

SGH ETHICS COMMITTEE APPLICATION #21/2000

Thermographic Imaging for Breast Cancer in the Department of Diagnostic Radiology: A Joint Project between NTU and SGH

Enclosed please find full patient information sheet and consent form.

VOLUNTEER INFORMED CONSENT FORM

Thermographic Imaging for the detection of Breast Cancer : A Joint Project between Nanyang Technological University and Singapore General Hospital

You are invited to be in the above research study. Please decide whether you want to participate or not. Please take your time to decide after reading this form. If you have questions, please be free to ask the attending investigator.

Breast Cancer is the commonest Cancer in Singaporean women. Film mammography is the standard modality to detect Breast Cancer. Mammography is often supplemented by other modalities eg. U/S breast scans, CT and MRI for improved sensitivity and specificity.

The aim of this project is to study and develop Thermographic Imaging of the Breast as another adjunctive tool to screen patients for the early detection of breast cancer. Breast Thermograms can detect physiological changes in temperatures in the breasts and is said to be able to detect focal increase in temperature from the presence of a breast cancer. The advantages lie in the thermographic equipment being inexpensive, non-invasive and totally safe due to the absence of radiation. The investigators wish to collect data on breast thermograms and to test the sensitivity and specificity of the instrument to detect breast cancers.

In this project, all patients presenting for a mammograms at the Department of Diagnostic Radiology can volunteer for a breast thermogram. There is no exclusion criteria for age, past surgery or medical history as the procedure is a non touch technique.

The Thermographic technique

The investigator (Female) will interview you after you have consented to volunteer. She will explain the procedure to you. It will add 30 to 45 minutes of your time longer when you come for your mammogram. Briefly, you have to sit quietly to equilibrate for 20 minutes in a private room with constant temperature of 22°C to 24°C. After that, your thermogram will be recorded for the next few minutes by a female investigator. You will have total privacy during the examination.

Will there be any Drugs to be used or Payment?

There will be no drugs or intervention during the investigation. You are one of the 500 volunteers which we are recruiting for this project. The principal investigators thank you for your participation and time. There will not be any payment in cash or kind made to you. There will be no adverse effects on you whether you participate or not in this project. The findings in the breast thermograms will not influence, delay or have any outcome effect on your management which will be solely dependant on your mammogram results.

Who will see my records?

If you agree to become part of the study, your name and individual results will be held in strict confidence. Only the investigators, staff and doctors involved in the study, independent ethics committee and inspectors from government regulatory agencies can have access to your medical records to check on the study information.

Who do I call if I have a question?

As the procedure is done on the same sitting when you come for your mammogram, or when you attend the surgical outpatient clinic, the investigator/attending doctor will answer your questions and concerns before the examination.

If you have further queries, please contact the following:

Dr Ng Fook Cheong
Tel 3265030
Pg 94153384

Dr Chen Ying (Ms)
Tel (O): 790-5911

Ms Ung Lin Na
Tel (O): 790-4004
Pg: 9 510-4583

Can I refuse to be in the study?

Your participation in this study is voluntary. You can choose not to participate in this study. You will not lose any benefits to which you are entitled. You will also be not prevented from participating in future studies by the hospital.

I have read and understood this consent form. All my questions have been answered. I volunteer to take part in this study.

Name & Signature of Volunteer

Date

Name & Signature of Person
Conducting Review of Consent

Date