Anti-TNF therapy). Tumor necrosis refers to cell damage or death. Anti-TNF therapy utilizes pentoxifylline, (PTX) and ciprofloxacin, (CIPRO), drugs which may prevent cell death in healthy cells.

PTX has been safely prescribed for more than 10 years to treat leg cramps due to poor circulation with little or no side effects. Recent studies suggest that PTX prevents kidney, lung and liver damage in patients receiving transplants. When PTX was given along with an antibiotic called ciprofloxacin (CIPRO) to patients undergoing bone marrow transplant, no kidney, liver or lung damage was seen in 10 patients. We plan to see if the combination of these drugs can prevent damage to the kidney, liver and lungs in patients receiving bone marrow transplant. Initial information in patients undergoing bone