The Hospital of Central Connecticut is conducting a clinical trial to evaluate three IMAGING TECHNIQUES FOR DIAGNOSIS OF EARLY BREAST CANCER *in women at high risk for such cancer. Specifically, the trial is studying breast-specific gamma imaging (BSGI), ultrasound and magnetic resonance imaging (MRI). The trial, funded by the Connecticut Breast Health Initiative, Inc., is called Mammography Comparison using BSGI, Whole Breast USG (ultrasonography), and Breast MRI in High-Risk Patients.*

What follows are ANSWERS TO QUESTIONS *you may have about the trial.*

The Hospital of Central Connecticut

at New Britain General and Bradley Memorial

The Hospital of Central Connecticut

CLINICAL TRIAL ON BREAST IMAGING TECHNIQUES

FOR POSSIBLE DIAGNOSIS OF EARLY BREAST CANCER

A GUIDE FOR POTENTIAL PARTICIPANTS

What is a clinical trial?

A clinical trial is a research study that involves people and aims to help doctors find ways to improve health, namely through disease prevention, diagnosis or treatment. This study, for women at high risk of breast cancer, will compare BSGI to breast ultrasound and breast MRI to evaluate for possible diagnosis of early breast cancer. It is hoped that study information will eventually help you and other women at risk for breast cancer.

What are my choices?

Study participation is voluntary. If you participate, you may leave it at any time for any reason. Leaving the study will not result in penalty or loss of benefits to which you are entitled. Instead of study participation, you might choose to discuss screening options with your physician. If you'd like to participate, please discuss this study and other breast screening options with your doctor.

Who can participate?

Women at high risk for developing breast cancer. For this study, high risk means one or more of the following:

- a prior history of breast cancer
- a strong family history
- a prior biopsy with atypical ductal hyperplasia (ADH), lobular carcinoma in situ (LCIS), or atypical lobular hyperplasia (ALH)
- having a BRCA-1 or BRCA-2 genetic mutation

What are BSGI, ultrasound and MRI tests?

- Breast-specific gamma imaging (BSGI) is a non-invasive test similar to a mammogram but uses less compression. Before imaging, patients receive an intravenous radiotracer dye. The dye reveals as a bright spot during the test if cancer is present since the dye is more easily absorbed by cancer cells, which have a higher metabolic activity.
- Ultrasound uses sound waves to obtain an image of organs and tissues. It may be used to diagnose various breast diseases, including breast cancer, cysts, fibroadenomas (non-cancerous tumors).
- MRI breast study is a non-invasive technique that produces cross-sectional images of the breast from various angles. MRI does not involve radiation.

How long will this study last?

The study start date is August 2010; it will conclude December 2011.

What will this study mean for me?

Study participation may or may not provide a direct medical benefit to you. You will have a bilateral (both breasts) screening ultrasound, BSGI and MRI at no charge, in addition to a bilateral mammogram. This may result in:

- providing you and your doctor with baseline readings of your normal breasts.
- earlier diagnosis of any breast cancer, which could lead to:
  - prevention or delay of death from breast cancer;
  - prevention of, or reduction in, symptoms from breast cancer;
  - milder treatment, leading to fewer side effects from breast cancer treatment.

What will happen in this study?

Each of the four tests will be scheduled within four weeks of each other. Also, you will be asked a series of questions about any lumps, abnormal nipple discharge, or skin changes in the breast or under your arm. You will learn exam results after all tests and interpretations are complete. If abnormalities are found, additional tests, such as the following, may be required at no cost to the participant:

- mammographic views
- ultrasound imaging
- needle aspiration – removing a small amount of breast fluid through a needle
- biopsy – removing a small amount of breast tisue for analysis

Is there any risk to me?

Any of these screening tests — mammogram, BSGI, ultrasound, MRI — has the potential to identify areas of concern. Most of these will not be cancer. Out of 100 women who have a screening breast ultrasound, two to 10 of them will need a biopsy done by either removing a small amount of breast tissue using a needle or removing a small amount of breast fluid through a needle. On average, 12 in 100 will show cancer and 88 will not.

There is also a risk that even after clinical breast examination, mammogram, and ultrasound, you will have a breast cancer not found through these tests. Even when breast cancer is found early, before it can be felt, some women will die from the disease.

For more study information, please contact:

Jean Weigert, M.D.
Comprehensive Breast Center
The Hospital of Central Connecticut
860-827-0525

Donna Boehm R.N., M.S.N., M.P.H.
Comprehensive Breast Center
The Hospital of Central Connecticut
860-224-5900 Ext. 6307