CONSENT FORM FOR PARTICIPATION IN A RESEARCH STUDY

Title: Breast Cancer Risk Assessment Using Optical Breast Spectroscopy (OBS).

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Introduction
You are being asked to take part in a research study called Breast Cancer Risk Assessment Using Optical Breast Spectroscopy (OBS). Before agreeing to participate in this research study, it is important that you read and understand the following explanation of the proposed study procedures. The following information describes the purpose, procedures, benefits, discomforts, risks and precautions associated with this research study. It also describes your right to refuse to participate or leave the study at any time. In order to decide whether you wish to participate in this research study, you should understand enough about its risks and benefits to be able to make an informed decision. This is known as the informed consent process. Please ask the study contact person (Samantha Dick) or the principal investigator (Dr. Lothar Lilge) to explain any words you don’t understand before signing this consent form. Make sure all your questions have been answered to your satisfaction before signing this document.

Background
Transillumination Breast Spectroscopy (TiBS) is a medical device under investigation in this current research study. Data from these previous studies suggests that we can monitor changes
in the breast tissue over time and we can distinguish between normal and different types of abnormal tissue.

**Purpose**
You have been asked to participate in a research study to serve as a healthy control to women who carry a mutation in the breast cancer susceptibility gene, BrCa1 or BrCa2. Both BrCa1 or BrCa2 carriers and non-carriers (controls) will be assessed using the Transillumination Breast Spectroscopy procedure every 6 months for 4 years to monitor breast tissue changes during this time period. This information will help us understand how the breast tissue changes over time between women with different breast cancer risk levels.

The goal of this research study is to develop a safe and non-invasive technique that can be used frequently on women at high risk of developing breast cancer to assist these women and their physicians in deciding when changes in monitoring or intervention (e.g. biopsy, etc) are required.

**Procedures**
If you decide to take part in this research you will be asked to come to the research department of Princess Margaret Hospital to meet with a female research assistant. Visits will be scheduled at about a six-month interval, for 8 visits. This study related visit should take between thirty and forty-five minutes.

During each visit, two procedures will be performed.

1. We will measure your height and weight and then measure your waist, hip and neck circumference with a measuring tape.

2. The female technician will examine the breast tissue using transillumination breast spectroscopy (TiBS). You will be asked to undress from the waist up, sit at an examination table, and undergo eight measurements (four per breast). We will shine white light from a standard Halogen lamp into the tissue and detect and analyze the light that leaves the breast on the other side. Measurements will be taken in the dark (1 minute for each measurement maximum). This is similar to collecting mammograms but only with a minimal amount of pressure on the breast tissue using a thumb sized light source on the breast tissue. No plate compression will be applied.

You will also be asked to complete a questionnaire during the visit including information about your age, weight, height, diet, family history of breast and ovarian cancer, ethnic background, parity and menopausal history. This information will also be used to complete the pre-test Penn II BrCa1 and BrCa2 Mutation Risks Evaluation. If you are found at great risk of having a BrCa1 or BrCa2 mutation, you will be offered an appointment with one of the Familial Programs at Princess Margaret Hospital or Mount Sinai Hospital to further discuss the potential for genetic testing with a genetic counselor.

If applicable, your medical charts from the Ontario Cancer Registry will be reviewed for up to 20 years to access information (e.g. whether you have developed breast cancer, when you were diagnosed, the type of breast cancer) directly relating to this study. Your first name, last name,
date of birth, and health card number will be used to perform the search in the registry. The Ontario Cancer Registry is a database of information on all Ontario residents who have been diagnosed with cancer. The Registry is supported by the government of Ontario.

Risks and Benefits
There is no health risk involved in this study. The skin is not pierced and no chemical or ionizing radiation, such as x-rays, is used. This type of optical radiation or light is known to not affect your health. This instrument was approved by Health Canada for investigational testing at Princess Margaret Hospital. There is no immediate benefit of this study to the participant. Note this study is not intended to replace mammography or any other monitoring or prescribed intervention. Please do not alter your habits of a breast self-exam or other screening should you have entered a screening program, or plan to do so. This study will not affect or influence any further diagnostic or treatment programs should you require them.

Confidentiality
All information obtained during this study will be held in strict confidence. You will be identified with a study number only. No names or identifying information will be used in any publications or presentations. During the regular monitoring of your study or in the event of an audit, your medical record may be reviewed by the University Health Network Research Ethics Board and/or Health Canada. Upon completion of the study all identifying information will be removed from the data.

Participation
Participation in this study is voluntary and you are free to refuse to answer any specific question and/or leave the study at any time.

Compensation
If you become ill or are physically injured as a result of participation in this study, medical treatment will be provided. The reasonable costs of such treatment will be covered by your health insurance for any injury or illness that is directly a result of participation in this trial. In no way does signing this consent form waive your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities.

You will be reimbursed (up to $10) for travel expenses to and from the hospital for all visits related only to this study.

Questions
If you suffer any side effects or other injuries during the study, or if you have any general questions about the study, please call the doctor in charge of this study, Dr. Lothar Lilge at 416-581-8642. You may also call the study coordinator at 416-946-4501 ext. 4202.

If you have any questions about your rights as a research participant, please call Dr. R. Heslegrave, Chair of the University Health Network Research Ethics Board at (416) 340-4557. This person is not involved with the research project in any way and calling him will not affect your participation in the study.

Version Date: 12-Nov-09
Consent
I have had the opportunity to discuss this study and my questions have been answered to my satisfaction. I agree to complete the study questionnaire and authorize the release of my mammogram and, if applicable, imaging, surgery and pathology reports and the information gained through the transillumination procedure to PMH. I authorize the release of my information collected from the Ontario Cancer Registry to PMH. I voluntarily consent to participate in this study with the understanding that I may leave the study at any time. I understand that by signing this consent form I do not waive any of my legal rights. I have retained a signed copy of this consent form for my personal records.

____________________________                     __ _________________     _______________
Study Participant’s Name (Please Print)  Study Participant’s Signature  Date

I confirm that I have explained the nature and purpose of the study to the subject named above. I have answered all questions.

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Name of Person Obtaining Consent  Signature  Date